

Université de Montréal

L'éthique de la valorisation des bases de données et des banques de matériel créées à des fins de recherche : une étude empirique et normative

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Ce mémoire intitulé :
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fins de recherche : une étude empirique et normative

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Résumé

Ce mémoire examine plusieurs questions d'éthique auxquelles font face les chercheurs universitaires en ce qui concerne la valorisation (le partage, la réutilisation et la commercialisation) des bases de données et des banques de matériel. Dans un premier temps, nous présentons les résultats d'une étude qualitative du point de vue de vingt-deux chercheurs à l'Université de Montréal, qui révèle les nombreuses limitations à la valorisation, y compris le manque de ressources, le consentement à la recherche, la confidentialité des participants ou patients et la compétition entre chercheurs. Malgré ces limitations, le partage de bases et de banques est la forme de valorisation la plus acceptée par les chercheurs à l'Université de Montréal. De plus, ce partage est préconisé dans la documentation scientifique comme un idéal de la science. Dans un deuxième temps, nous démontrons que si le partage de bases et de banques est *primaefacie* une norme éthique généralement acceptée, les limitations à cette norme devraient être davantage comprises et justifiées. Pour ce faire, nous présentons une analyse des limitations principales du partage des bases et des banques qui révèle que la plupart de ces limitations sont causées par des manquements à l'intégrité de la recherche (manque de collégialité ou de confiance). Dans un troisième temps, nous terminons en proposant des recommandations et des pistes de réflexion afin de susciter un plus grand *partage éthique* des bases de données et des banques de matériel tout en respectant certaines contraintes justifiables.

Mots-clés : Éthique, valorisation, base de données, banques de matériel, partage des données, partage du matériel, intégrité.

Abstract

This master's thesis focuses principally on the ethical issues faced by university researchers in the valorization (sharing, reuse and commercialization) of databases and material banks. First, I present the results of a qualitative study on the perceptions of 22 researchers at the Université de Montréal regarding various limitations to valorization, including the lack of resources, consent processes, participant confidentiality and competition between researchers. Despite these shortcomings, the sharing of databases and material banks is the mode of valorization most accepted by researchers at the University of Montreal. This sharing is advocated in the scientific literature as an ideal or norm of science. Second, I argue that if such sharing is *prima facie* ethical and beneficial, then practices which would limit sharing should be better understood and justified. I present an analysis of the main limitations to sharing which reveals that instances of a lack of integrity in research (that undermine collegiality or trust) are at the root of many of these limitations. Third, I conclude with reflections and general recommendations to achieve greater *ethical sharing* while still acknowledging the existence of certain justifiable constraints.

Keywords: Ethics, valorization, databases, material banks, sharing, integrity.

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Liste des abréviations

BRDV	Bureau de Recherche-Développement-Valorisation
CAI	Commission d'accès à l'information du Québec
CÉRFAS	Comité d'éthique de la recherche de la Faculté d'Arts et Sciences
COPE	Committee on Publication Ethics
CRSNG/NSERC	Conseil de recherche en science naturelle et en génie / National Science and Engineering Research Council
CRSH/SSHRC	Centre de recherche en science humaine / Social Sciences and Humanities Research Council
ÉPTC/TCPS	l'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains / Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)
ESDS	Economic and Social Data Service
FRSQ	Fonds de recherche en santé du Québec
ICMJE	International Committee of Medical Journal Editors
IRSC/CIHR	Instituts de recherches en santé du Canada / Canadian Institute of Health Research
MTA	Material Transfer Agreement
MPI	Mobilisation de la propriété intellectuelle
NIH	National Institutes of Health
NSF	National Science Foundation
REB	Research Ethics Board
UNESCO	United Nations Economic, Social and Cultural Organization
VINCI	Valorisation des Innovations et du Capital Intellectuel

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Introduction

Depuis les années 1990, les bases de données et les banques de matériel ont fait couler beaucoup d'encre dans la documentation en bioéthique. Dans son analyse critique de la documentation sur les banques et les bases, Hoeyer explique l'émergence de l'intérêt pour ce sujet d'étude par plusieurs facteurs, dont, notamment, la génétique, les droits des patients et la commercialisation. [1] Avec les développements de la génétique, les échantillons de matériel humain, autrefois perçus comme de simples « déchets », sont devenus une source pouvant révéler plusieurs informations liées au patrimoine héréditaire des individus, des familles et même des communautés. [2] On peut comprendre pourquoi, parallèlement, il était ainsi devenu primordial de protéger les droits des participants à la recherche. Par ailleurs, la commercialisation possible des bases de données ou des banques de matériel sème le doute sur les principales intentions des chercheurs durant leurs recherches : Veulent-ils avant tout développer la connaissance ou plutôt en tirer un profit économique ? On le constate rapidement, le chercheur peut, de toute évidence, se retrouver en conflit d'intérêts. Malheureusement, l'objectivité d'un chercheur risque d'être détournée par l'attrait du gain financier résultant de la commercialisation d'une base de données ou d'une banque de matériel. [3, 4]

Plusieurs chercheurs se sont ainsi penchés sur les enjeux éthiques des bases de données et des banques de matériel, et ce, particulièrement en ce qui concerne la génétique humaine. Les thèmes les plus souvent abordés sont la confidentialité des données et du matériel [5], le droit de retrait des participants à la recherche [6], l'utilisation secondaire des données [7], la discrimination [8] et, surtout, le consentement des participants à la recherche. [9-12] Ces thèmes sont directement liés à la protection des individus et des communautés, souvent considérée comme l'un des objectifs principaux en éthique de la recherche. En effet, l'éthique de la recherche universitaire s'inscrit dans un processus plus large qui vise « le respect de la dignité, de la liberté et du droit des êtres humains ». [13]

L'intérêt croissant que portent les chercheurs à la protection des participants à la recherche laisse quelque peu en plan plusieurs autres enjeux éthiques touchant d'autres acteurs de la recherche. Même si la protection des sujets de recherche reste un enjeu important, une éthique qui encadre la relation entre les différents chercheurs concernés est nécessaire pour assurer une valorisation profitable au développement du savoir. Le chercheur décide s'il partage, réutilise ou commercialise ses bases ou ses banques et la manière dont il le fera (bien que certaines normes ou politiques doivent être appliquées lors de recherches avec des participants humains). Les chercheurs sont à la fois responsables d'assurer une norme éthique dans leurs recherches tout en considérant la valorisation de leurs bases et de leurs banques. Ce projet vise à mieux comprendre les tensions entre la valorisation et l'éthique de la recherche, lors de recherches relatives à des bases de données et des banques de matériel créées à des fins de recherche. Plus précisément, ce projet vise à mieux concilier les obligations éthiques des chercheurs avec les initiatives gouvernementales et institutionnelles de valorisation des bases de données et des banques de matériel créées à des fins de recherche.

Concepts et définitions

Les banques de matériel sont des outils qui enrichissent et stimulent le développement de la recherche universitaire. Ces outils peuvent être définis comme une collection structurée d'échantillons de matériel organiques (tissus, sang, cellules, plantes, insectes) ou inorganiques (minéraux, vidéos, enregistrements). Dans certains cas, des bases de données sont liées à ces banques, comme des bases contenant des données épidémiologiques ou des dossiers de patients. À l'inverse, d'autres bases de données sont constituées sans banque de matériel. Elles peuvent contenir, par exemple, des données statistiques, des données informatiques ou des transcriptions d'entrevues. Qu'elles soient liées à une banque de matériel ou non, les bases de données sont souvent organisées selon une structure conceptuelle décrivant les caractéristiques des données qu'elles contiennent. Dans les sources documentaires et dans la pratique, il n'existe aucun consensus sur la terminologie qui devrait être utilisée pour désigner ces ressources de la recherche. [14] Il y a ainsi un véritable foisonnement des termes employés, dont principalement « collection », « centre de ressources biologiques » ou « biobanques ».

[15]¹ Pour simplifier la terminologie dans ce mémoire, seuls les termes « base de données » et « banques de matériel » seront utilisés.

Avec les avancements technologiques et l'évolution des méthodes de stockage et de jumelage, le nombre de bases de données et de banques de matériel ne cesse de croître. [16] L'augmentation et la diversification des bases et des banques s'observent dans une variété de domaines de recherche universitaire, autant dans les sciences de la santé et les sciences expérimentales que dans les sciences appliquées et les sciences sociales. Les bases et les banques sont considérées comme des produits secondaires issus de la création d'un produit principal lors d'une recherche. Ces produits secondaires, aussi nommés « sous-produits de la recherche », ont souvent une valeur technique et scientifique pour les chercheurs universitaires. Cette valeur peut être accrue en transformant des bases ou des banques en collection nationale ou internationale, en les commercialisant ou en les partageant entre les chercheurs. Ce processus de transfert de connaissances d'un milieu à un autre par lequel une valeur (scientifique, sociale, économique, etc.) est ajoutée aux sous-produits de la recherche se nomme la valorisation.

Dans les milieux académiques francophones, le phénomène de valorisation n'est décrit que de manière générale. [17, 18] Les enjeux éthiques ne font ainsi pas explicitement partie de ce domaine de la documentation scientifique. Du côté de la documentation anglophone, le mot « valorisation » n'est pas utilisé dans un contexte tel qu'il est décrit dans ce projet de mémoire. Les auteurs anglophones n'abordent jamais la valorisation de manière générale, mais traitent plutôt de ses différentes formes plus spécifiques, telles que l'utilisation secondaire, le partage et la commercialisation des données ou du matériel.

¹ Dans la documentation anglophone plusieurs autres termes sont utilisés, notamment *data (or material) repository*, *biological and environmental repository*, *biolibrary*, etc.

La problématique de recherche

Différentes organisations internationales, nationales et provinciales prônent la valorisation des sous-produits de la recherche, comme les bases de données et les banques de matériel. L'Organisation de coopération et de développement économique (OCDE), par exemple, est reconnue comme étant un agent important dans le partage et l'intégration des données de la recherche et pour l'optimisation de leur utilisation. [19] À l'échelle provinciale, les Fonds de recherche en santé du Québec (FRSQ) soutiennent que « la recherche en santé impliquant des banques ne peut contribuer efficacement au bien public que si elle est animée par une volonté de partage des connaissances et une ouverture aux collaborations locales et internationales ». [20] Il existe plusieurs sociétés de valorisations affiliées aux universités canadiennes pour soutenir les chercheurs dans leur choix de valoriser leurs produits et sous-produits de la recherche. [17]

Toutefois, dans la majorité des cas, les sociétés de valorisation traitent encore peu de demandes incluant des bases de données et des banques de matériel. Les enjeux éthiques, tels que le consentement des participants à la recherche, la confidentialité des données ou du matériel, et la propriété intellectuelle et matérielle, compliquent énormément la valorisation. De ce fait, les comités d'éthique de la recherche au Canada ne sont pas certains du rôle qu'ils devraient jouer dans la création de bases de données et de banques de matériel. [21]

La valorisation de la recherche est une préoccupation majeure au Canada, puisque le savoir joue un rôle prépondérant dans son développement économique et social. Malheureusement, comme le constate Alain Grisé, au Canada « [...] les inventions et les nouveaux savoirs découlant de la recherche universitaire se transforment trop rarement, faute de ressources suffisantes ou de mécanismes appropriés, en applications concrètes ou commercialisables ». [22] C'est dans cette optique que l'initiative de Valorisation des Innovations et du Capital Intellectuel (VINCI) fut mise sur pied à l'Université de Montréal et dans ses institutions affiliées, en collaboration avec des sociétés de

valorisation et des partenaires de recherche (annexe 1).² Lors du projet VINCI, un des éléments à l'étude fut les sous-produits de la recherche ayant un potentiel de valorisation élevé et peu exploité (par exemple, les bases de données et les banques de matériel). C'est dans la mouvance des travaux du groupe de recherche VINCI que le sujet du présent projet de mémoire fut concrétisé.

Cadre conceptuel et analyse des sources documentaires

De manière générale, les chercheurs ayant écrit sur les bases de données et les banques de matériel mettent l'accent sur la commercialisation plutôt que sur toute autre forme de valorisation. [17] La prédominance de la valorisation comme élément essentiellement entrepreneurial ou économique découle de la notion de « l'économie du savoir ». Cette notion, mise en avant notamment dans les rapports de l'OCDE, renvoie à des « économies qui reposent directement sur la production, la diffusion et l'utilisation du savoir et de l'information ». [23] Le développement du savoir et l'innovation technologique, auparavant perçus comme des influences externes au système de production, deviennent ainsi des facteurs indispensables dans l'économie. [24] La recherche publique, incluant la recherche universitaire, devient par conséquent un vecteur du développement économique. Dans l'économie du savoir, l'optimisation de l'utilisation des ressources, comme les bases de données, par exemple, est essentielle pour minimiser les intrants et maximiser les extrants économiques de la recherche.

Contrairement à cette vision de la valorisation axée exclusivement sur la commercialisation, nous avons choisi d'inclure plusieurs formes de valorisation dans ce projet de mémoire, ce qui nous permet un regard holiste du système de production des sous-produits universitaires. Notre cadre théorique veut ainsi dépasser la notion de « l'économie du savoir » pour étudier davantage une « société du savoir ». De son côté, la notion de la « société du savoir » est une vision plus complexe et holiste du système de production, d'échange et de diffusion du savoir. Les sociétés du savoir, telles qu'elles sont décrites par l'UNESCO, « prennent en compte des dimensions sociales, éthiques et

² Les institutions affiliées, les sociétés de valorisation et les partenaires de recherche sont notés dans l'annexe 1.

politiques plus larges ». [25] L'économie n'est plus l'élément central du système de connaissance, mais plutôt une dimension parmi tant d'autres. La production du savoir est déterminée, entre autres, par les relations entre les sociétés, les organisations, la production industrielle et les individus. [26] Selon une telle vision de la société, les sous-produits de la recherche ne devraient pas seulement être exploités en vue d'un profit économique, mais aussi et surtout, pour le bien de la société de manière générale.

La notion de valorisation utilisée dans ce mémoire s'inscrit dans le paradigme général de la société du savoir. Étant donné le caractère englobant et holiste de ce paradigme, nous allons considérer plusieurs formes de valorisation et une diversité de connaissances à valoriser. Dans le passé, la majorité des études sur le développement de la connaissance sont restées limitées aux innovations dans le domaine des sciences pures et aux avancées technologiques. [27] Un constat semblable peut également être fait en ce qui concerne les sources documentaires sur les bases de données et les banques de matériel. En effet, les études sur les banques et les bases sont très souvent confinées dans les disciplines des sciences pures et dans les domaines médicaux. Toutefois, d'autres connaissances universitaires, en sciences humaines ou sciences sociales, peuvent avoir une grande valeur. [28] Ceci est également vrai pour les sous-produits de la recherche issus de ces ensembles de disciplines scientifiques, comme les bases ou les banques.

Même si le concept de la « société du savoir » développé par l'UNESCO peut sembler intéressant en théorie, il existe malheureusement peu de documentation démontrant comment valoriser des données ou du matériel dans la pratique universitaire. C'est bien ce qu'explique Välimaa dans son article sur les discours liés à la société du savoir :

[...] looking [at] these goals [of knowledge society] with a critical eye, it can immediately be seen that these multiple expectations describe higher education from the outside, looking in. There are no operational arguments saying how societies should develop their higher education to realize these comprehensive, multifaceted challenges. Furthermore, there is no indication that the limitations of universities and other educational establishments are understood.[26]

Selon l'auteur, il n'y a pas de schème organisationnel ou méthodique qui permette de mettre en pratique une « société du savoir » dans un établissement limité financièrement, tel que l'université. De plus, le concept de la « société du savoir » est trop vague pour être efficacement opérationnel. L'argument principal de l'auteur, développé à partir des pratiques générales des établissements universitaires, pourrait également s'appliquer à la valorisation des sous-produits de la recherche. La valorisation est donc également un processus mal défini et, par conséquent, difficile à mettre en pratique. La conciliation des normes éthiques avec l'application d'un processus de valorisation ambigu devient particulièrement complexe.

Toutefois, malgré son ambiguïté cette notion de valorisation ne cesse d'être prônée. Les tenants de cette vision soutiennent que l'une des façons d'assurer une efficacité de la recherche est de partager ou, plus généralement, de valoriser les bases de données et les banques de matériel. [29] Plusieurs arguments soutiennent ce postulat. Par exemple, il est souvent avancé que l'accès aux données et au matériel donne plus de possibilités aux chercheurs et permet de faire avancer davantage leurs projets de recherche. [30, 31] Les bases et les banques seraient ainsi mieux exploitées en créant une forme « d'allocation des ressources » qui favoriserait la production de connaissances.[32] Le partage des bases et des banques crée un besoin de dialogue entre les acteurs faisant en sorte qu'il y ait une plus grande collaboration de recherche.

De plus, même si la plupart des auteurs soutiennent le partage et la valorisation des bases de données et des banques de matériel, certaines difficultés pratiques peuvent survenir. Par exemple, plusieurs projets qui nécessitent l'utilisation de bases ou de banques se font en collaboration avec plusieurs chercheurs. La reconnaissance individuelle des chercheurs est ainsi largement limitée. [31] Dans le cas des recherches sur les sujets humains, il n'existe aucun consensus sur les modalités du consentement lors de la réutilisation des données ou du matériel. [10] Plus l'accès à une banque ou à une base est large, plus la confidentialité des participants est difficile à protéger. [33] Foster et Sharp ont montré que les politiques prônant le partage ou un accès quasi illimité aux données en génomique ne font pas nécessairement preuve d'efficacité en

recherche. [34] Le partage excessif des données ou du matériel peut créer une désorganisation de ces ressources et une duplication des analyses scientifiques. De plus, le partage des données ou du matériel d'autrui limite l'initiative de créer de nouvelles bases ou de nouvelles banques et risque ainsi de diminuer leur diversité dans les milieux de recherche. Foster et Sharp ne sont pas contre toute forme de partage de données ou de matériel, mais ils défendent plutôt une politique qui limiterait et organiserait certaines formes de valorisation dans l'intérêt de la diversité des acteurs inclus dans ce processus.

À l'échelle internationale, plusieurs institutions mettent en avant des lignes directrices sur la gestion des bases de données et des banques de matériel. Par exemple, l'UNESCO[35] et l'OCDE[36] ont émis de telles lignes directrices concernant les données et le matériel utilisés en génétique humaine. Toutefois, il n'y a aucun acteur supranational à même de mettre en œuvre ces normes et de les faire respecter. Ainsi, chaque pays décide des normes qui seront appropriées pour gérer leurs bases de données et leurs banques de matériel. Par conséquent, il arrive parfois que des normes nationales soient discordantes. Les collaborations internationales, incluant l'échange de bases de données et de banques de matériel, s'avèrent difficiles. [37]

Au Canada, il n'y a pas système de gouvernance harmonisé pour encadrer la recherche sur les bases de données et les banques de matériel dans les milieux universitaires. [38] Toutefois, dans le cas des recherches avec des bases ou des banques sur des sujets humains, une réglementation éthique et légale s'applique souvent pour protéger la dignité des individus et des communautés. Par exemple, *l'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains* (ÉPTC) [39] formalise les règles éthiques minimales dans le cas des recherches financées par l'un des trois organismes subventionnaires canadiens (l'IRSC, le CRSH et le CRSNG)³. De plus, la Commission d'accès à l'information du Québec (CAI) a plusieurs politiques qui ont comme but d'assurer la protection des renseignements personnels tout en permettant un accès contrôlé aux documents des organismes publics. [40]

³ Les acronymes indiqués correspondent aux institutions suivantes : IRSC, Instituts de recherche en santé du Canada; CRSH, Conseil de recherches en sciences humaines du Canada; CRSNG, Le conseil de recherches en sciences naturelles et en génie du Canada.

À l'échelle institutionnelle, les universités ont amorcé le processus de création de lignes directrices concernant la gouvernance des bases de données et des banques de matériel. Ces lignes directrices sont particulièrement liées à la propriété intellectuelle et matérielle. Par exemple, selon les politiques de l'Université Laval, l'institution est propriétaire des bases de données et banques de matériel créées à des fins de recherche. [41] De son côté, l'Université de Montréal se penche actuellement sur la question de la propriété matérielle et intellectuelle des bases de données et des banques de matériel. Aucune prise de position n'a été confirmée. Il sera intéressant d'étudier l'évolution des normes à venir qui auront probablement un impact sur l'éthique de la valorisation des bases de données et des banques de matériel créées à des fins de recherche universitaire.

Objectifs de la recherche

La valorisation des sous-produits de la recherche repose entre autres sur l'engagement et la coopération de plusieurs acteurs. Parmi ceux-ci se trouvent les chercheurs responsables des bases de données et des banques de matériel. Les chercheurs sont à la fois responsables d'assurer une norme éthique dans leurs recherches et de considérer la valorisation de leurs bases et de leurs banques. Bien que plusieurs acteurs (par exemple, les comités d'éthique de la recherche ou les sociétés de valorisation) peuvent conseiller les chercheurs, seuls ceux-ci décident d'exploiter ou non le potentiel de valorisation d'une banque ou d'une base.

De manière générale, ce mémoire portera sur les tensions entre le cadre de l'éthique universitaire et celui de la valorisation (partage, réutilisation et commercialisation) des bases de données et des banques de matériel à l'Université de Montréal. Il comprend deux chapitres principaux, chacun est rédigé comme un article scientifique. Dans un premier temps (chapitre 1), nous allons présenter les résultats d'une étude qualitative sur la perspective de vingt-deux chercheurs quant à la valorisation des bases et des banques créées à des fins de recherche. Les objectifs de ce premier chapitre sont : 1) d'identifier et de caractériser les types de bases de données ou banques de matériel présentant un potentiel de valorisation ; 2) d'évaluer l'intérêt de la communauté universitaire pour les

questions de valorisation des bases de données et des banques de matériel ; 3) d'identifier les difficultés associées à la valorisation de bases de données ou de banques de matériel soulevées par les chercheurs, en particulier la question de la propriété des banques.

Les résultats obtenus suggèrent qu'il y a plusieurs limitations à la valorisation, notamment le manque de ressources, le consentement à la recherche, la confidentialité des patients et la compétition entre les chercheurs. Malgré ces limitations, le partage de bases et de banques est la forme de valorisation la plus acceptée par les chercheurs à l'Université de Montréal. De plus, ce partage est encouragé dans la documentation scientifique comme étant un idéal de la science. Ainsi, dans un deuxième temps (chapitre 2), nous démontrerons que si le partage de bases et de banques est *prima facie* une norme éthique généralement acceptée, les limitations à cette norme devraient être justifiées. Pour ce faire, nous allons présenter une analyse des limitations principales du partage des bases et des banques (le consentement, la confidentialité, la compétition et la reconnaissance). Cette analyse montre que les manquements à l'intégrité de la recherche (manque de collégialité ou de confiance) créent la majorité des limitations du partage des bases et banques. Celles-ci sont peu abordées dans la documentation en éthique et sont, par conséquent, peu prises en considération par la communauté scientifique. Il est nécessaire de faire davantage de recherches empiriques et théoriques sur les limites du partage liées à l'intégrité de la recherche, si l'on veut promouvoir l'idéal du partage des bases de données et des banques de matériel.

Devis de recherche

La plupart des études empiriques sur les bases de données et les banques de matériel concernent la perception du public ou des patients. Ces études se penchent plus précisément sur l'utilisation des banques médicales de tissus de sujets humains (par exemple, les banques et les bases génétiques [42], les banques de tissus de femmes enceintes [43], les banques de tissus liées au cancer [44], les banques pédiatriques [45]). Ces études sont souvent justifiées, entre autres, par le fait que la création des bases et des banques repose sur la participation du public (ou des patients). [46] Ceci est vrai,

a fortiori, lors de recherches avec un grand nombre d'échantillon, comme des projets incluant des bases ou banques populationnelles. Il existe plusieurs tendances relatives à la perception des patients concernant l'utilisation de tissus humains dans les banques. Par exemple, alors que la majorité du public désire que leurs données ou leurs informations soient utilisées de façon à garantir (dans la mesure du possible) leur confidentialité tout en assurant une efficacité de la recherche [47], seulement une minorité de la population refuserait catégoriquement de participer à des études incluant des bases ou des banques. [1]

Une étude empirique est ainsi nécessaire pour mieux comprendre le processus de valorisation des bases de données et des banques de matériel du point de vue des chercheurs. Certaines recherches empiriques ont comme objet d'étude la perception des chercheurs concernant les enjeux éthiques, économiques et organisationnels entourant la gestion des bases de données et des banques de matériel. [48, 49] Bien que celles-ci traitent parfois de la réutilisation des données ou de leur commercialisation, elles ne se penchent qu'indirectement sur les obligations éthiques des chercheurs liées à la valorisation de la recherche universitaire. De plus, ces études se limitent souvent aux bases de données et aux banques de matériel développées au cours de projets en sciences de la santé ou en sciences expérimentales. Ces recherches n'englobent pas les bases de données et les banques de matériel de la recherche universitaire en général, c'est-à-dire autant dans les domaines des sciences de la santé et des sciences de la nature que dans ceux des sciences sociales et des sciences humaines. Une connaissance plus approfondie de la perception des chercheurs provenant de différents champs disciplinaires serait utile pour mieux comprendre les différentes obligations éthiques rencontrées dans un cadre universitaire. Cette connaissance nous semble nécessaire afin de diminuer les tensions entre les obligations éthiques des chercheurs et les initiatives prônant la valorisation.

Méthodologie

Dans le premier chapitre/article de ce mémoire, nous résumons une étude qualitative exploratoire menée dans le cadre du programme de Valorisation de l'Innovation et du Capital intellectuel (VINCI)⁴ en collaboration avec le Bureau de Recherche-Développement-Valorisation (BRDV) à laquelle j'ai participé en tant qu'agente de recherche. Cette étude exploratoire a été menée en collaboration avec Catherine Olivier, agente de recherche, sous la direction de Michel Bergeron. L'étude visait à sonder l'intérêt des chercheurs universitaires en ce qui concerne la valorisation des bases de données et des banques de matériel créées à des fins de recherche. Nous avons ainsi colligé de l'information sur l'intérêt manifesté par les chercheurs envers la valorisation des bases de données et des banques de matériel et sur les modalités et les difficultés liées à cette valorisation.

Étant donné le manque de documentation descriptive sur le sujet, nous avons opté pour une approche qualitative exploratoire. Généralement, une approche qualitative a pour objectif de « donner sens, de comprendre des phénomènes sociaux et humains complexes. » [50] Dans le cadre de notre étude, l'exploration qualitative permettra de mieux comprendre les détails et les éléments contextuels de la valorisation des bases et des banques selon les chercheurs universitaires. Nous voulons ainsi explorer et « donner sens » à la tension qui existerait, selon les chercheurs, entre l'éthique et la valorisation.

Identification de la population cible et échantillonnage

Comme nous l'avons déjà mentionné, les chercheurs sont des acteurs importants dans le processus de valorisation et dans l'application des normes éthiques liées aux bases et aux banques. La population cible de notre étude est, par conséquent, la communauté des chercheurs travaillant avec des bases de données et des banques de matériel créées à des fins de recherche. L'Université de Montréal s'est avérée être un endroit propice pour

⁴ Les institutions affiliées, les sociétés de valorisation et les partenaires de recherche participant à l'initiative VINCI sont notés dans l'annexe 1.

recruter les participants de cette étude, étant donné la diversité de recherches utilisant des bases et des banques qui s'y trouvent.

Nous avons établi un échantillonnage par « choix raisonné » pour cibler des chercheurs travaillant sur les bases de données et banques de matériel. Nous voulions composer un « échantillon par choix raisonné » de façon à « orienter [notre] recherche sur un type de phénomène ou d'individus qui se distinguent des autres selon certaines caractéristiques ». [51] Nous avons ainsi sélectionné des participants potentiels à l'aide des profils de chercheurs disponibles sur les sites Internet des divers départements et institutions affiliés à l'Université de Montréal. Le profil d'un chercheur décrit ses orientations de recherche et ses publications les plus récentes. D'après ces informations, nous avons déduit si le chercheur en question utilisait une base de données ou une banque de matériel.

Nous avons sélectionné des chercheurs qui utilisent des données ou des matériaux correspondant à l'une des six catégories suivantes : sciences informatiques, médecine, sciences expérimentales, sciences appliquées et sciences humaines qualitatives ou quantitatives (voir tableau I). Nous avons ensuite mené de trois à quatre entrevues par catégories. Un échantillon de vingt-deux chercheurs a été constitué pour cette étude. La typologie choisie reflète notre volonté de couvrir le plus large éventail de bases ou de banques potentiellement utilisées dans la recherche universitaire. Puisqu'il s'agit d'un projet de type exploratoire, l'échantillon ne prétend pas à la représentativité. Il vise plutôt à atteindre une perspective suffisamment large et sur la position des chercheurs. À cause du caractère exploratoire de ce projet et de l'échantillon particulièrement diversifié, nous n'avons pas ainsi comme objectif d'atteindre le point de saturation. Le tableau suivant résume la typologie des bases de données ou des banques de matériel ciblées en fonction des disciplines universitaires.

Tableau I : Typologie des bases de données ou des banques de matériel ciblées en fonction des disciplines universitaires

Types de données ou matériel	Disciplines académiques couvertes	Participants
Informatique	Bio-informatique, imagerie, génomique	3
Médical	Médecine, pharmacologie, santé publique, pathologie	4
Sciences expérimentales (organique et inorganique)	Sciences biomédicales, chimie, médecine dentaire, optométrie	4
Sciences appliquées (organique et inorganique)	Biologie, écologie, géophysique, anthropologie	4
Sciences sociales et humaines (quantitatif)	Sociologie, anthropologie, nutrition, psychologie	4
Sciences sociales et humaines (qualitatif)	Sociologie, droit, service social	3

Les participants à cette étude travaillent à l'Université de Montréal depuis une période variant de un à trente-trois ans (pour une période moyenne de quatorze ans). Parmi ces participants, il y avait douze hommes et dix femmes. Seize des vingt-deux chercheurs ont affirmé avoir recours à des bases de données ou des banques de matériel liées à des sujets humains. La participation de cinq cadres de département a permis de mieux comprendre les complications administratives causées par la valorisation des bases de données et des banques de matériel.

Le recrutement

Le recrutement fut initié après avoir reçu l'approbation (annexe 2) du Comité d'éthique de la recherche de la Faculté des arts et des sciences de l'Université de Montréal (CÉRFAS). Les participants à la recherche ont été recrutés par appel téléphonique. Les agentes de recherche ont par la suite fixé l'heure des entrevues avec les chercheurs et leur ont envoyé le formulaire de consentement (annexe 3) par courriel. Ce formulaire résume les grandes lignes du projet de recherche et permet ainsi aux participants de prendre connaissance de leur rôle dans le cadre de cette étude. Toutes les questions supplémentaires posées par les chercheurs ont été répondues par courriel, par appel téléphonique ou avant de commencer les entrevues. Deux copies papier du formulaire ont

été signées par l'agente de recherche et le participant avant l'entrevue (une copie pour le participant et une pour l'équipe de recherche VINCI).

Collecte des données

Nous avons collecté les données à partir d'entrevues semi-dirigées avec les chercheurs participants à l'étude. Une entrevue dite dirigée aurait été trop rigide pour répondre à la nature descriptive de cette étude, étant donné le peu de documentation sur l'éthique de la valorisation. À l'inverse, une entrevue ouverte n'aurait pas été plus appropriée, si nous considérons les objectifs spécifiques de cette étude. Les réponses des chercheurs risquaient de s'écarter considérablement de ces objectifs. Les entrevues semi-dirigées permettent une certaine flexibilité tout en limitant la discussion aux objectifs établis.

Les questions posées aux chercheurs lors des entrevues semi-dirigées s'articulaient autour de quatre thèmes généraux. On retrouve ces thèmes dans la grille d'entrevue (annexe 4) : 1) le contexte de recherche ; 2) l'identification des données et/ou du matériel ; 3) l'intérêt manifesté par les chercheurs pour la valorisation des bases de données et des banques de matériel ; 4) les modalités et les difficultés de cette valorisation. La grille d'entrevue a été révisée par un comité sur la valorisation des bases et des banques.⁵ Les membres de ce comité ont fait en sorte que la grille en question soit directement liée aux objectifs de l'étude et que les questions posées soient bien compréhensibles.

Les entrevues furent réalisées entre les mois de juin et d'octobre 2008. Selon la préférence des chercheurs participant à l'étude, les entrevues ont eu lieu en français ou en anglais. La longueur de ces entretiens variait entre trente minutes et une heure et demie, selon la longueur des réponses des participants. Les entrevues ont été enregistrées sur support audio, pour être ensuite transcrites en éliminant les onomatopées. Au moment de leur transcription, les entrevues ont été dénominalisées afin d'assurer la confidentialité des participants. Toutefois, l'appartenance du participant à un domaine de recherche

⁵ Le groupe sur la valorisation des bases de données et des banques de matériel est un sous-groupe de recherche du programme VINCI.

donné (département, institution et/ou types de données recueillies) a été conservée afin de permettre l'inclusion de ces dimensions dans l'analyse des données.

Analyse des données

L'analyse qualitative de ce projet a été faite par codage thématique. Selon cette méthode d'analyse, l'approche inductive utilisée permet de développer des thèmes ou des concepts qui aideront à mieux comprendre l'éthique de la valorisation dans le contexte universitaire. Des études plus poussées pourraient néanmoins tenter de théoriser ces phénomènes.

L'analyse des données a commencé par une lecture approfondie des transcriptions. Lors de cette lecture, les agentes de recherche se sont familiarisées avec le contenu afin de cibler les éléments importants et récurrents. Ensuite, des catégories préliminaires, aussi appelées des codes⁶ préliminaires, ont été créées pour regrouper des sections de texte sémantiquement indépendantes et représentant des phénomènes communs. [54] Afin de mieux organiser ces catégories, les transcriptions d'entrevues furent importées dans le logiciel d'analyse qualitative *QSR NVivo 7*. Nous avons par la suite développé des sous-catégories de codes à partir des données empiriques de manière inductive. L'organisation des catégories et des sous-catégories a été faite de manière hiérarchique, des thèmes plus généraux aux thèmes plus spécifiques. Il en a résulté une arborescence de codes nous permettant de schématiser les thématiques et leurs liens. [50] Nous avons pu ainsi, finalement, mieux conceptualiser le phénomène à l'étude.

Certaines catégories et sous-catégories ont été regroupées. Les codes redondants ont été jumelés et ceux qui n'étaient pas liés aux objectifs de la présente recherche furent ôtés. Toutes les entrevues ont été contre-codées par une autre agente de recherche pour assurer un seuil d'objectivité. Nous pouvons ainsi assurer une fidélité inter-codeur de l'analyse. Finalement, les codes ont été croisés dans plusieurs matrices (tableaux) pour concrétiser

⁶ Dans le cadre de cette étude, les codes, les catégories ou les nœuds sont définis comme suit : « une production textuelle se présentant sous forme d'une brève expression et permettant de dénommer un phénomène perceptible à travers une lecture conceptuelle ».[15]

l'existence des liens entre les codes et les éléments de l'échantillonnage (par exemple : domaine d'étude, type de données, poste cadre). Ces étapes de l'analyse ne se sont pas succédées dans un ordre linéaire, mais plutôt de manière itérative et aléatoire, favorisant ainsi un va-et-vient entre les différentes étapes de l'analyse.

Dans le deuxième chapitre/article, une section de l'analyse précédente, c'est-à-dire les données concernant les difficultés des chercheurs à valoriser leurs bases et leurs banques, sera le sujet principal à l'étude. Pour limiter la portée de ce chapitre, les difficultés purement pratiques ou organisationnelles seront mises de côté. De plus, nous analyserons seulement une forme de valorisation des données, soit le partage de données ou de matériel entre chercheurs de la même discipline ou de discipline connexe.

L'éthique du partage des données et du matériel sera étudiée à partir de la documentation actuelle (articles et livres publiés après 2005) et les données empiriques. Pour sélectionner la documentation, nous aurons recours au moteur de recherche *Google Scholar*. Cet outil permet une recherche interdisciplinaire et actuelle liée aux thèmes à l'étude. Les mots clefs « banque de données », « base de données », « biobanque », « partage de données », « partage de matériel » et « valorisation » seront employés pour trouver des textes généraux. Nous utiliserons également les thèmes de la liste des difficultés du partage créée lors du codage thématique, tels que « compétition », « règlements éthiques » et « consentement ».

À partir de la documentation ainsi trouvée, nous analyserons premièrement les arguments qui sont favorables au partage des données et du matériel. Ensuite, nous examinerons comment les difficultés d'ordre éthique et organisationnel limitent ce partage. Cette analyse nous permettra de mieux décrire et comprendre la nature des tensions entre l'éthique et la valorisation. Pour terminer, nous suggérons des recommandations pour assurer le partage éthique des bases de données et des banques de matériel en limitant les tensions entre l'éthique et le partage.

Quelques avantages et inconvénients

Il y a plusieurs avantages à utiliser une méthode de recherche qualitative et une analyse par thème dans le cadre de ce mémoire. Par exemple, notre méthode de collecte de données, l'entrevue, permet des réponses nuancées et riches pour explorer la perception des individus. Nous pouvons aussi assurer une certaine validité interne à ce projet. Ceci s'explique par le fait que nous étions deux agentes de recherche à faire les entrevues et le codage (incluant l'intercodage). La révision mutuelle et constante du travail assure une solidité des résultats obtenus.

À l'inverse, les inconvénients à utiliser cette méthode dans le cadre de ce mémoire sont aussi nombreux. D'abord, cette méthode est difficilement généralisable car elle est de nature exploratoire et limitée. La validité externe de ce projet est, par conséquent, faible. Enfin, il existe une panoplie de biais possibles lors d'un entretien. Pour Jean Poupart, ces biais peuvent être divisés en trois catégories générales : « les biais liés au dispositif d'enquête, les biais associés à la relation intervieweur-interviewé et à leur situation respective, et enfin les biais rattachés au contexte de l'enquête ». [55]

Les limites de temps, tout comme la forme et le contenu des questions, sont des dispositifs de recherche susceptibles de créer un biais. Par exemple, dans le cas de notre étude, les chercheurs dont les horaires étaient particulièrement chargés avaient souvent peu de temps à nous accorder. Il est ainsi possible qu'ils aient limité ou omis certaines réponses pour raccourcir le temps de l'entrevue. Quant à la relation intervieweur-interviewé, les réactions de l'intervieweur, telles que les hochements de tête, les expressions faciales et la posture, peuvent influencer les réponses du répondeur. Même si les agentes de recherche sont restées aussi neutres que possible dans le cadre de notre recherche, les réactions souvent spontanées peuvent avoir eu un effet de biais. De plus, les caractéristiques sociales des individus : le sexe, l'âge ou la classe sociale peuvent amener les interlocuteurs à avoir une communication plus ou moins ouverte et authentique. Cette communication peut aussi être limitée si les individus sentent une répercussion possible liée au contexte de l'étude. Ceci est particulièrement vrai dans le cadre de notre étude, car les agentes de recherche étaient mandatées par l'université dans

le cadre du projet VINCI. Certains chercheurs pouvaient hésiter à parler ouvertement, par peur de représailles, lorsque leurs réponses reflétaient une vision négative de l'université. Nous avons tenté de limiter ce biais en insistant sur la confidentialité du participant à la recherche.

L'échéancier

Ce travail de mémoire repose sur une étude empirique réalisée dans le cadre du projet VINCI. L'identification et le recrutement des chercheurs travaillant avec des bases de données ou des banques de matériel ont eu lieu pendant les mois de juin et juillet 2008. Les entrevues ont débuté pendant le dernier mois du recrutement, soit en juillet 2008, et se sont échelonnées sur une période de quatre mois. La transcription des enregistrements audio obtenus s'est déroulée entre les mois de février et mai 2009. Ensuite, la lecture approfondie des transcriptions, l'identification des catégories de codage, l'affinement et le regroupement des codes et l'identification des relations entre ces différents codes furent effectués du mois d'avril à septembre 2009. Pour finir, nous avons rédigé un rapport dans lequel nous avons décrit la perception des chercheurs universitaires concernant la valorisation des bases de données et des banques de matériel.⁷ Le premier chapitre de ce mémoire est influencé par certaines sections du rapport.

Pour utiliser les données du rapport dans le cadre d'un mémoire de maîtrise, il a fallu restreindre le cadre de cette recherche aux tensions entre les enjeux éthiques et la valorisation. Une analyse des sources documentaires ciblant spécifiquement ces tensions a commencé dès janvier 2010 et s'est terminée en mai 2010. La rédaction du premier chapitre/article de ce mémoire a commencé en parallèle et s'est terminé en décembre 2010. L'analyse du deuxième chapitre/article a été effectuée de novembre 2010 à janvier 2011. Enfin, la rédaction du deuxième chapitre, de l'introduction et de la conclusion de ce mémoire a été peaufinée et achevée entre février et juin 2011.

⁷ Ce rapport fut écrit par Elise Smith et Catherine Olivier, sous la direction de Michel Bergeron.

Division des tâches de recherche entre les co-auteurs

La recherche du premier chapitre de ce mémoire est le résultat d'un travail de collaboration réalisé par Michel Bergeron, Catherine Olivier et moi-même. M. Bergeron avait déjà entamé une recherche plus globale sur l'éthique de la valorisation en 2006. Mme Olivier et moi-même avons été embauchées comme agentes de recherche en 2008 pour mieux comprendre les enjeux liés aux bases de données et aux banques de matériel. Un projet sur les bases et banques a ainsi été créé et entamé par Mme Olivier et moi-même avec les conseils du groupe VINCI. Catherine Olivier et moi-même avons fait les entrevues, le codage et la revue de la littérature pour le premier chapitre de ce mémoire. Ensuite, Mme Olivier et moi-même avons écrit un rapport sur la valorisation des sous-produits de la recherche. [56] Le travail pour ce rapport a été divisé de façon égale entre Mme Olivier et moi-même. M. Bergeron et M. Guillaume Paré (membre du groupe VINCI) ont révisé et commenté le rapport final. Mme Olivier et moi-même avons intégré les commentaires dans le rapport.

Le premier chapitre de ce mémoire est un résumé des résultats du rapport écrit par Mme Olivier et moi-même. L'écriture du premier chapitre/article de ce mémoire a été entamée par moi-même. Suite à l'écriture de cet article, Mme Olivier a donné plusieurs commentaires et critiques pour améliorer le texte et pour qu'il reflète adéquatement les résultats de la recherche et du rapport. M. Bergeron a également donné des commentaires et des suggestions sur la dernière version du texte. Le reste de ce mémoire, soit l'introduction, la méthodologie, le deuxième chapitre et la conclusion, est le résultat d'un travail de recherche individuel. M. Bryn Williams-Jones a dirigé ce processus de recherche du début à la fin.

Présentation du premier article

Ce premier article a été écrit dans le cadre d'un des projets de l'initiative sur la Valorisation de l'INnovation et du Capital Intellectuel (VINCI). Les objectifs spécifiques du programme VINCI étaient regroupés sous quatre volets concordant avec les buts prioritaires du projet :

*(1) offrir des services continus et personnalisés de première qualité aux chercheurs afin de valoriser les résultats de la recherche plus efficacement; (2) organiser et promouvoir le transfert de connaissances et du savoir-faire en particulier dans les domaines non technologiques; (3) **exploiter les sous-produits de la recherche;** (4) **examiner les enjeux et questions d'éthique en valorisation ainsi que fournir un soutien en cette matière.** Un élément important du programme visait une attention particulière à la valorisation en sciences sociales et humaines. [56]*

Les points 3 et 4 de la citation précédente furent les buts ciblés lors du développement du projet menant à ce premier article. L'un des groupes de travail du projet VINCI a décidé que l'un des projets se concentrerait en priorité sur la valorisation des bases de données et banques de matériel, c'est-à-dire celles présentant vraisemblablement le plus grand potentiel de valorisation. Sous la direction de Michel Bergeron, la contribution de Catherine Olivier et les précieux commentaires du groupe VINCI sur les bases de données et des banques de matériel, nous avons eu la chance de présenter un rapport [56] ainsi que cet article empirique[57]. Ce travail constitue l'une des rares initiatives de recherches réalisées auprès des chercheurs concernant leur perception quant à la gestion et à la valorisation des sous-produits de leurs recherches. Il permet, par cela, d'apporter un éclairage nouveau en ce qui concerne le potentiel de valorisation des sous-produits de la recherche, la gouvernance des bases et banques et les limites de cette valorisation.

Accord des coauteurs

A) Déclaration des coauteurs d'un article

1) Identification de l'étudiante et du programme

Elise Smith

Programmes de bioéthique (2-495-1-1)

2) Description de l'article

Smith, E. Olivier, C. Bergeron, M. « Researchers' Perceptions on the Valorization of University Databases and Material Banks » *Review of Higher Education*, soumis pour publication.

3) Déclaration de tous les coauteurs autres que l'étudiant

À titre de coauteur de l'article identifié ci-dessus, je suis d'accord pour qu'Elise Smith inclut l'article identifié ci-dessus dans son mémoire de maîtrise qui a pour titre :

L'éthique de la valorisation des bases de données et des banques de matériel créées à des fins de recherche : une étude empirique et normative.

Chapitre 1

Researchers' Perceptions on the Valorization of University Databases and Material Banks

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Submitted to *Review of Higher Education*

Abstract

The objective of this study is to understand the perceptions of university researchers towards the valorization of databases and material banks (e.g. the sharing of data and materials, the use of these resources for social purposes and commercialization). Semi-directed interviews were conducted with 22 researchers from diverse fields of research at the Université de Montréal (Montreal, Canada). Findings show that although there are many limitations and difficulties (ethical, technical, etc.) in valorization processes, certain databases and material banks have much untapped valorization potential.

Introduction

Over the last few decades, databases and material banks have been acknowledged and utilized as valuable resources or tools in research and innovation. While some databases or banks serve as research infrastructures (e.g., population databases and biobanks), most are considered and treated administratively as “by-products” of academic research. This contrasts with the perception of research results or findings as being the *primary* products of research development and technological innovation.

The size of databases and material banks varies from small banks (such as disease specific banks in medical research, or a series of interviews), to much larger banks (as in national or population-wide databases and material banks), and databases may be linked to material banks or exist independently. Because of this variability in size and type, there is no common terminology to define or neatly categorize the range of databases and material banks. [15] A database may be called a “data repository” or a “biolibrary”, and a material bank may be referred to as a “biobank” or a “biological and environmental repository”. In order to avoid confusion, the simplified terminology of “databases and material banks” will be used throughout this paper when referring to the various collections of data or material used for research.

The growing complexity and size of databases and material banks present a number of significant challenges for the research community. These challenges include: availability of short term and long term funding, obtaining a sufficiently large sample size of research participants (in cases of research with human subjects), and the implementation of effective governance frameworks for the management of and access to such banks. [58] Discarding or destroying databases or material banks may occur when finances run out for example, constituting a potential waste of valuable resources. Re-using these banks can help researchers to more fully exploit the inherent value of such resources, to optimize the investment (in terms of time and money) in their initial development and to maximize the contribution of participants. [20] Specifically, databases or banks can be re-used through: sharing of data and materials, their conversion into public collections, their use for social purposes, and/or commercialization. Their value can be measured in terms

of the development of social goods or the advancement of scientific knowledge; it need not be measured strictly in financial terms.

In the contemporary French-language scientific literature, the word '*valorisation*' is used to describe various value-adding processes or knowledge transfer activities that enable increased access to a diversity of knowledge resources by users other than those initially envisaged. Such knowledge transfer allows resources such as databases and material banks to gain value beyond their original application or purpose. [22] In comparison, the English-language literature concerning university research administration and resource transfer deals mostly with issues associated with data and material sharing or their commercialization (e.g., intellectual property, control of data, confidentiality). In this study we have chosen to employ a broader view of such processes by using the French notion of valorization.

The concept of valorization is fairly new in empirical research on databases or material banks. Most empirical research has been limited to analyses of certain types of material or data, or to specific fields of research, e.g., genetic banks [42], banks linked to pregnancy outcomes [43], cancer tissue banks [59], and pediatric banks [45]. In this paper, we examine the implications of sharing various data and material across a broad range of research fields, including quantitative and qualitative data (e.g., patient health records, interviews and surveys), and organic (e.g., biobanks) and inorganic collections (e.g., mineral, soil, or video collections). While researchers in some specific fields may share these databases or material banks, others do not. Data and material transfer systems in the field of genetics (e.g., Genebank), and certain sub-specialties in physics and computer sciences, are considered sharing successes. However, these successes are largely the exception in academic sciences; most researchers simply do not share, and many actively withhold data or materials. [60, 61]

International ethical guidelines and legal norms concerning the secondary use and general access to databases and material banks have yet to be established and consistently applied across disciplines. The literature on genetic and genomic banks shows that while many

international or national documents propose governance models, there is no consensus regarding legal regulation or ethical norms. [49] In the US, many funding agencies (e.g., NSF, NIH) make sharing a requirement for funded projects [29]; and with the Bayh-Dole Act, university-industry relationships and the commercialization of research results are encouraged. In Canada, there is no specific harmonized governance system (and thus none for valorization) of databases and material banks. [38] While Canadian federal and provincial funding agencies promote the sharing of data and material, they do not enforce such measures. However, for databases and material banks involving human subjects, there exist legal and ethical regulations to protect the dignity and security of research participants and communities. For example, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* [62] formalizes the minimal ethical requirements for research financed by one of the three Canadian Federal funding agencies.⁸ Nonetheless, these requirements do not specifically address issues linked to the valorization of databases and material banks. In practice, research ethics committees in Canada have little formal basis upon which to provide guidance to researchers in the ethical use of databases or material banks. [21]

Without clear and well articulated ethical and administrative guidelines in Canada concerning the creation, use and diffusion of databases and banks, researchers who create these repositories in a university context are often left individually responsible to establish their own governance and valorization processes. Researchers are responsible for meeting research ethics requirements concerning, for example, human subjects' protection (e.g., respect for confidentiality, development of consent agreements, the possible return of research results to the participants) or the scientific value of their research. However, researchers often feel they have the freedom and right to decide (and restrict) who can access the databases and material banks they have created. This perspective is also common in other countries. For example, a US based empirical study by Blumenthal and colleagues found that 44% of geneticist and 32% of other life scientist participated in some sort of data withholding. [63] Such a practice can greatly limit the

⁸ Federal funding agencies in Canada include: the Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council of Canada (NSERC).

extent of valorization that can take place for these databases. The further development or amendment of ethical and administrative guidelines for the governance and valorization of databases or banks could, we suggest, benefit from a better understanding of researchers' experiences and views on the matter.

In our study, we chose to interview researchers at the Université de Montréal from a wide range of research disciplines and fields. The Université de Montréal is the largest French-speaking research and teaching university in Québec, and amongst the leading Canadian research institutions. The University's valorization bureau – the *Bureau de Recherche-Développement-Valorisation* (BRDV) – promotes and facilitates industry relations and provides necessary guidance concerning contract agreements and intellectual property. And the valorization of databases and material banks is a topic of interest for the BRDV and the university administration. The aim of our study was: 1) to determine the researchers' interest in the valorization process of databases and material banks, 2) to identify researchers' concerns and difficulties associated with this valorization, and 3) to identify and characterize the types of databases or material banks that hold potential for valorization in different disciplines and fields of research. Although this is a study of one particular setting – that of the Université de Montréal – similar issues surrounding the valorization of research produces and resources are present in many other countries, and thus the results obtained in our study may shed light on aspects of valorization processes that are relevant across national settings.

Method

To investigate university researchers' perceptions regarding the valorization of research databases and materiel banks, an initial list of possible participants was created through a search of the university web site, categorized by the type of data or material they used in their research, i.e., computer science, medicine, basic / experimental sciences, applied sciences, quantitative social sciences and humanities, qualitative social sciences and humanities (Table II).

Table II : Number of researchers interviewed for each type of data or material constituting databases od banks in various academic fields

Types of data and material	Academic Fields	Number of researchers
Computer data	Bioinformatics, genomics	3*
Medical data or material	Medicine, pharmacology, Public Health, Pathology	4
Experimental sciences data or material	Biomedical sciences, chemistry, dentistry, ophthalmology	4
Applied sciences data or material	Biology, Ecology, Geophysics, Anthropology**	4
Social sciences and humanities quantitative data	Sociology, Nutrition, Psychology, Criminology	4
Social sciences and humanities qualitative data	Sociology, Law, Social services	3*

*The interview of three researchers in these categories was deemed sufficient to understand the interest in the valorization of databases and material banks pertaining to those types of data or material in our study.

**This typology was created based on the type of data or material used. As such, researchers in anthropology that worked with organic or inorganic material were classified in the applied sciences category.

Three to four researchers were interviewed for each type of data or material. This sampling approach aimed to capture the diversity of data and material use found in academic research. Twenty-two researchers (12 male, 10 female) participated in our study. They had worked at the Université de Montréal between one and thirty-three years, with an average of fourteen years of research. Of the twenty-two researchers interviewed, sixteen worked with data or material concerning human subjects. Five of the researchers also held administrative positions on top of their research responsibilities, which allowed us to also explore the administrative challenges associated with the creation and use of databases and material banks.

After approval by a University Research Ethics Board, participants were recruited by telephone and a consent form was then sent by e-mail. Upon obtaining free and informed consent from participants, interviews were conducted in English or in French depending on the researcher's preference (quotes in this paper that were originally in French have been translated). Interviews were conducted between June and October 2008. The semi-directed interviews were structured around four themes: 1) the context of research, 2) the identification of data or material, 3) the researcher's interest(s) regarding value-adding

processes for databases and material banks, and 4) the modalities and difficulties of valorization. Interviews lasted between thirty minutes and an hour and a half, were recorded, and then transcribed omitting any nominative information to protect the participant's confidentiality.

Our analysis employed thematic coding to extrapolate inherent general concepts that could help us better understand the implications of valorization. The preliminary coding groups for the analysis were structured according to the themes developed in the questionnaire and were followed by additional nodes developed in an inductive manner through the creation of themed coding groups. The *QSR N-Vivo 7* qualitative software program was used for the analysis of the data and inter-judge coding was performed in order to ensure objectivity. The different coding groups were then cross-matched in a variety of different matrices (tables) to identify links or relationships between the different themes and the elements of the sampling (e.g., discipline of research, type of data or material, years of seniority).

Results

The results of our interviews are organized into four major areas: 1) potential and interests for valorization; 2) challenges and limitations; 3) modes of governance (past, current, preferred); and 4) property rights and control.

1. The potential of databases and material banks for valorization

Researchers expressed their preferences in the following four categories of processes that may be used to valorize their databases and material banks: 1) the secondary use of databases and material banks in one discipline or across different disciplines (either as interdisciplinary academic research or through direct transfer to other disciplines); 2) the pairing of databases or material banks in university research, 3) the commercialization of databases or material banks, and 4) the use of databases and material banks for social purposes. (Table III)

Table III : Proportion of researchers interested in different valorization processes

Valorization processes	Number of researchers
Secondary use of databases and material banks in one discipline	18
Secondary use of databases and material banks across different disciplines	17
Pairing of databases or material banks in university research	9
Commercialization of databases or material banks	4
Use of databases and material banks for social purposes	5
No potential for valorization*	11

* A number of researchers had created or used databases or material banks composed of different types of data or material. Their interest in valorization processes differed depending on the databases or material banks being discussed. These researchers saw a potential of valorization for certain databases or material banks and none for others.

Of the twenty-two researchers, eighteen acknowledged the possibility of and confirmed their interest in sharing their databases or material banks with other university researchers in the same field of research. This type of value-adding was the most common method of valorization used by the researchers we interviewed. The sharing of data or material is a cost-effective way for researchers to develop knowledge by accessing existing databases or material banks instead of spending resources duplicating existing structures. In certain circumstances, data developed or material obtained from a previous research project can be useful in the development of a new project. Many researchers mentioned that the possibility of sharing data or material was considered and included at the project planning stage. For example, the collaboration of multiple researchers in a research centre or in research programs often includes formal or informal agreements about open-access, by members, to resulting databases or material banks. This type of data and material sharing contributes to the overall knowledge advancement and group achievements.

Databases or material banks can also be shared by researchers working across many disciplines and between or within various fields of research. Seventeen of the twenty-two participants were interested in collaborating with researchers in other disciplines in order to share or exchange their databases or material banks. This quote from a social science researcher working with qualitative databases illustrates the desire to build bridge

between different areas of research: *“It seems to me that someone with a different perspective could analyze the material in a different way. One could also imagine different methodological perspectives in a meta-analysis of this material.”* (Participant #13)

According to the participants, innovations in communication technology facilitated collaboration among researchers from various disciplines, different institutions and even from different countries. However, managing such research, including the governance of databases or material banks, can be complex because of the many and diverse norms and practices specific to the researchers’ institutions or countries. Some participants recognized this situation and expressed the need for a common set of standards to be developed for the governance of databases and material banks. Issues regarding governance of databases and material banks will be discussed more fully below.

Nine of the twenty-two researchers expressed interest in developing collaborations that would allow them to pair their databases or material banks with those of other researchers. While the sharing of databases or material banks does not usually imply or require further data collection activities, the pairing of various databases or banks often requires an important contribution on the part of the researchers involved. Pairing up databases or material banks for comparison across time periods or geographic locations is common in some academic research, e.g., in longitudinal studies, and provides the possibility of obtaining larger sample collections. In cases where the data or material samples are very rare or hard to obtain (e.g., a rare genetic marker), pairing up banks can help create a new or enhanced bank in a timely and less expensive fashion.

Resource constraints in academia have led some researchers to consider private funding for their research. Six of the interviewees explained that they had forged – or that they would like to establish – partnerships with industry in order to acquire the necessary resources to complete their research. However, most researchers we interviewed were reluctant to establish any formal relationship with industry that would include sharing or commercializing their databases or material banks. This reluctance did not reflect a lack

of commercial value for these databases or material banks; in fact, four researchers noted that their databases and material banks had both academic value as well as significant economic value in the marketplace. The following quote from a researcher working with genetic databases and material banks illustrates this point:

Well, I'm not interested [in a formal relationship with industry]. I chose to do academic research. I have worked with industry, then I made the choice to do academic research. The commercialization of genetics? I do not think so. (Participant #7)

In this case, the decision to deliberately avoid collaboration with industry was driven largely by the type of data or material used in research. Commercialization of certain types of data or material is even illegal in a number of research areas. For example, some archeological and geological material collections are considered to be part of a society's collective heritage. Even though they cannot be commercialized, these material banks could nonetheless benefit from some sort of valorization.

While sharing with other researchers for academic purposes is an interesting option, the secondary use of databases and material banks for social purposes could also be considered. Five of the twenty-two researchers interviewed mentioned that public institutions could have uses for their databases or material banks. For example, material banks of insects in the Montreal Botanical Gardens (an institution affiliated with the Université de Montréal and public organizations) have a public value because they promote public knowledge and understanding, as with any other museum collection.

Among other things, insects from specific projects will often be put in collections. There is the collection here at Robert Violette Pavillon Marie-Victorin. Or in the provincial or national collections, either with the Ministry of Agriculture in Québec or in Ottawa. There is a huge collection of insects here. So often we will distribute our specimens in different collections. Then, it is accessible to everyone. (Participant #15)

In conclusion, researchers identified various types of valorization for their databases and material banks. While most felt comfortable sharing with other researchers, a minority also considered commercialization or transfers to public institutions.

2. The difficulties and limitations of valorization

When asked about the potential valorization of their databases or material banks, researchers noted the complexity of such an initiative and identified important limitations. Three main types of difficulties were discussed: 1) those associated with the nature of the data or material, 2) those linked to the inadequacy of research resources, and 3) those inherent to academia in general. (Table IV)

Table IV : Number of researchers associating difficulties with valorization

Difficulties	Number of researchers
Specificity of the database or material bank	6
Lack of resources	12
Lack of time	6
Competition between researchers	10
Lack of training and information	7
Low quality of the data or material	8
Lack of computer resources	5
Research ethics procedures	9
Durability of the data or material	3

Six researchers mentioned that some if not all of their databases or material banks were too specific to be reused. For example, incompatible research protocols or research objectives may limit the feasibility of sharing or exchanging data or material. Databases and material banks that have a highly focused technical and scientific purpose and primary value in a specific discipline or in a specific project may not have easily identifiable use or application in other contexts. Three researchers mentioned that their databases and material banks were perishable and/or had particularly short life spans, thereby reducing the potential for valorization. A researcher in organic chemistry mentioned that many of his material banks were thrown out, largely because the proteins involve were wrongly folded, and so were disposed of in order to make room for more samples. Similarly, biological samples are subject to stresses in their environments and

may lose quality, be degraded (in the case of genetic material or proteins) or be contaminated. Even for databases and material banks that have a long lifespan, the quality of the data or material may be compromised.

To allow for optimal valorization, it is essential that data and material be properly collected, processed, used and stored to ensure quality. Eight researchers expressed concern that other researchers or research teams do not, or might not, be using comparable, acceptable or current standards in their collection, processing and storage of databases or material banks. It is also sometimes difficult to assess whether a database or material bank is of scientific quality, when complete information concerning the collection process is unavailable for review. Whatever the reason, doubts about quality reduce the value of databases or material banks that could be selected for valorization. Therefore, valorization was less relevant or viable to researchers when they had significant uncertainty about quality. In creating their own new databases or material banks, researchers can control the methods used to collect, process and store the databases or material banks, and thus have a greater certainty as to their quality.

As previously mentioned, substantial human and financial resources are needed to create and maintain databases and material banks, but these resources are often difficult to obtain. Twelve of the twenty-two researchers identified access to long term stable funding as one of the major hurdles in the valorization process.

[...] The problem is that with the nature of these databases there should be, there must be an update that is done, [...] it is for the governance of these banks, there is no financial resource that is easily accessible for the maintenance of databases. We receive grants for research projects, but I've never seen a grant that is given only for the maintenance of databases.
(Participant #9)

In addition to financial resources, in many cases there is also a need for human, institutional and informatics resources to sustain any value-adding processes. In the case of large banks or databases, individuals need to be competent in the creation, conservation, organization and monitoring of data and materials. According to the

researchers we interviewed, the lack of such competent research assistance limits their capacity to valorize databases and material banks. Moreover, the lack of physical and virtual space to store data, samples or specimens limits the duration of their conservation, thus constraining their potential for valorization. Indeed, five researchers mentioned that the university computer network could not support the level of archiving needed to store their databases. Others noted that the information security firewalls in different university settings (especially those linked to hospitals) made the sharing of databases between institutions particularly difficult.

Six researchers mentioned that they were already extremely busy with their academic obligations and simply did not have the time to go through the valorization process, specifically when technical steps such as initial preparation and long-term maintenance were required. The general academic context can also reduce the interest of researchers in sharing their databases and material banks. In a competitive environment with limited funding, researchers are recognized and rewarded according to their productivity; that is, the quantity and quality of their published work. Sharing databases and material banks could, according to almost half of the researchers we interviewed, provide a competitive advantage to other researchers, thus creating an important and obvious disincentive to engage in valorization processes. *“It happens all the time in science when there is competition. There are people who are nice for five years, they start to lose money, they have no subsidy, then begin to be a bit nastier.”* (Participant #2)

In Canada, university research is governed by comprehensive research ethics requirements that are, according to nine researchers, a limit on the valorization process, particularly concerning the secondary use of databases or research material. For example, seven researchers considered that the procedures to ensure proper consent of participants pose an important limitation to the secondary use of research data or material. When research involves human subjects, research participants must know and agree to well-defined research projects. To allow secondary use of databases or banks, it might be necessary for participants to re-consent to a following project. In discussing the issue,

researchers identified three different types of consent approaches that could be used: specific consent, open consent with certain restrictions, and broad consent (Table V).

Table V : Number of researchers favoring specific versus open or broad consent

Types of Consent	Proportion of researchers that agree with this type of consent
Specific consent	4/16
Open consent	4/16
Broad consent	6/16*

* Two researchers did not give answers to the questions about consent because they did not have any contact with the research participants and thus did not follow consent procedures.

Specific consent, the more traditional notion, takes place when research participants are cognizant of how and why the data or material they have provided will be used in a specific research project. In the event that the data or material they have provided is to be used in subsequent research projects, it is understood that consent must once again be obtained. Only four of the sixteen researchers working with human data or materials expressed their preference towards this type of consent; another four preferred a more open type of consent with certain restrictions, e.g., where participants acknowledge that the data or material they have provided will be used for other purposes in a given field of research. However, six of the sixteen researchers working with human subjects suggested that broader consent could be used to allow secondary use of data or material. In this case, consent from participants is obtained only once and includes the possibility for researchers to reuse research data or material in any further research, regardless of the field of research. Broad consent includes a promise from the researcher that they will ensure a certain level of participant confidentiality.

Parallel to the positions expressed regarding consent, seven of the researchers interviewed acknowledged their own lack of training in research ethics and valorization, a situation that could lead to increased difficulties. As one researcher noted,

It was well established in practice, but when a new researcher wants access to tissue samples for the first time, he lacks a lot of information and tools to

*learn how to navigate. What is his responsibility? What does he need to do?
Who should he go to for advice? (Participant #4)*

Researchers thus suggested that access to training could help them better plan for or factor into their work the rules and procedures regarding research ethics and valorization.

3. Governance of databases and material banks

The valorization of databases and material banks can be greatly facilitated by enhancing their accessibility for the research community, industry, governments and society; accessibility depends largely on the management and governance systems implemented. Participants identified six main approaches to the governance of databases and material banks: 1) little or no regulation, 2) the use of contracts and permits, 3) policies and laws, 4) sharing through repositories or registries, 5) network sharing, and 6) open access (Table VI).

Table VI : Researchers' practices and preferences regarding governance

	Used governance methods	Preferred governance methods
	<i>Number of researchers</i>	<i>Number of researchers</i>
Little or no regulation	15	15
Contracts or licenses	11	7
Policies or laws	11	10
Sharing through repositories or registries	3	15
Network sharing	7	7
Open access	6	8

*Several researchers mentioned more than one type of governance methods since they had more than one database or material bank.

Little or no regulation

Fifteen of the twenty-two researchers shared their databases and material banks with collaborators without having made formal agreements. In most cases, it was noted that researchers with common or related research interests freely exchange databases or banks

to enable greater use of these research by-products. The modalities depend on informal agreements and tacit understandings. Convenience, ease and simplicity of the exchange are the main reasons for researchers to privilege this approach; but it is also through these exchanges and collegial agreements that mutual trust and respect is developed.

Of the twenty-two researchers interviewed, fifteen wished to continue using informal exchange agreements to govern the valorization of some if not all of their databases or material banks. These researchers were invariably skeptical about all forms of institutional governance; as one explained

I do not want to have any [governance bodies]. If there is no value added, I do not know why we pay people just to put a spoke in the wheels. That's for sure [laughs]. It already works pretty well, do not fix things that work.
(Participant #2)

According to many of the researchers, the establishment of a management system or of an institutional governance body would be a waste of already scarce resources. They felt that the circumstances requiring an institutional body responsible for the governance and supervision of research were rather rare and so did not warrant the investment.

According to several researchers, databases or material banks that are already available in the public domain (e.g., in open repositories on the Internet) should not be subject to any institutional governance systems. However, the same researchers generally believed that any valorization of databases and material banks that might threaten the privacy of individuals should be subject to protection measures or privacy protocols. In our study, researchers who exchanged data and material informally either did not have studies that included human subjects or did not have any direct contact with human subjects. The only exception was the case of researchers in the biomedical sciences. Even if most had a direct contact with their research participants, these researchers felt that the current governance measures were onerous and required standardization and simplification to improve their efficiency.

Contracts and permits

Parallel to such informal systems of exchange, eleven of the twenty-two researchers confirmed that they sometimes shared databases and material banks through contracts or licenses. The most common form of these is the Material Transfer Agreement (MTA). In the fields of applied or medical sciences, MTAs are often used, particularly when international collaborators are involved. In other research areas, governmental authorization may be required. This is particularly the case for material such as archeological artifacts that are part of the national heritage. These authorizations can be extremely complex to obtain and use.

Many researchers noted that when possible, they tried to avoid lengthy procedures (and application forms) associated with obtaining a license, signing a contract or a MTA. As one researcher explained, *“So I would not necessarily be against the use of a small contract, a very simple model that people could use to transfer their banks. But it would have to be extremely simple, because otherwise it will just kill the databases.”* (Participant #3) Seven of the eleven researchers who had previously used a contract or license did however wish to continue to exchange databases or material banks in this way.

Policies and laws

Generally, researchers expressed their desire to spend as much time as possible on research and teaching. Any time spent fulfilling bureaucratic requirements was considered a significant deterrent to engaging in valorization. By contrast, formal regulations, policies or laws were considered to be more convenient. Half of the researchers interviewed mentioned that they followed policies, rules or specific laws concerning the governance of and access to some of their databases or material banks. Seven researchers mentioned that they followed the “rules” of their research ethics committee, and that these rules were important when taking specific decisions regarding the destruction, transfer and sale of data or material. It should be noted that in Canada, and more specifically in the province of Quebec, research ethics committees do not set out formal “rules”. What the researchers were referring to was the application of existing

ethics frameworks such as the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. [62]

Apart from ethics requirements, four researchers mentioned that the rules set out by the scientific journals in which they publish have a significant impact on the accessibility of their databases or material banks. Two mentioned that the journals required access to their databases or material banks to allow review or verification of the reliability and veracity of research findings. Two researchers explained that providing access to the databases or material banks through scientific journals helped them give broader access to the international scientific community. This broader access can result either from the transfer of specimens from a material bank (e.g., insects) to a national collection, or in the fields of genetics and proteomics, by making the databases available via electronic links on the journal's website. As the following researcher, an advocate of open access to databases and material banks, explained:

...there are rules that, now, that in most of the journals, that if you submit a paper to this journal then you should make your database available to other qualified researchers. So, obviously we usually deposit these databases, we send them to the journal and it has it also somewhere on the website. (Participant #10)

In order to maintain confidentiality when participants are involved, it may not be desirable or possible to give open access to certain types of data or material. In these circumstances, researchers acknowledged that there are a variety of regulations to ensure participants' confidentiality. However, these regulations sometimes lead to discrepancies between the requirements of the aforementioned policies and the recommendations of research ethics committees, creating an unease regarding the valorization process. Moreover, the significant number and complexity of policies, recommendations and guidelines can be daunting, in part because most of these policies have not been created with the goal of governing databases or material banks, and so are sometimes difficult to apply.

Ten researchers expressed interest in having simple, rationalized guidelines in order to help them engage in the valorization process of databases or banks. Interestingly enough, there was no general agreement as to specific directives, guidelines or terms that should be included in these guidelines. However, most

researchers were in favor of having a general policy governing databases and material banks for the University and its affiliated hospitals. Medical researchers working on multi-center projects expressed a strong desire to see a standardized regulatory framework in research ethics that would apply to multiple institutions. One of the medical researchers even noted that a policy at the provincial or national level would be useful for the valorization of databases and material banks. Conversely, some researchers expressed a desire for policies tailored to different research practices and fields of research. For example, three researchers expressed the desire for a policy specific to social sciences research that would take into account the particularities of their practices. They argued that most databases and material bank guidelines and policies have emerged from the biomedical sciences and so leave out distinctive and important aspects specific to social sciences research.

Repositories or registries and network sharing

Regulations may also govern the sharing of databases or material banks through data or material repositories or registries. A repository is a physical location where researchers can deposit databases or material banks; information about the databases or banks can also be posted in a registry. Three researchers stated that they had already shared data or research materials through a repository. Similarly, fifteen researchers agreed with the idea of establishing a registry or repository that would include information about the different databases and material banks stored at the University and its affiliated institutions. However, researchers felt that universities should not devote resources to establishing such repositories or registries since other external repositories or registries already exist, are accessible and meet their requirements.

Seven of the researchers indicated that they were part of research networks that influenced data or material sharing modalities. In these cases, instead of sending information, data, or material to a central repository or registry, they exchange databases or material banks within these networks. Interestingly enough, these researchers seemed to be more often associated with the health sciences. The networks were often governed by policies that defined the procedures and contracts to which researchers must adhere. The establishment of research networks is a considerable and time-consuming endeavor, but one that brings important efficiencies thereafter:

I mean, we did it [a network] with the idea of promoting ethical and legal methods of sharing samples. Thus, the work to put in place the entire structure has been enormous, but once it was setup after that, sharing samples is easy because there is a procedure to follow. (Participant #4)

However, networks have not all developed formal management systems for sharing data or research material. Many rely on informal exchanges. Such informal exchanges were especially common to experimental scientists participating in networks that were not initially created with a primary goal of sharing databases or material banks. One of the researchers noted that his network was primarily a place of “*interpersonal relationships between people*” (Participant #9). Once this relationship of trust was built, the sharing of databases and research materials could be facilitated.

The majority of researchers who were part of a network preferred sharing banks through these infrastructures. A variety of reasons can explain this preference. For example, one researcher mentioned that the constant exchange of databases or material banks within networks provided greater transparency and exposed the banks to ongoing critical assessment of the veracity and scientific validity of the data and material. Also, researchers indicated that the sharing of databases and material banks through networks facilitated broader, more extensive advancement of knowledge. There was a general consensus among researchers that sharing databases and material banks reduces the costs of certain forms of research. Yet, despite these benefits or advantages in the health and

applied sciences, our study found that the formalization of sharing networks was virtually nonexistent in the humanities and in computer science.

Open access

The last category of governance methods used for the valorization of databases and material banks within the university setting was the provision of complete open access to all researchers. Six researchers confirmed that some of their databases or material banks were available to all researchers. In the majority of cases, the data or material in these was not of human origin and thus raised no confidentiality concerns. The most popular method for providing open access was to put the database online, or in the case of material banks, to provide information online through posting pictures on websites.

As mentioned previously, scientific journals may require or strongly advise researchers to make their databases or material banks openly accessible, following publication. Five of the researchers we interviewed made their databases accessible online through a venue dedicated to their field of study; some researchers put their databases on a private research network website, while others put their databases on a publicly accessible website. Material banks are accessible to the public when they are used to build collections at the provincial, national or international level, or as part of museum exhibits. It should be noted that eight researchers said they wanted to ensure that their databases or research materials were made accessible in the future. One researcher described this evolution towards open access:

But there is something concerning proteomics, there is something that is going to change, there is a huge world-wide database that has been, I think the initiative is from the United States, but I think the whole computing would be outsourced to India, where all proteomic databases could be deposited and there would be a search engine so everybody could just go and for a particular protein find its expression, find its profile and have access to databases on different levels. (Participant #10)

Despite the enthusiasm for sharing databases and material banks through open access, researchers identified certain drawbacks. Notably, open access to databases or material

banks gives little or no control to the initiating researcher. Moreover, access to data or material related to human subjects presents particular concerns and risks that must be carefully managed. Interest in sharing was predominant among researchers who were usually not involved in a close relationship with research participants, who did not work with identifiable databases, or who did not work with human subjects. No qualitative social sciences researcher was in favor for the widespread sharing of databases or material banks; these researchers showed the greatest concern for protecting information and ensuring participant confidentiality. Researchers' opinions varied greatly on how they would like their databases and material banks to be managed. Nonetheless, we found a significant willingness on the part of researchers to discuss different methods of management, which may indicate a readiness to see evolution in the governance of databases and material banks.

4. Property rights and ownership of databases and material banks

Researchers identified a significant range of material and intellectual ownership arrangements for databases and material banks, a variety that can present difficulties for valorization. Eleven key actors were identified as holding various intellectual and/or material property rights: 1) funding agencies, 2) researchers, 3) specific communities, 4) students, 5) the public, 6) hospitals, 7) private companies (industry), 8) scientific journals, 9) laboratories, 10) research participants, and 11) the University. Table VII illustrates how researchers distributed property rights between the different actors. Researchers agreed, disagreed or remained ambiguous as to the just attribution of property rights to the various actors. This ambiguity manifested itself in different ways, notably when researchers contradicted themselves over the attribution of ownership, when negotiating different property rights depending on the bank, or when having a number of banks with different property sharing arrangements.

Table VII : Researchers' perception on ownership of various actors

Actors	Agree	Disagree	Ambiguous *
Funding agencies	4	N/A	N/A
Researcher	19	7	5
Specific communities	2	N/A	N/A
Students	6	4	8
The public	13	N/A	N/A
Hospitals	3	N/A	N/A
Industry	7	1	8
Scientific Journals	1	N/A	N/A
Research laboratories	7	N/A	N/A
Research participants	3	1	1
University	12	14	16

N/A: Not applicable. Researchers did not express opinion on the subject during the interviews.

* This ambiguity was manifested in different ways, notably when researchers contradicted themselves over the attribution of ownership, when negotiating different property rights depending on the bank, or when having a number of banks with different property sharing agreements.

The issues relating to intellectual and material property of databases and material banks were considered a high priority by most of researchers interviewed. In fact, only one researcher said that he was not interested in the concept of property as related to databases and material banks. Most researchers in our study saw themselves as holding intellectual and material property rights for their databases and material banks. Of the twenty-two researchers, only five were uncertain about having ownership rights when it came to some of their banks. Nineteen researchers agreed to designate themselves as partial owners of certain databases or material banks and only seven researchers disagreed completely with taking ownership of some of their databases or material banks. It is important to note that the researchers' individual opinion on ownership varied across the different databases or material banks they held. This made it difficult to obtain consensus on the relevance of the identified actors when regarding intellectual and material ownership of databases or banks. While the researchers were reluctant to define themselves as true "owners", they wanted to have full control and responsibility of the databases or material banks. In fact, sixteen researchers preferred to describe their role as one of a manager, custodian or trustee of their databases or material banks.

Twelve researchers recognized that the University has certain property rights to some of their databases or material banks. Sixteen researchers were noncommittal about allocating some property rights to universities; this contrasts with three researchers who worked in hospital settings and attributed complete ownership of databases and material banks to the hospital. Researchers working with specific ethnic communities did not consider themselves as owners of the databases and material banks; instead, it was understood that the communities' themselves were the primary owners of the collected data and materials. These communities sometimes had elected or nominated groups to represent and protect their rights to own data or material arising from research.

Researchers were less inclined to attribute partial or full ownership of databases and material banks to industry (7 researchers), students (6 researchers), funding agencies (4 researchers), research participants (3 researchers), or to scientific journals (1 researcher). Researchers were willing to attribute partial ownership to more than one actor at a time, demonstrating that the question of intellectual and material ownership of databases or banks is far from being resolved. Interestingly, thirteen researchers from various fields agreed to assign certain ownership rights over research databases and material banks to the general public. The researchers justified such recognition of the public's role in research databases and material banks ownership by the investment of society in academic research. Products and by-products of research could thus be perceived as a common capital, similar to a social heritage.

[...] and types of projects that we're doing where we are trying to constitute the biobank as a kind of a "patrimoine public", where people could eventually as their ideas develop be able to rapidly test their ideas in an existing biobank, then the biobank itself becomes a, you know, it should be the property of the research community as opposed to any given individual, or any specific university I would say. (Participant #19)

The investment that society provides to academic research comes through public funds and therefore it should follow that the benefits of research (and their by-products) should return to society. Moreover, in some cases the types of data or samples were identified as

public heritage subject to government regulations and laws, as in the example of archeological finds.

Researchers acknowledged that they had property rights because of the role they played in the development, conservation and eventual destruction of databases or materials; and they maintained their right to unilaterally destroy their databases and material banks. In addition, eleven researchers said that they had the right to the databases and material banks resulting from their research if they left their university, while five said they could negotiate this with their institution. A smaller number of researchers saw it as their duty to give or bequeath databases or material banks to colleagues at their university in the event of their departure. The majority of researchers from across disciplines agreed that property rights were to be shared by the researcher and the institution with which they were affiliated (e.g., the university or the hospital). However, researchers in the experimental sciences, and the quantitative social sciences and humanities, felt that they had complete property rights to their databases or materials banks. As noted by this experimental scientist:

[...] Who is the owner? It is essentially the researcher or the group of researchers, who initiated the bank. They were the ones that stored it in their freezers. So finally it is they who are the owners to some extent. [...] So, we would have to see with them if we were interested in having access to samples. (Participant #9)

Most of the researchers interviewed who also held an administrative position at the university shared this position that material property belonged almost exclusively to the researcher. Their position was based on the fact that property rights relate to the creation and destruction of databases or material banks. They argued that researchers were most knowledgeable about the data or material included in databases or banks, and therefore were best suited to make decisions regarding their disposition.

Discussion

The development of databases and material banks is fundamental in academic research and represents an important investment of resources. It is therefore of interest to institutions and to researchers to optimize the utility of such databases and banks in order to advance knowledge. Valorization can help in developing and establishing the value of banks and databases for various purposes or applications and as such, inform decisions relating to their management and use. The purpose of this exploratory study was to understand the perspective and preferences of researchers from the Université de Montréal, one of the largest research-intensive French speaking universities in the world, regarding the valorization of their databases and/or material banks. Our study had three specific objectives: 1) to determine the researchers' interest in the valorization process of databases and material banks, 2) to identify researchers' concerns and difficulties associated with this valorization, and 3) to identify and characterize the types of databases or material banks that hold potential for valorization in different disciplines and fields of research.

1) Researchers' interest in the valorization process

Our interviews demonstrate that researchers at the Université de Montréal are engaged in various practices or forms of valorization of databases and material banks. Most share part or even all of their data or material with colleagues working in the same area of research, and occasionally in related areas of research. These data or research materials are often shared as series of samples or specimens, but can also be exchanged through an access to databases or material banks. This sharing between colleagues promotes or facilitates further collaboration, and results in the broader recognition of the individual researcher(s) who created or developed the bank.

Researchers usually require that they be named as authors in publications that used the databases or material banks resulting from their research; minimally, they should be included in the acknowledgements. This type of recognition encourages researchers to further engage in the sharing of databases and material banks, expanding their use beyond the initial research project that led to their creation. The sharing of databases and

material banks is thus instrumental to advancing scientific knowledge more broadly, as well as to save resources that would otherwise be spent building similar banks. For these reasons, researchers showed a clear interest towards this form of valorization. Similarly, in the genetics database literature, it is often noted that increased access to databases enables researchers to further advance their research. [30, 31]

However, it is also noted in the literature on databases and material banks that collaborative research, as in the case of multi-centre banks, provides less individual recognition for the researcher in the long run. [31] Moreover, ethical considerations presented in publication guidelines often stipulate that the exchange of data or material is not grounds for authorship [64], but they remain unclear as to whether the creation of an entire database or material bank counts as grounds for authorship. This lack of clarity and consistency about authorship can make researchers more reluctant to share their banks with fellow researchers who are also competitors for funding and professional recognition. Not surprisingly, the researchers we interviewed preferred to maintain some control over the future uses and transfers of these banks, when engaging in valorization. Loss of such control was a major deterrent to valorization.

Fear of losing control of the future use of their databases or material banks, or of being less competitive in publishing or obtaining research funds, may explain why researchers find it more difficult to share data or material – as a public good with social value – with public institutions. In our study, only five of the twenty-two researchers saw this type of valorization as a viable possibility. Not only did researchers not see the relevance of public institutions using their databases, they also saw collaboration with public institutions as complex and time consuming. Hence, the competitive nature of research can be a significant barrier to the valorization of databases or material banks. However, the issue of competition can be less problematic in certain cases, most notably when there are other valorization processes in place with certain communities or with collective collections (e.g. archeological or biological collections).

Similarly, most of the researchers were not interested in the commercialization of databases and material banks, and this was true even for those who often worked with industry. They rarely shared databases or research materials with industrial partners, something that runs counter to the goals of Canadian federal and provincial programs and commercial initiatives designed to encourage industry-academia collaborations in commercializing research results. [65] Many scholars, such as Crespo and Dridi for example, have stressed that in parallel with their academic values, university researchers are increasingly following an “entrepreneurial ethos” and working closely with industry. [66] But studies of Canadian universities show that researchers in these institutions are substantially more focused on knowledge production than they are on industry-collaboration and commercialization. [67] Our study corroborates these last findings, showing that the sharing of databases or material banks with industry is not a common practice, regardless of government initiatives. The desire of researchers to keep a certain level of control on the ongoing and future uses of their databases and material banks remains strong, even when financial value can be attached to these research by-products.

2) The difficulties of valorization in the academic context

During our interviews, researchers identified a number of impediments to the valorization of research databases or material banks. First, the quality of research data or material can be an important challenge, particularly when they are perishable or their quality is questioned. In many cases, it is extremely difficult to guarantee the quality of the database or material bank. Researchers noted that resource constraints in academia limited the time available for them to format, organize and manage databases and material banks for valorization. Preparation and follow-up of data or materials is essential to allow for the transfer from one researcher to another. To be able to use preexisting databases or material banks, researchers need to have access to all the relevant associated information.

Another significant drawback was the lack of institutional policies regarding material and intellectual property, a situation that left many researchers questioning the legal implications of valorization processes. For example, a majority of researchers would like

more clarity and simplification of valorization processes, notably through standardized or rationalized policies, regulations or simple contract agreements. Researchers thought that the valorization process could be simplified if they had full control over their databases or material banks, eliminating the complexities involved with having the university or hospital as a partner. However, where commercialization was considered a viable option, researchers felt that the institution should have a role in facilitating any industrial partnerships.

Universities have been involved in the process of commercializing the products of research for a few decades. It is not surprising then, that many researchers are also in favor of their institution playing a role in the commercialization of research by-products. Universities have developed an expertise in this type of valorization; at Université de Montréal these processes are managed through the *Bureau Recherche - Développement - Valorisation (BRDV)*. Private valorization societies such as Univalor also collaborate with the University's research administrators in order to maximize the valorization of research products through commercialization. In certain contract agreements, databases and material banks are the property of the private investors and thus must be transferred to them along with the research results. Yet one may wonder if the resources developed for the commercialization of research products are appropriate for other types of non-commercial valorization, and in particular for the valorization of research databases and material banks.

Finally, researchers noted that further training and information are needed to promote common standards or practices in the development, constitution and conservation of databases or material banks. They also indicated that the development and communication of a common set of ethical guidelines or parameters for application by research ethics committees would help in guiding them through the valorization process. However, even with a more streamlined and effective governance structure, researchers still questioned the feasibility of valorization in light of the significant limitations noted above. They suggested that many of the challenges associated with valorizing databases and material banks could be overcome if the university allocated sufficient resources to

allow them to implement the necessary management and governance structures for their databases and material banks. This seems highly unlikely, however, since Quebec universities are already operating on extremely tight budgets. [68] Although over the long term valorization may be cost-effective, broaden knowledge and open the way to new research opportunities and resources, the expenses incurred at the outset remain a significant deterrent.

3) Practices of valorization

The third objective of this study was to identify and characterize the types of databases or material banks that hold potential for valorization in various research disciplines. Our findings allowed us to identify certain practices of valorization in different fields of research, and to raise a number of issues for further consideration.

The researchers interviewed, involved mainly in the health sciences, saw databases and material banks in their area as having a higher potential for valorization. Although they were subject to significant oversight and control based on ethical guidelines and policies aimed at protecting the human participants, these researchers seemed nonetheless willing to share data and material in a way that was more spontaneous than researchers in other disciplines. Such sharing was often done through organized networks of researchers with established methods governing their exchanges. It is important to note, however, that the health sciences category also includes researchers from the social sciences, thus occasionally leading to multidisciplinary networks where individuals with more clinical backgrounds interact with individuals from the social sciences. [69]

Many groups or networks, especially those in qualitative social science research, did not share databases or material banks. This can be explained partly by the need to protect the confidentiality of participant's personal information and the close relationship that may develop between the researcher and the research participant. Social science researchers expressed concern that research participants might limit their participation and responses during qualitative research if they become aware that other researchers could reuse the data for other purposes. There was a fear on their part that the bond of trust necessary for

much social science research would be jeopardized; and the more personal or intimate the information provided by participants, the stronger the bond of trust required for the success of the project. [70, 71] It is not surprising, then, to observe apprehension on the part of researchers who have a tight bond of trust with research participants when requests may come to share this information without knowing the purpose for which it may be used. These researches rarely favored broad consent and invariably restricted the sharing of their research data or material.

Conversely, those researchers who did not share a close bond with their research participants tended to favor more open or broad consent to increase the re-usability of databases or material gathered during their research. This was the case for researchers in the computer sciences. They perceived that their databases had a high potential for valorization, a finding that is congruent with the literature on commercialization in computer science, which shows that many research developments can be moved directly to the market with little to no modification. [72] Three researchers in our study had applied mathematical equations to raw databases in order to build new databases, and they rarely if ever had direct contact with research participants when working on databases from human subjects. Accordingly, these researchers did not perceive the sharing of databases as a breach of trust. This suggests that the proximity between the researcher and the participant strongly influences the researcher's interest for the valorization of databases or material banks.

None of the researchers in our study who were from the applied sciences worked with human subjects, as their databases or material banks were composed of animal or geological materials. Their concerns regarding valorization centered on the regulations and legislations dealing with materials in national collections and of significance for national heritage. Indeed, much of their material included rare animal species or soil and rock samples that were or became part of national collections or national heritage. These researchers noted that the valorization of such material is so important that there are laws governing banks consisting of geological material; [73] their valorization process is thus

determined to a large extent by specific legal parameters, and thus has much less to do with researcher or institutional practices.

The sharing of material from animal tissues is subject to less governance or regulation than the sharing of national collection samples or human participant material and data. Researchers sometimes shared this type of material through contracts, such as MTA, although the transfer of material through MTA is not specific to researchers in the applied sciences. Experimental scientists also shared some of their samples through such agreements, yet these researchers expressed little interest in pursuing the commercialization of their databases or material banks because they saw them as having little or no commercial value. Further, researchers working with animal tissue banks showed little interest in the valorization of these banks, suggesting that this type of material had little potential for valorization. The materials, they argued, were often too specific to their study, were of poor quality, or were perishable and could not be re-used. These characteristics all limit the transferability of such material and thus undermine the interest in pushing for their valorization.

To summarize, the various fields of academic research involved with databases or material banks have their own practices of valorization. Multidisciplinary networks create complexity, however, when attempting to clearly delineate or define disciplinary valorization processes for databases or material banks. Nonetheless, our findings show that researchers perceive certain databases or material banks as more suitable for valorization than others, a perception that is undoubtedly influenced by specific research practices. It is important to note that our sample did not allow for an in-depth and comprehensive analysis of disciplinary practices of valorization; this would be something very useful to explore in the context of a larger international study.

Conclusion

In this study, we examined researchers' perceptions of the governance and valorization of databases and material banks at the Université de Montréal. Although our findings reflect particular cultural, political, social and economic realities, the issues we identified

relating to the valorization of databases and material banks are broader than our case study. Our findings bring new insight to the potential use of these research resources, while also clarifying some significant difficulties and challenges associated with valorization. Many fields of academic research are amenable to and have significant potential for valorization of databases and material banks. Yet, in practice, the valorization of databases and material banks is rather limited, and explained by three main factors: 1) concern by researchers regarding the control of their databases or banks during and after valorization, 2) the proximity of the researcher to their research participants, and 3) the nature of the information or material constituting the databases or material banks.

All of the researchers in our study noted that the governance of databases or material banks and their property rights have to be addressed to facilitate the valorization process. And while researchers had different opinions about governance and property rights, most favored a model that would allow them to exercise control over the valorization process. Many researchers did not like to use the word “owner” when talking about intellectual and material property related to their databases or material banks, but nor did they want to see other players assume or take majority ownership. Most researchers would prefer to share ownership with the university (or hospital) as long as they retained decision-making power concerning the creation, use and valorization of the database or material bank. Until institutional policies on governance and property rights (ownership) of banks are clarified, researchers will remain reluctant to embark in the valorization of their research by-products. Additionally, to effectively carry out the valorization process, training for researchers (and administrators) in the ethics and governance of databases and material banks is needed to both raise awareness of the challenging issues associated with sharing and valorizing databases and research material, and to help disseminate effective and ethical practices.

Valorization – in the broadest sense – will only succeed where there are effective policies, guidelines and practices that both ensure the autonomy and ownership rights of the researcher, and protect the confidentiality of research participants whose data or

material is the basis of research databases and material banks. These databases and material banks are important and even essential resources that can enable significant advances in knowledge and innovation, but they can only function optimally when there is effective cooperation between all the key actors, namely universities, research hospitals, and researchers.

Présentation du deuxième article

Le chapitre/article précédent présente des données empiriques sur la perception des chercheurs quant à la valorisation des bases de données et banques de matériel créées à des fins de recherche. Les résultats montrent qu'il y a un potentiel de valorisation de certaines bases de données et de banques de matériel. La forme de valorisation la plus acceptée par les chercheurs participant à l'étude précédente est le partage des bases de données et des banques de matériel entre chercheurs travaillant dans la même discipline ou dans des disciplines connexes. Ce type de valorisation permet d'accroître la connaissance liée à des données ou à du matériel sans allouer plus de ressources pour créer une autre base ou une autre banque. La valeur scientifique d'une base ou d'une banque est ainsi mise de l'avant et promue par les chercheurs universitaires participant à la recherche. Toutefois, plusieurs difficultés limitent grandement le partage entre chercheurs.

Nous débutons notre réflexion dans le prochain article, avec la prémisse suivante : si le partage est, *prima facie*, une norme éthique, alors les difficultés limitant ce partage peuvent être problématique. Ainsi, une analyse de ces limites permettra de mieux comprendre les tensions entre le partage et la valorisation. Nous abordons aussi quelques pistes normatives pour faciliter le « partage éthique » des bases de données et des banques de matériel. Cependant, nous limiterons cette prochaine analyse aux difficultés liées à l'éthique de façon générale. En d'autres mots, nous abordons des enjeux liés à l'éthique de la recherche (notamment le consentement et la confidentialité) et à l'intégrité de la recherche (la collégialité et le partage de la reconnaissance, par exemple). Malgré ces limites, nous n'allons point contraindre cette étude à une discipline scientifique ou à un champ de recherche. Plusieurs champs de recherche seront évoqués par des exemples provenant de divers milieux universitaires.

Contrairement à l'article précédent qui a été écrit en collaboration avec Michel Bergeron et Catherine Olivier, seule l'auteure de ce présent mémoire a contribué à l'article suivant.

Chapitre 2

The limits of sharing: An ethical analysis of the arguments for and against the sharing of databases and material banks

Smith, E.

Accepted in *Accountability in Research*

Abstract

In this article, I study the challenges that make database and material bank sharing difficult for many researchers. I assert that if sharing is *prima facie* ethical (a view that I will defend), then any practices that limit sharing require justification. I argue that: 1) data and material sharing is ethical for many stakeholders; 2) there are, however, certain reasonable limits to sharing; and 3) the rationale and validity of arguments for any limitations to sharing must be made transparent. I conclude by providing general recommendations for how to *ethically share* databases and material banks.

“Sharing is *de rigor* – at least in principle”.

[29]

Introduction

During the past decade, there has been much socio-ethical and legal discussion in the academic literature about the use of biobanks in research, particularly with regards to genetic data or material. [74, 75] Genetic databases and material banks are significant since they contain “uniquely private or personal information” about an individual and their family’s medical condition and future. [76] Because of this emphasis on genetic biobanking in the ethics literature, there is less discussion of – and consequently fewer regulations and ethical guidelines regarding – non-genetic information, material and data. [77] For example, a study by Gibson and colleagues [21] found that Canadian research ethics boards (REBs) are less preoccupied with or aware of the ethical issues associated with databases and material banks when genetics is not involved. Nonetheless, there are clearly still important ethical issues related to the creation, maintenance and use of qualitative and quantitative “databases” (e.g., surveys, interviews, patient health records) in academic research. As such, practices of ethical governance are needed when promoting (allowing or expanding) the use “material banks”, including organic (e.g., biobanks) and inorganic collections (e.g., mineral, soil, or video collections).

In the past, these databases and material banks have often been considered as “by-products”, secondary to actual research findings. However, significant time and resources go into the creation, manipulation and management of databases and material banks. In order to maximize the use of research resources (including funds, materials and human resources), many regional, national and international organizations now actively encourage the reuse, transfer and increase in value of databases and material banks. For example, the Canadian Institute of Health Research (CIHR) states that:

Data sharing for research purposes is an important way of enabling socially valuable research. It avoids unnecessary data collection, which reduces the burden on individual respondents and permits researchers to use their resources more productively. [78]

The Organisation for Economic Co-operation and Development (OECD) recognizes that “A global organization could be a driving force and the agent for change leading to greater sharing of data, integration, and research utilization”. [79] Indeed, promotion of the reuse, transfer and value of databases and material banks has become a central theme in many organizations. Accordingly, it is timely and appropriate to extend ethics research beyond a focus on genetics biobanks to address the reuse and transfer of diverse sorts of databases and material banks.

The *Valorisation de l'Innovation et du Capital Intellectuel* (Valorization of Innovation and Intellectual Capital, VINCI) project conducted at the Université de Montréal (2005-2009) included an exploration of the ethical use of different types of materials and data in diverse fields of research seldom covered in the ethics and scientific literatures. [56] In the French-language scientific literature, the word ‘*valorisation*’ has been used to describe various value-adding processes that convert or increase access to knowledge resources developed in research settings. In the case of databases and material banks (e.g., biological, archaeological), this access and reuse augments their value beyond their original application or purpose. [22] Although the notion of valorization is often limited to commercial uses and gains, [17, 80] increased value may also be achieved through various other applications, such as the reuse of databases or material banks for educational or social purposes, or in the development of public policy. The sharing of databases and material banks among researchers can be instrumental in advancing scientific knowledge. To summarize, the value added may be social, educational, scientific or economic.

The goal of one of the VINCI projects was to better understand the valorization potential of diverse research databases and material banks (both genetic and non-genetic, human and non-human). This involved an analysis of researchers’ perceptions of the valorization of databases and material banks created in their respective university research settings. Twenty two researchers from various disciplines at the Université de Montréal were interviewed using a structured questionnaire designed to identify the following: 1) the context of research, 2) the identification of data or material, 3) the researcher’s interest(s)

regarding value-adding processes for databases and material banks, and 4) the modalities and difficulties of valorization. These researchers worked with a diversity of databases and material banks. The study findings revealed an untapped potential for valorization for a number of databases and material banks; while the researchers interviewed mentioned that the sharing of databases and material banks between researchers was the most commonly accepted valorization process, it was nonetheless problematic. [56]

The policies of many science journals (e.g., *Science*) often promote sharing by requiring the full disclosure of all relevant research data and sources with the journal before publication. Publication is thus a means of sharing results through public access or at least with the journal's subscribers, and allows other researchers to know that databases and material banks have been created and could potentially be shared. Funding organizations in Canada (e.g., Canadian Institutes of Health Research, Social Science and Humanities Research Council of Canada) and the US (e.g., National Institutes of Health, National Science Foundation) have policies that promote or even require sharing with other researchers. [81-83]⁹ The scientific literature in diverse fields also promotes data and material sharing [34, 84, 85]; "sharing is *de rigor* – at least in principle." [29, 34] However, the VINCI study and the ethics and science literatures reveal that the sharing of databases and material banks is fraught with important challenges and limitations. [32, 60, 63] For example, consent forms are often written in a way so as to inform the participant of the study taking place. Yet, when it comes to the reuse of data or material, it is often impossible to predict all the potential uses of a database or material bank, thereby creating serious challenges for the traditional informed consent process. [86-88]

The aim of this article is to reflect on the limitations of database and material bank sharing in academic research. I assert that if sharing is *prima facie* ethical, then practices that limit any sharing require justification; unjustified practices that limit sharing may be considered inappropriate and even unethical. To test this statement, I first define the

⁹ The types of sharing required may differ substantially. For example, for funding organizations, sharing by researchers is often required either during the research or after a certain period of time. And the sharing of study data and disclosure of sources of data/material with the funder is often required to promote transparency. Some funders (e.g., NIH, CIHR) and certain journal also promote sharing through Open access publications.

general notion of sharing and then argue that generally speaking, data and material sharing is ethically sound, thereby validating the founding premise that sharing is *prima facie* ethical. Using data from the VINCI study and the ethics and scientific literatures, I then map out and analyze limitations to sharing databases and material banks. I qualify a limitation as “justifiable” if the arguments in support of the limitation are ethically persuasive and sound. Lastly, in the concluding section, I propose a series of recommendations to promote sharing while considering its justifiable limitations. This paper will not tackle *all* the ethical implications of sharing, since there are simply too many. However, it will serve to initiate and hopefully promote reflection concerning the reasonable limitation of sharing.

Drawing upon a variety of examples from the VINCI study, this article also explores the impacts that different academic disciplines have, through their respective norms and practices, on data and material sharing. While sharing is commonplace in some fields (e.g., molecular biology, physics), in others, it may be rare or even non-existent (e.g., some social sciences). There are certain “sharing successes”, such as in genetics and certain sub-specialties of physics and computer science, but these successes may actually be exceptions. The VINCI data and other studies demonstrate that despite publicly espoused norms of sharing, many researchers simply do not share and sometimes even actively withhold data or materials. [60] It is thus relevant to consider why some disciplines succeed in sharing while others do not. Technical difficulties and resource constraints in data and material sharing are clearly important inhibitory factors or limitations to sharing. Nonetheless, my focus in this paper is on those sharing limitations associated with research ethics (e.g., consent, confidentiality, research ethics procedures) and research integrity (e.g. competition, just recognition of credit), as these were often noted as important constraints by participants in the VINCI study.

What is sharing and why should researchers share?

“If I have seen a little further it is by standing on the shoulders of Giants.” [89]

Databases and material banks are shared in many different ways. Research data can be made available to academic researchers and to the general public via the Internet. Alternatively, a multi-disciplinary network of individuals working collaboratively on a particular theme may share data or material. As this article deals with the practices of academic researchers, my analysis focuses on sharing that may be defined as the transfer, allotment or division of material or data between researchers. As Milanovick concluded in his empirical study of sharing in the biosciences, there are different means of exchanging biological samples and related data: some researchers adopt a collaborative approach; some exchange data for purposes of authorship; and others establish formal contractual agreements. [15] In the VINCI study interviews, one researcher noted that he collaborated with both social and biomedical scientists in sharing a registry of various databases and material banks. However, most researchers indicated that they collaborated primarily through networks with colleagues in their own discipline or field of study. The VINCI study also found far fewer exchange regimes in the humanities and social sciences as compared to the applied or biomedical sciences.¹⁰ As explained by a researcher in criminology: “Personally, I find that we do not really share. There is not much transparency in what we do [...] yet they say we live in an era of the major networks and sharing.” (Participant #13) While a few social science networks shared knowledge products (e.g., research results or methodologies), data or material was rarely exchanged or made accessible to other researchers. This does not mean that the researchers are not interested in sharing; rather, it is not a common practice in their particular field.

The main premise and underlying principle of this article is that sharing material banks or databases in academic research is an ethical practice, whether it be in the humanities, social sciences, engineering, biomedical sciences, applied sciences or experimental sciences. As Fisher and Zigmond explain, three main benefits favour sharing in academia: 1) scientific progress, 2) increased efficiency in scientific work, and 3) an enhanced sense of community among scientists. [29]

¹⁰ For more detail on the different types of databases and material banks that present a valorization potential (which includes a sharing potential) and a detailed discussion of the empirical VINCI study, see [56]

Regarding the first benefit, the contribution to scientific progress, Teeters and colleagues explain the importance of sharing data in computational neuroscience. Researchers seek to understand how the brain functions by creating models that can integrate complex experimental data. Data sharing is essential in such a process. In computational neuroscience – as in many disciplines – sharing experimental data allows researchers with diverse perspectives to participate in data analysis. [32] In the fields of genomics (e.g., Human Genome Project) and astronomy (e.g., International Virtual Observatory Alliance), scientific research seems to have evolved rapidly, in large part aided by increased computational capacity and data and material sharing.

Research and knowledge advances not only as a result of increased access to data or material, but also through access to researchers from various disciplines. [29] This multi-disciplinary dimension broadens the scope of research and contributes valuable expertise, insight and knowledge. Interdisciplinary groups in particular can bring many different and potentially complimentary epistemologies to bear on challenging and otherwise intractable questions. [90] For example, archaeologists who participated in the VINCI project spoke of sharing a material bank of rocks from an archaeological dig with chemists. As a result of further analysis, additional knowledge was obtained about the historical site being studied. Similar benefit may be achieved through database sharing. Data collected for one purpose may have a fresh and additional use to a researcher in a different field; for instance, a sociologist who shares a dataset on social determinants relevant to alcoholism could provide useful information to a toxicologist.

Fisher and Zigmond also note that sharing allows resources to be used more efficiently. The notion of efficiency surfaces in many types of research, especially where a large number of samples is involved. The field of genomics promotes data sharing via large open access data banks such as the Human Genome Project and the HapMap Project. [87] It is much more cost-effective to simply reuse this data than to collect it anew. In medical research, tissue samples can take a long time to collect and they require a considerable amount of resources to store and manage. Central repositories (e.g., for tumour tissue, blood samples, stem cell lines) are thus a way to save time and resources, and facilitate

access to researchers once a formal application is approved by a material and data access committee. While researchers in the social sciences seem less enthusiastic about data sharing, there are nonetheless some large scale initiatives. For instance, in the United Kingdom, the Economic and Social Data Service (ESDS) Qualidata provides support and access to a wide range of qualitative and mixed methods databases. Researchers funded by the ESDS must share their data with the service provider for use in future research and teaching. [91] Such initiatives were not mentioned by participants in the VINCI study as there is no equivalent data sharing service available in Canada.

The quality of data and material may also be enhanced when it is shared or made more readily available. Reuse, scrutiny and analysis is more likely to bring to light errors or misconduct (e.g., falsification or fabrication). [92] Researchers may be more careful when collecting and organizing data and material when they know that others may use (and assess) their work in the future; as such, sharing serves an informal quality control function. Since sharing typically follows once there is at least one research publication, this quality control is delayed. However, verification and validation of past publications is, and has always been, an important part of science. This is particularly true when large amounts of data and material are used and journals only have limited resources to perform their own quality control (aside from peer-review). It is thus reasonable to suggest that sharing is part of the “responsible management of data”. [85, 93] More explicitly, greater transparency and openness (notably through sharing) can be effective in ensuring and promoting the integrity of research. [94] Lastly, the maximization of available resources is a significant consideration. Efficiency gains realized through the reuse of data or material and the minimization of duplication can offset to some extent the constraints of limited research funding.

This efficiency is valued not only by researchers and funding bodies, but also by research participants. As Hansson (2006) argues, research participants donate material or data to science and expect their contribution to be fully utilized:

The efficiency concern of the patient is also a reminder for the scientific community about the need to find appropriate models for sharing of samples and information. It is the interest of both scientific efficacy and of

patient needs to develop and facilitate collaborative research among scientists and different biobanks. [47]

A collaborative research environment, where sharing is a common practice, benefits from such efficiency. As one participant in the VINCI study mentioned, “... I would say there is an ethical responsibility to try to be productive when using samples, because when you ask someone for a sample to do research [...] their expectation is that we work on his samples there to help the plight of patients...” (Participant # 4)

Collaboration can lead to greater productivity and the sharing of data and materials can foster a positive professional and interpersonal dynamic. For large interdisciplinary multi-centre research groups or smaller research teams, the sharing of databases or material banks enables cooperation and collaboration. Also, many researchers actively collaborate in order to increase their citation rate [95], and increase their profile as authors in different published studies. There is evidence that the number of multiple author publications has increased, especially in the biosciences and in health sciences [96-98]. While this does give more credit to researchers, it becomes difficult if not impossible to discern the specific contribution of each author; problems may thus arise in attributing responsibility for these contributions (especially when misconduct is detected). [99]

Research is always a “work-in-progress” in that researchers build on and continue the work of their peers to further advance knowledge; the creation of knowledge is a “cumulative process”. [94] The continuing and expanded use (and sharing) of databases and material banks is also part of this cumulative process, and the principle of sharing must be inherent to the scientific system. As Merton wrote “The substantive findings of science are a product of social collaboration and assigned to the community. They constitute a common heritage in which the equity of the individual producer is severely limited”. [100] Merton named this norm “communism”, and in this we see the principle of sharing as intrinsic to the broader notion of scientific knowledge as a “common good”.

In the VINCI project, researchers expressed a need to give back to the community through their work, and reciprocate by contributing to the “common good”. While researchers did not make a formal statement per se, they did hint at or suggest that a degree of solidarity and reciprocity was inherent to the scientific system itself, in wanting to “give back” to society. Such principles have been acknowledged particularly in genetics research [101, 102], but they are arguably present in many other fields of research. Although the benefits to research participants may not be immediately and directly evident [46], researchers should consider possible long term benefits to individuals or communities.

Interestingly, values such as reciprocity and solidarity have been raised in the debate about benefit-sharing, especially with regards to biomedical research and genetics. However, in the scientific literature the definition of “benefit-sharing” varies for the respective disciplines (e.g., law, ethics, philosophy). [103] While some researchers view sharing of data or material as a form of benefit sharing [37], benefit-sharing can also be interpreted more narrowly as the distribution of specific benefits – financial gain, innovative pharmaceutical products, new medical procedures – derived from research results. Further discussion of the principles underlying data and material sharing and benefit sharing is warranted but beyond the scope of this study.

In addition to the above arguments favouring sharing, many prestigious journals (e.g., *Science*) require full disclosure of all relevant research data and sources as a prerequisite to publication. As already mentioned, publication itself is a form of sharing either with the public and the broad academic community (e.g., through Open Access) or with journal subscribers. Also, funding organizations in Canada, the US and in Europe promote and sometimes require data or material sharing. In the US, the federal funding agencies (e.g., NSF, NIH) require that researchers explain in their grant proposals how they plan to make data available and useful to other researchers. [92] In Canada, sharing databases and material banks is not mandatory but is strongly encouraged. For example, researchers that receive funding from the Canadian Institutes of Health Research (CIHR)

or the Social Sciences and Humanities Research Council of Canada (SSHRC) must strive to make data and material accessible and comply with reasonable sharing requests. [104, 105] SSHRC points to the “principle of public ownership of data that should guide all decisions” regarding sharing of data resulting from funded research. Public funding organizations also highlight in their grant funding decisions that monies for scientific research come from the taxpayer and it follows that research results should be considered as a common good. Finally, at an international level, the First International Strategy Meeting on Human Genome Sequencing in 1996 developed a set of sharing principles called “the Bermuda Principles”, that stipulate “that all human genomic sequence information, generated by centres funded for large-scale human sequencing, should be freely available and in the public domain in order to encourage research and development and to maximise its benefit to society”. [106]

The Limitations of Database and Material Bank Sharing

Many of the previously discussed theoretical, practical and political reasons in support of the sharing of databases and material banks were raised in the course of the VINCI interviews. [56] Although the general consensus in the literature is that sharing material and data should be considered good ethical conduct or “responsible management conduct” there are also justifiable reasons not to share. As stated previously, Canadian funding organisations mention that researchers must strive to make data and material accessible and comply with “reasonable sharing requests”. [104, 105] Such “reasonable requests”, while not officially defined, could be defined as requests that do not create serious, legitimate concerns or limitations. For example, Shamoo and Resnik (2009) mention that such legitimate limitations may include (but are not limited to) concerns regarding intellectual property, claiming priority (being the first to discover or publish), protecting a researcher’s reputation, protecting confidential information pertaining to human subjects and avoiding wasted time. [107] Although sharing is said to be *prima facie* ethical, certain factors may make sharing “unreasonable” in some circumstances and ultimately justify imposing certain restrictions. Nonetheless, restrictions on sharing have their limitations, and some restrictions that are suited to certain types of sharing (e.g., open access) are not appropriate for other methods of sharing (e.g., between

collaborators on the same team working on similar themes). Regardless, if sharing is *prima facie* ethical, then any practices that limit sharing require justification.

The researchers interviewed in the VINCI study brought up many of the limitations that impede or make sharing difficult, burdensome or disadvantageous, but it was unclear whether these limitations were in fact justified. In the following sections, I will analyze the justification of limitations on sharing and critically assess related recommendations from the ethics and research integrity literature.

Research Ethics: Procedures, Consent and Confidentiality

“... I think that with the matter of consent and the specific rules of the ethics committee, it prevents us from doing good business, because it really limits us there.” (Participant #16)

Researchers interviewed in the VINCI project mentioned that research ethics procedures and requirements limited the sharing of their databases or material banks. Those who included human participants in their research said they found the research ethics boards (REB in English Canada, Research Ethics Committee in French) particularly strict about the secondary use of data or material. REBs must ensure that secondary use follows the main policies protecting human subjects, including the Tri-council Policy in Canada [62], or Human subjects protection laws in the US. [108] Researchers noted that the process itself was very complicated and burdensome, especially for multicentre studies. While certain REBs might approve a project and any prospective sharing possibilities, others may require various changes to the same project. Consequently, researchers mentioned that harmonization of policy requirements and procedures was necessary to eliminate inconsistencies and contradictions.

Harmonization of diverse policies has been considered for many multicentre processes, whether or not database or material bank sharing is involved. Although most REBs will ultimately give approval to multicentre projects, their initial responses, recommendations,

and comments vary greatly, making the research ethics review process unduly laborious and complicated. [109] Moreover, since there is disagreement as to what constitutes appropriate data and material sharing in research ethics, REBs will have various opinions or positions regarding best practices. Empirical research on Canadian REBs reveals a lack of clarity about their role in the research process, including dealing with the creation of registries and biobanks. [21] Since REBs have traditionally been involved in the approval of well-defined projects, they may not have the expertise or familiarity necessary to deal with databases or material banks. REBs would need a much broader perspective and relevant knowledge in order to effectively analyze past projects where data and material were created, and then to determine (understand) valorization for other research endeavours. Obviously, limitations cannot be imposed after the fact or retroactively on past projects. To further complicate matters, the databases or material banks may have been created in different institutions or in different countries where legislation and ethical cultures differ. Knoppers and colleagues mention three main topics which are controversial with regards to international collaboration concerning population genomic databases: “1) the kind of consent required to obtain participants’ data; (2) data access policies and practices relating to various different categories of users; (3) ethical approval and oversight provisions”. [37]

It has been argued that national-level harmonization should be considered given the increasing number of university projects involving databases and material banks, especially in the health sciences. [110] There have been efforts to simplify the research ethics review process in multicentre studies, [111] but multicentre projects that include data and material sharing arguably require a different type of ethics review than that applied to traditional single-site projects. As an example, cloud computing allows researchers to upload large amounts of information to grid computing (e.g., BOINC,) and/or cloud storage services (e.g., Dropbox, iCloud). While this facilitates multicentre projects as data may be more readily available to the research team, there may also be confidentiality concerns [112] that differ from those common to single site projects. As noted by Hub Zwart, with this new type of knowledge production (e.g., large scale, multicentre and data and material sharing studies), the focus of research ethics must shift

from “duties of the autonomous research subject (micro-ethics) to responsibilities of institutionalized research networks in managing and processing large amounts of bio information (macro-ethics)”. [113] Traditional “micro-ethics” can no longer be the single or primary focus of research ethics review. The multicentre approach would apply, for example, when a REB is considering a project in biomedicine where a network of individuals plan to reuse a material bank of samples and its database of patient information. In addition to ensuring that consent to sharing was obtained in accordance with widely accepted ethical norms, it will also be critical that the REB verify that the governance guidelines and practices regarding the future use of material (and the linked data) adequately protect confidential information.

A variety of methods have been introduced to safeguard participants’ confidentiality in databases and material banks. Researchers may anonymize all their data or material, or alternatively, use a coding technique. [114] These methods are sometimes sufficient to effectively protect individual information and identity but they do have their limitations. Methods can and do evolve with time as new techniques of data access emerge and are endorsed by the research community. Confidentiality concerns are closely linked to, and limited by, technical challenges or concerns (which were not analyzed in the VINCI study). Until it is technically possible to ensure confidentiality and respect for privacy with human participants, it is arguably justifiable to limit the sharing of certain types of data or material. As explained by Resnik, there are many different methods to re-identify de-identified data in genomic databases, for example, through the use of statistical techniques or cross referencing using identified DNA samples. [115] This potential for re-identification provided the grounds for the NIH to permit certain restrictions on database sharing, notably with regards to Genome-wide Association Studies (GWAS). [116]

In other cases, especially sensitive data or material may only be collected if the researcher has the research participant’s full trust. In studies on sensitive topics, such as criminal behaviour and attitudes, sexual assault, or involving mental illness, many participants will only provide material or reveal their opinions, experiences and

perceptions if they are assured, and trust, that their data will not be shared. This covenant between researcher and participant is essential to eliciting truthful and accurate responses in qualitative and quantitative studies, and to obtaining the necessary sample size. In such cases, data can only be collected if sharing is prohibited and full confidentiality is maintained. Understandably, there are cases where the nature of the data or the inadequacies of available technical methods do not allow researchers to provide an assurance or guarantee of confidentiality. Participants must be informed of any such limitation, but they may nonetheless consent to have their information used by other researchers. If, however, the sharing of data presents a high risk of a loss of confidentiality that could have damaging ramifications to an individual's family or community (as in the case of genomics data), sharing restrictions will most likely be warranted. [115] An REB must thus weigh the risks and benefits of this type of research and require the implementation of appropriate restrictions or limitations to ensure an appropriate level of confidentiality.

Appropriate informed consent is another one of the main aspects that REBs must look for in their ethics review. Traditionally, informed consent has been understood as the requirement that researchers disclose to potential participants, the risks, benefits and material information (objectives, methods) about the study, and the extent and implications of any data sharing. [117] Consent as applied in large-scale genetic and genomic biobanks has been the topic of much debate [10, 118, 119], because there is significant concern about the uncertainty or unpredictability of unspecified potential future uses of data and materials, and the resulting impact of such use (e.g., discrimination of individuals or vulnerable communities). In particular, the development of these biobanks has raised questions about re-consent. [118] If there are changes to the research project, should researchers have to ask participants for consent again? What is the nature and extent of change that would necessitate new consent? In the VINCI study, researchers working in the field of genomics mentioned that recruitment can be particularly difficult in the case of individuals with rare chromosomal anomalies, and so trying to find these individuals to re-consent when research changes or further research is needed proved very challenging. Although these concerns are prevalent in genetic and

genomic research where data and material sharing are commonplace, there may be a general level of concern on the part of researchers and REBs, for any project that includes the sharing of human material or data. The simple fact that we cannot always predict the future use of data or materials with absolute certainty makes governing this sharing – and explaining it appropriately to participants – extremely complex and ethically challenging.

In the VINCI study, researchers mentioned that in order to promote sharing, they had moved beyond the notion of traditional consent (also called specific consent) and used different consent models, such as broad consent or open consent with certain restrictions. Broad consent was defined as consent that allows researchers to use data or material in any future research (ensuring certain norms of confidentiality); on the other hand, open consent with certain restrictions allows researchers to use data or material in a given field or conduct research within specified parameters. Some of the researchers interviewed mentioned that participants should be able to choose the type of consent they wanted to give for a designated project. “When we seek consent, consent is sought by posing a choice; do you want it [the biological material] to be used just for Ovarian Cancer, Cancer in general or other diseases...” (Participant 4) Of note, the type of consent favoured by researchers differed depending on the type of data and material that they used. Researchers using social science data (qualitative or quantitative) were more likely to favour specific consent, while researchers using computer science and medical data or material, especially in genetics or genomics, were more likely to choose broad consent. The preferred method of consent is influenced by the particular culture of a discipline as well as the proximity of the researcher to the participant. [56]

There is considerable discussion and debate in the literature of different consent methods. [120-122] The application of one general rule to promote one specific type of consent, say traditional informed consent, may limit a participant’s autonomy or respect for autonomy [123] and restrict sharing initiatives. However, extensive use of broad consent may not adequately protect confidentiality of material or data in all cases. I thus do not advocate for any particular “best practice” in academic research as there is no “one-size-fits-all” solution. Appropriate standards of practice are those that are suited to the nature

of the research study and that can be effective in ethically managing the type of data or material involved. REBs have the responsibility to weigh the benefits and risks, pros and cons of different methods of consent while keeping in mind the benefits of sharing in research. The topic of open consent is important and deserves further discussion, but goes beyond the scope of this study.

The changes to informed consent to responsibly manage the sharing of databases and material banks may be interpreted as an indication that sharing is sufficiently valued to be a significant factor in the evolution of certain practices. This is not to suggest that the principles underlying informed consent, such as autonomy and respect for self-determination, should not prevail, but simply that the approaches to, and parameters for, ensuring appropriate informed consent may take different forms. Openness to such responsible change will be instrumental in facilitating greater sharing.

I suggest that sharing be considered a principle of ethical conduct. As such, it should be considered in relation to other principles of ethics (consent, confidentiality). In many studies, appropriate confidentiality and consent can be maintained while at the same time designing and implementing sharing initiatives that do not put individuals at unreasonable risks. While one type of sharing (e.g., open access) may not be suitable or justified (because of an inability to protect confidentiality, for example), this does not mean that all forms of sharing should be rejected. REBs need to fully assess methods that limit sharing and that may present unwarranted risks, while allowing other types of sharing that respect traditional research ethics values.

In practical terms, the ongoing national and international efforts to harmonize research ethics guidelines (see for example [111, 124]), should include sharing as integral to research ethics. In the VINCI study, researchers mentioned that training on the ethical valorization of data was necessary. However, it must be recognized that implementing training programs as well as putting new methods of sharing into practice will require considerable effort and may be complex. If researchers want to carry out projects that include significant sharing with diverse networks in different countries, stronger

collaboration between the REB and the researcher will be essential. The REB can help researchers in defining a project that addresses traditional ethics concerns (e.g., consent, confidentiality) while also allowing the sharing of data or material. Granted, additional resources would be required to promote such initiatives in research, and this would give rise to the perennial question of “who should pay”. The return on investment would arguably be achieved through future efficiencies enjoyed by research teams in other projects.

Intellectual and Material Property, Competition and Lack of Recognition

It is often noted that data sharing and the ownership of intellectual and material property are related issues. [125] Ownership was the subject of much debate among certain participants in the VINCI study. In many cases, especially where researchers worked in a health care facility or institution, the database or material bank belonged to that institution. Similarly, many universities in the US retain ownership of data resulting from research conducted within their respective institutions. [93] In the VINCI study, researchers preferred using terms such as “manager, custodian or trustee” to label or define their responsibility for database or material banks (concerning the creation, management, sharing, destruction, etc.). It was clear during discussions with researchers that the focus on ownership was not driven by interests in commercial exploitation or patenting, but rather by a desire to control the future uses of one’s databases or material banks.

The academic literature may sometimes underscore the role of intellectual property as a limiting factor in sharing. For example, intellectual property and patenting have had major impacts on material and data sharing specifically linked to genetics. The patenting of DNA and other biological material was even critique for producing a “tragedy of the anti-commons”, as it was said to block access to useful findings and technologies necessary to other research and the evolution of science. [126] However, as Caulfield and colleagues argue, a number of empirical studies have shown that patenting rarely ever limits sharing (in fact, patenting ensures that data on an innovation be made public),

although it may slow it down. [127] According to Caulfield, we have confused patenting with the real limiting factor to sharing, that is, interpersonal competition.

Although a few empirical studies have highlighted the negative impacts of patenting in specific fields [128], the conclusions of Caulfield's study and the VINCI study are similar: intellectual property and patenting were not considered a primary limitation to sharing by researchers. Researchers noted that the desire to have control over data and material was a more important (and justifiable) limitation to sharing. Similarly, in their book on genetic biobanks, Tutton and Corrigan noted the same preoccupation: "[...] the issue is not only one of commercial exploitation it is also about control." [129] While the public sharing of data may make some discoveries/innovations unpatentable (the case for public genomic data or open source software), there may still be desire or need to control how, when and by whom this shared data are used.

In the VINCI study, we sought to understand the underlying rationale for control as a key concern if indeed it was not driven by an interest in commercial benefit. We found that control was closely linked to academic potential, opportunity and prestige. In other words, researchers wanted to maintain sufficient control over their datasets and material banks (limiting sharing) to have some exclusivity in doing further research with these knowledge resources. [56] This would provide a competitive advantage over colleagues who would not have the same access. Competition within the research community seemed to be at the root of limitations to sharing and this was further confirmed in the VINCI study interviews. Although competition for contracts with industry was mentioned by a few, most researchers and research groups said that they competed mainly for academic recognition. By exclusively exploiting their datasets and material banks and limiting sharing, researchers noted that they can publish more, obtain more recognition and benefit from the work they had invested in creating and maintaining a dataset or material bank.

Conversely, in accordance with many journal and policy guidelines, when researchers share resources after the first publication, others can exploit these knowledge resources to

publish further research and gain recognition without having invested time or money in creating the initial material or data. In order to more fully exploit the significant potential of their datasets or material banks, researchers were reluctant to limit their exclusive use to one publication; they were ready to withhold data or material until a second or third publication before sharing with other researchers. Researchers interviewed cited competition as grounds for limiting sharing after a first publication.

There is another group in the United States, Fourteen post-docs. [...] I am not able to compete with a lab like that. It's my data. Then, if I put it on the Internet, they could use my data to complete a study we were doing. Then complete it faster than we can and publish it before us. We would get scooped by our own results, which are analyzed by another team. (Participant 21)

There is not a consistent and convincing body of empirical evidence regarding the exact impact of competition on data and material sharing. Blumenthal and colleagues' survey of data withholding included a sample of 2,893 geneticists and other life scientists (clinical and non-clinical) and it found that competitiveness had only a modest influence on the tendency to withhold. [63] This contrasts with findings of the VINCI study, although it should be noted that the Blumenthal and VINCI studies differ in several respects. The VINCI study included semi-structured interviews with 22 researchers from diverse academic fields, while Blumenthal's study employed a questionnaire to survey a much larger number of participants, but focused exclusively on life science researchers. Blumenthal and colleagues' quantitative analysis provides a different perspective than VINCI's qualitative analysis; the former gives breadth, while the latter depth. Thus Blumenthal and colleagues note that the perceptions of researchers in their study may not adequately demonstrate the extent and nature of competitive pressures. The VINCI study identified in greater detail the perceptions and tendencies of researchers according to research context and discipline, and revealed the pressures on researchers to publish more than their colleagues, and to achieve recognition for their time and resources spent in developing databases or material banks.

Contrary to Blumenthal, Vogeli and colleagues arrive at conclusions that concur with the VINCI study. [130] Vogeli provides data on the extent, nature and consequences of

withholding data as perceived by life science trainees; he correlates competitive environment with data and material withholding: “Trainees [...] in highly competitive research groups were almost twice as likely as trainees in low competition research groups to report having denied another’s request for information, data or materials.” [130] This shows that a very competitive environment may be conducive to more individualistic and selfish attitudes that favour self-promotion at the expense of scientific progress; researchers may feel that there is no clear benefit to sharing. [32] Fisher and Zigmond note that negative career impact is among one of the deterrents of sharing in science. [29] Similarly, Piwowar mentions that the lack of recognition in the health sciences is regarded as a crucial unresolved obstacle to the establishment of a data sharing culture. [30] While I stated at the outset of this article that sharing clearly has benefits for science generally, the benefits for individual scientists may not be evident or sufficient to offset the competitive professional advantage of data withholding.

To deal with this ethical dilemma regarding competition and withholding, more theoretical and empirical research is necessary to better understand the phenomena. There have been few developments or advances in credit allocation to facilitate or promote data sharing. Academic research is a meritocracy, where credit allocation takes place predominantly through authorship. In Canada, the cost of the National Science and Engineering Research Council (NSERC) grant peer review system is said to exceed the cost of allocating a baseline grant to every qualified researcher, [131] a situation that is likely similar in other jurisdictions. However, in North American and Europe, science funders have chosen not to distribute equally (through baseline grants), but to allocate funds based on merit, measured in large part by the number and quality of publications.

In general, guidelines on publication ethics and authorship from organizations such as International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE) do not recognize purely technical contributions in the determination of authorship. More specifically, material support or data acquisition alone are not considered grounds for authorship. According to the ICMJE, technical contributions such as the “systematic collection of data” is only considered as warranting

authorship if the researcher(s) also participate in “drafting the article or revising it critically for important intellectual content” and “final approval of the version to be published”. [64] Yet, researchers that did not participate in the drafting and revision of the manuscript may consider their work in organizing a database or material bank to be a substantial intellectual and technical contribution and thus meriting personal recognition. This argument was made by researchers in the VINCI study who felt that all publications resulting from a database or a material bank should recognize the creators of the data or material as authors, regardless of whether they contributed to the subsequent analysis or drafting of the paper. [56] There is no logical basis for such a practice [99] since publication itself is the act of sharing results, theories and methods with the scientific community. Researchers have published philosophical theories and then had these reused and transformed by others, but one would not consider naming the creator of a theory as an author on all subsequent publications dealing with that theory. The only relevant difference between a theoretical publication and one that is the result of datasets or material banks is that the latter is concrete. This means that material or data can be withheld and even used as a bargaining chip for individual gain (i.e., authorship on downstream publications).

While individual recognition is attributed in publications to acknowledge the creator of shared datasets and material banks, the management of data and material often goes unrecognized in the academic world. Management may be a very important or a very simple task depending on the data or the type of material. As such, allocating merit for management can be complex. In those instances where management is considered a substantive contribution to science, it may be appropriate to acknowledge such activities in the researcher’s CV, so that it may be considered in funding requests.

There are ethical ways to achieve personal recognition through collaboration with other researchers and sharing datasets or material banks. For example, a researcher in sociology who has created a qualitative dataset on the perceptions of a certain community and published results linked to this data might collaborate with a fellow researcher who has done similar research using quantitative methods. Both researchers know their datasets

best and could collaborate to further their knowledge through mixed methods and publish another significant study. A third researcher may wish to access their datasets, to conduct work on a different subject, or may represent unwanted competition if studying the same issues. It might be possible and in fact advantageous to all parties, if this third researcher were to join this research team; this would eliminate competitiveness, add additional resources, and also possibly introduce a fresh perspective. However, researchers might not be able to work together because of personal or professional differences, although such differences do not justify the exclusion of an individual from access to data.

It should be pointed out that competition is not always unethical or undesirable. Competition can, in certain cases, create healthy initiatives and increase productivity; competition becomes problematic and even unethical when it is a deterrent to sharing. Withholding data to simply get ahead of one's competition is not an ethical means to an end. While it is important to receive due recognition for the creation of material banks and databases, limiting access to these resources for professional gain can impede the advancement of science. Moreover, data or material withholding for reasons of competition may promote an unhealthy work environment. Vogeli argues that "data withholding, may contribute to a culture of mistrust and professional isolation both within and between groups in the scientific community to the extent that those who have experienced the personal and professional consequences of denial will see this as a normative pattern to be repeated". [130] It is thus important to prevent data withholding where possible and to build a culture of sharing in science. Establishing a culture of sharing must take into consideration the norms of community and collegiality in science. While such norms were presented as a key part of research integrity with Merton [132] in the 1940s, they have become less of a focus in the contemporary ethics literature. It is thus important to re-emphasize research integrity in order to promote data and material sharing as an ethical norm in academia.¹¹

¹¹ For more information on research integrity linked to the promotion of sharing as an ethical norm in academia, see [107, 133].

Conclusions and recommendations

The aim of this article was to reflect on the limitations of database and material bank sharing in academic research. To do so, I argued that generally speaking, data and material sharing is ethically sound – in other words, sharing is *prima facie* ethical. As such, practices that limit sharing require ethical justification. I mapped out limitations identified during the VINCI study and reflected on their justification and impact on sharing. At the outset, I considered consent, confidentiality and research ethics processes and how they relate to data and material sharing. In certain cases, fundamental principles such as autonomy, self-determination and respect of the person (human dignity) justify the legitimate withholding or limiting of sharing of databases or material banks. However, while there may be ethical justifications to limit sharing, there are also creative ways currently in use or being developed to conceal identity, ensure appropriate confidentiality and thus facilitate consent and sharing while still respecting ethical principles of research. This analysis leads, I suggest, to the following recommendations linking research ethics and the sharing of databases and material banks:

- 1) REBs should recognise that various types of sharing are key to the ethical conduct of research.
- 2) Training should be provided to assist both REBs and researchers in determining and promoting appropriate sharing protocols and practices for various research contexts.
- 3) Collaboration between researchers and REBs should be encouraged in order to facilitate ethical sharing in research projects.

Secondly, I explored challenging issues around intellectual property, competition and lack of recognition. While intellectual property was not a major issue in the VINCI study, competition and lack of recognition were highlighted as important limitations. Competition is not inherently bad but it can lead to behaviours that are selfish and even unethical, and that ultimately undermine scientific progress. Moreover, since advances in science are usually publically funded, it is unethical to restrict or withhold knowledge that could contribute to the public good only to serve the professional and competitive advantage and benefit of one or a few individuals. The advancement of science may bring

with its great personal prestige; however, the quest for personal prestige by being the first to publish should not hinder collaboration and the sharing of knowledge. Although sharing was not considered a traditional research ethics norm in the past, it has become accepted as a fundamental aspect in the “responsible conduct of research” and more specifically in “responsible data and material management”. Sharing should thus be treated as an ethical responsibility in research. This analysis leads, I suggest, to the following recommendations linking research integrity and the sharing of databases and material banks:

- 1) There should be continued promotion of communal norms in universities that encourage cooperation among researchers.
- 2) It should be deemed unethical to withhold or restrict for an unlimited time period any knowledge that could contribute to the public good, when the limitation is intended to serve individual and professional gain or for competitive advantage.
- 3) Additional research should be performed to better understand and to update and adapt mechanisms of credit allocation in competitive environments, so as to promote and acknowledge sharing.

These recommendations are no doubt preliminary as further reflection and analysis must be done regarding the ethical sharing of databases and material banks in different fields of study. Furthermore, while the need to integrate data sharing education into curricula and practice has been mentioned in the ethics and science literatures, [30] there have been few practical applications. To facilitate consistent and ethical practices in data and material management, it may be helpful to identify best practices (but accepting that there is no one “best” practice), tools and training as part of the university curriculum and in other professional development. There are courses that teach scientific methods to lessen bias and promote objectivity; it may be time to include in these methods, instruction on effective and ethical data and material sharing.

Conclusion

Les éléments clefs de cette étude

Dans l'introduction de ce mémoire, il a été constaté que plusieurs organisations internationales, nationales et provinciales prônent des initiatives de valorisation des sous-produits de la recherche, comme les bases de données et les banques de matériel. Toutefois, la mise en œuvre de ces initiatives reste limitée, car il semble que le cadre d'éthique de la recherche en œuvre dans les universités canadiennes soit en tension avec la valorisation.

Selon notre analyse des sources documentaires, les bases de données et les banques de matériel ont déjà été le sujet de plusieurs études en bioéthique. [134-138] Toutefois, dans ces études les auteurs se concentrent principalement sur la protection des droits des participants à la recherche. Ils incluent rarement d'autres enjeux éthiques concernant la valorisation des bases et des banques, tels que l'intégrité scientifique des chercheurs dans les réseaux de partage. Pour mieux comprendre les enjeux éthiques de la valorisation des bases et banques, il est apparu nécessaire de réaliser une étude empirique sur le sujet. Dans notre recherche, nous étions donc davantage intéressés à la perception des chercheurs, puisqu'ils sont des acteurs centraux dans le processus de valorisation. En effet, le chercheur décide s'il partage, réutilise ou commercialise ses bases ou banques et la manière dont il le fera même si la recherche sur les bases et les banques est encadrée indirectement par différentes normes et politiques. [20, 62]

Nous avons ensuite présenté notre méthode de recherche qui comporte deux parties (chapitres/articles) bien distinctes. La première porte sur une étude empirique concernant la perception des chercheurs. La méthode inclut : un échantillonnage par choix raisonné, un recrutement par appel téléphonique, une collecte de données par entrevues semi-dirigées et une analyse de données par codage de thèmes. La seconde partie de notre méthode se base sur des données empiriques issues de la partie précédente. Plus précisément, nous avons fait une analyse fondée sur la documentation académique et sur

les données empiriques pour mieux comprendre les limites du partage des données et du matériel entre les chercheurs.

Le premier chapitre/article présente l'une des rares études ayant été réalisées auprès des chercheurs en ce qui concerne leur perception quant à la gestion et à la valorisation des sous-produits de leurs recherches. Il permet ainsi d'apporter un éclairage nouveau sur le potentiel de valorisation des sous-produits de la recherche que constituent les bases de données et les banques de matériel. De plus, il permet de prendre connaissance des difficultés et des enjeux associés à valorisation et à la gestion des bases de données et des banques de matériel produites à des fins de recherche.

Cette étude empirique permet de conclure qu'il existe des bases de données et banques de matériel présentant un certain potentiel de valorisation quel que soit le domaine d'étude d'où elles proviennent. Les initiatives de valorisation ne devraient pas être limitées à certains domaines de la recherche, comme la médecine et la technologie. Cependant, ce n'est pas l'ensemble des bases de données ou banques de matériel produites dans un domaine de recherche donné qui est valorisable. Il y a donc des subtilités propres à chacune des bases de données ou banques de matériel en question, leur conférant un potentiel plus ou moins élevé de valorisation. Deux éléments principaux peuvent expliquer les différences quant au potentiel de valorisation et à la volonté des chercheurs de partager les données ou le matériel de recherche : soit 1) la proximité du chercheur avec les participants ; 2) la nature de l'information ou du matériel constituant les bases ou les banques.

Ces éléments sont directement liés aux difficultés à valoriser des bases de données et banques de matériel qui ont été identifiées par les chercheurs rencontrés au cours de cette étude. La position des chercheurs quant au mode de gouvernance qui serait privilégié dans la gestion des bases de données et banques de matériel est une difficulté de collaboration entre les chercheurs, l'institution (incluant les comités responsables) et les organismes subventionnaires. Cette position est, en fait, influencée par la perception

des chercheurs en ce qui concerne la propriété des bases de données ou des banques de matériel produites à des fins de recherche, qui, elle, est assez ambiguë.

Les chercheurs sont réticents à se qualifier de propriétaires des bases ou des banques, ils utilisent plutôt des termes comme gardiens, fiduciaires ou responsables de ces produits de la recherche. De façon générale, les chercheurs s'entendent sur le fait qu'il peut y avoir un partage de la propriété matérielle des bases et des banques issues de la recherche avec l'université ou des partenaires de recherche. Ce partage sous-entend que l'institution peut jouer un rôle prédominant dans le partage de l'information ou la commercialisation des sous-produits de la recherche avec d'autres institutions ou d'autres chercheurs. Notez que les chercheurs sont très peu favorables à un échange commercial de ces produits. D'autre part, les chercheurs témoignent d'un sincère désir de conserver le contrôle sur l'utilisation subséquente des données ou du matériel provenant de leurs recherches personnelles. Il y a donc une tendance vers une position de la propriété partagée asymétriquement avec l'université, en faveur du chercheur. Tant que la position institutionnelle concernant la propriété des bases de données et banques de matériel ne sera pas clarifiée, le partage des responsabilités en terme de gestion des bases et des banques entre les différents acteurs identifiés ne pourra être effectué de façon efficace.

L'efficacité de la valorisation des bases de données et des banques de matériel créées à des fins de recherche dépend largement de la gestion des difficultés qui y sont liées. Le deuxième chapitre/article présenté dans ce mémoire tentait d'analyser la présence des tensions entre une forme de valorisation (soit le partage des données et du matériel) et le cadre de l'éthique universitaire. Pour ce faire, nous avons premièrement présenté les raisons pour lesquelles les chercheurs devraient partager leurs bases et banques selon l'étude empirique de VINCI et selon la documentation courante sur le sujet. Les raisons pour partager sont multiples, les trois avantages suivants sont parmi les plus populaires. Premièrement, le partage des bases et des banques permet un progrès scientifique accéléré. Celui-ci suppose que le meilleur accès aux bases et aux banques permette à une diversité de chercheurs provenant de domaines différents d'utiliser ses ressources.

Deuxièmement, en partageant les bases et les banques nous utilisons les données et les matériaux plus efficacement en minimisant son coût, c'est-à-dire les intrants de la recherche tout en maximisant les extrants, ou les produits de la recherche. Enfin, le partage de bases et de banques encourage les collaborations, ce qui améliore le sentiment de communauté et de collégialité entre les chercheurs universitaires.

Ces arguments sont semblables aux prémisses avancées par les organismes subventionnaires canadien et américain prônant la valorisation et le partage des données et du matériel. Ainsi, nous avons argumenté que si le partage des bases et banques est, *prima facie*, éthique et bénéfique, alors les limites de ce partage peuvent être considérées comme problématiques. Nous avons ainsi analysé les difficultés principales identifiées au cours de l'étude VINCI pour mieux comprendre les tensions et les problématiques liées au partage. Tout d'abord, nous avons analysé les difficultés liées au cadre de l'éthique de la recherche traditionnelle : les procédures éthiques, le consentement et la confidentialité. Ensuite, nous nous sommes penchée sur les enjeux qui sont davantage liés à l'intégrité de la recherche : le contrôle lié à la propriété matérielle et intellectuelle, la compétition entre les chercheurs et le manque de reconnaissance.

Les résultats de ce second article montrent que, de plus en plus, le cadre de l'éthique de la recherche traditionnelle prend en considération des initiatives de partage. Le consentement ouvert, les tentatives d'harmonisation des procédures éthiques et les différentes techniques pour assurer la confidentialité des participants à la recherche sont tous des exemples de cette ouverture vers le partage des données et du matériel. Il faut toutefois noter que ces ouvertures ne sont pas justifiées, possibles ou évidentes pour tous les projets ou tous les contextes de recherche, surtout lorsque les projets comportent plusieurs risques pour les participants à la recherche.

L'éthique de la recherche traditionnelle, perçue comme la protection des patients de recherche, n'est pas ce qui causait le plus d'obstacles quant au partage des données et matériel. C'était plutôt des questions de contrôle, de compétition et de reconnaissance qui semblaient limiter le partage des bases de données et des banques de matériel. Selon

les chercheurs interviewés dans le projet VINCI, plusieurs limitaient le partage pour accroître leurs propres possibilités de recherche tout en limitant les possibilités de recherche à leurs concurrents. Dans une telle situation, il y a un conflit d'intérêts lorsque le chercheur a comme intérêt premier son prestige personnel au détriment de l'avancement scientifique. Le partage de la reconnaissance (surtout par le biais du droit d'auteur) diffère en fonction de la discipline et des champs de recherche et rend ainsi plus complexe le partage des bases et des banques. [99] Il est nécessaire d'effectuer plus de recherches pour savoir comment répartir la reconnaissance, particulièrement dans les projets multidisciplinaires au cours desquels on utilise des bases de données et des banques de matériel.

Quelques limites

Dans le cadre de ce mémoire, le concept de la valorisation s'inscrit dans une vision bien particulière de la société, celle de la « société du savoir ». Selon cette vision, les dimensions économiques, sociales, éthiques et politiques de la société sont d'une grande importance dans le développement de la connaissance. Bien qu'il soit important de considérer plusieurs sortes de valeurs, nous pensons que la généralité et l'ambiguïté du mot « valorisation » rend ce concept difficile à utiliser en recherche, car il inclut plusieurs sortes de réutilisations des données et du matériel (le partage, la réutilisation par les institutions gouvernementales, la commercialisation, etc.). Ainsi, utiliser ce concept dans une étude empirique fut très difficile. Toutefois, la généralité de ce concept nous a permis de découvrir la multitude de milieux de recherche pouvant valoriser les données et le matériel de recherche.

L'étude empirique du premier article était limitée à un petit échantillon de chercheurs de l'Université de Montréal. Elle sera donc difficilement généralisable aux autres contextes de recherche. Cette étude représente néanmoins une étape indispensable pour établir une meilleure mise en place des initiatives de valorisation des bases et des banques universitaires tout en assurant une norme éthique de ces pratiques.

La réflexion d'ordre théorique fondée sur les données empiriques trouvées dans le deuxième article comporte également quelques limites. Premièrement, l'analyse est limitée aux difficultés liées à l'éthique et non aux difficultés pratiques (par exemple : pérennité des données) ou économiques (ressources limitées). Cette décision n'a pas été prise sur la base de l'importance des sujets à l'étude, car ceux-ci sont tous importants pour assurer la mise sur pied des initiatives de valorisation des bases de données et des banques de matériel. Ce choix a simplement été fait pour limiter la portée de ce travail de mémoire au domaine de recherche particulier de l'éthique.

Des pistes pour l'avenir

L'étude exploratoire présentée dans le premier article a été réalisée auprès d'un petit échantillon de chercheurs. Il pourrait ainsi s'avérer utile de faire une étude avec un échantillon un peu plus grand dans chacun des domaines de recherche afin de mieux cibler les besoins et les craintes propres à chacun d'entre eux. Plus particulièrement, les recherches dans le domaine des sciences sociales et des sciences humaines semblent présenter des problématiques bien spécifiques quant à la relation entre les chercheurs et les participants à la recherche. Par exemple, certains chercheurs utilisant des données qualitatives sur des sujets particulièrement sensibles (les troubles psychologiques, le viol ou les comportements criminels) sont extrêmement réticents à partager leurs données. Ils soulignent le fait que les participants à la recherche ne seraient pas complètement honnêtes dans leurs réponses si plusieurs individus avaient accès aux transcriptions (verbatim) des entrevues. D'autres études empiriques (autant de types qualitatifs que quantitatifs) seront essentielles pour mieux comprendre le cadre de l'éthique et de la valorisation dans différentes institutions de recherche universitaire.

De plus, le vocabulaire utilisé généralement en référence aux bases de données et banques de matériel semble s'appliquer davantage à un contexte de sciences expérimentales, de sciences appliquées ou de la santé. Il faudrait donc voir à ajuster celui-ci afin de pouvoir mieux communiquer avec les chercheurs travaillant en sciences sociales ou humaines. Pour ce faire, la mise sur pied d'un comité ou groupe de recherche se penchant en particulier sur les questions éthiques entourant la gestion et la

valorisation des bases de données et banques de matériel issues de ce domaine de recherche, voire plus spécifiquement en recherche qualitative, serait une excellente première étape vers une augmentation du potentiel de valorisation de celles-ci.

Pour s'assurer de la mise sur pied des initiatives de valorisation des bases de données et banques de matériel, il pourrait s'avérer utile d'investir dans la formation en éthique de la valorisation des chercheurs de façon plus systématique dans le cadre de l'Université de Montréal et de ses institutions d'attaches. Une telle formation pourrait être dispensée sous la forme d'ateliers dirigés directement dans les divers départements ou sous la forme de capsules distribuées à même le courrier interne ou le service de courriel. Cette formation aurait pour but d'éveiller les chercheurs aux enjeux associés au partage des données et du matériel de recherche, mais aussi aux différentes possibilités de valorisation se présentant à eux en ce qui concerne les bases de données et banques de matériel issues de leurs travaux de recherche.

En somme, la valorisation des bases de données et banques de matériel produites à des fins de recherche est à la fois possible et souhaitable dans de nombreux cas. Il n'y a aucun doute que certaines bases de données ou banques de matériel sont des ressources pouvant être à la base de connaissances importantes à l'avancement du savoir, mais elles nécessitent une coopération entre tous les acteurs pour que leur potentiel soit actualisé. Le participant à la recherche doit être respecté en appliquant les normes d'éthique de la recherche traditionnelle telles que le consentement et la confidentialité. Toutefois, si nous voulons promouvoir une efficacité et un avancement de la recherche (qui eux aussi peuvent être dans l'intérêt des participants), nous devons être ouverts à l'idée que de tels projets ou de telles formes de valorisation, comme le partage, puissent être considérés. Ces projets doivent être créés et gérés dans un environnement où la collégialité entre les chercheurs est promue. Lorsque le chercheur pense avant tout à son prestige, cet intérêt risque de passer au détriment de la science. Intégrer des aspects de l'intégrité de la recherche (incluant le partage des données et du matériel) est certainement un début vers une meilleure valorisation des sous-produits de la recherche.

Bibliographie

1. Hoeyer, K., *The Ethics of Research Biobanking: A Critical Review of the Literature*. *Biotechnology and Genetic Engineering Reviews*, 2008. **25**: p. 429-452.
2. Jeffers, B., *Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks*. *Advances in Nursing Science*, 2001. **24**(2): p. 32.
3. Blumenthal, D., *Conflict of interest in biomedical research*. *Health Matrix*, 2002. **12**: p. 377.
4. Zhang, X., *Bioethical regulation and human genetic databases in Mainland China*, in *Human genetic biobanks in Asia: politics of trust and scientific advancement*. 2009, Taylor & Francis. p. 188-210.
5. Bregman-Eschet, Y., *Genetic Databases and Biobanks: who controls our genetic privacy*. *Santa Clara Computer & High Tech. LJ*, 2006. **23**: p. 1.
6. Helgesson, G. and L. Johnsson, *The right to withdraw consent to research on biobank samples*. *Medicine, Health Care and Philosophy*, 2005. **8**(3): p. 315-321.
7. Willison, D., *Privacy and the secondary use of data for health research: experience in Canada and suggested directions forward*. *Journal of Health Services Research & Policy*, 2003. **8**(Supplement 1): p. 17.
8. Genome, B., *The Prevention of Genetic Discrimination and a Broader Approach to Informed Consent for Biobanking and Research (2004) Recommendation*.
9. Clayton, E., *Informed consent and biobanks*. *JL Med. & Ethics*, 2005. **33**: p. 15.
10. Shickle, D., *The consent problem within DNA biobanks*. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences*, 2006. **37**(3): p. 503-519.
11. Maschke, K., *Alternative consent approaches for biobank research*. *The Lancet Oncology*, 2006. **7**(3): p. 193-194.
12. Brekke, O. and T. Sirnes, *Population biobanks: the ethical gravity of informed consent*. *BioSocieties*, 2006. **1**(4): p. 385-398.
13. Bergeron, M. and D. Laudy, *Chapitre 1. Le suivi éthique des protocoles de recherche en contexte nord-américain: des finalités à définir*. *Journal International de BioÉthique*, 2004: p. 15-32.
14. Knoppers, B. and M. Saginur, *The Babel of genetic data terminology*. *Nature biotechnology*, 2005. **23**(8): p. 925-927.
15. Milanovic, F., D. Pontille, and A. Cambon-Thomsen, *Biobanking and data sharing: a plurality of exchange regimes*. *Genomics, Society & Policy*, 2007. **23**(1): p. 17-30.
16. Gibbons, S.M.C., *Regulating Biobanks : A twelve-point typological tool* *Med Law Rev*, 2009. **17**(3): p. 313-346.
17. Mailhot, C., P. Pelletier, and V. Schaeffer, *La valorisation de la recherche: une nouvelle mission pour l'université?* *The Canadian Journal of Higher Education*, 2007. **37**(1): p. 45-65.

18. Lesemann, F., *La société des savoirs et la gouvernance: la transformation des conditions de production de la recherche universitaire*. Lien social et politiques, 2003. **50**: p. 17-37.
19. OCDE, *Turning Science into Business. Patenting and Licensing at Public Research Organizations*. 2003, Organisation de coopération et de développement économique: Paris.
20. FRSQ-MSSS, *Rapport final du groupe-conseil sur l'encadrement des banques de données et des banques de matériel biologique à des fins de recherche en santé*. 2007, Fonds de la recherche en santé du Québec, & Ministère de la santé et des services sociaux. : Montréal, Québec.
21. Gibson, E., et al., *Who's minding the shop? The role of Canadian research ethics boards in the creation and uses of registries and biobanks*. BMC Medical Ethics, 2008. **9**(1): p. 17.
22. Grisé, A., *La valorisation de la recherche universitaire - Clarification conceptuelle*. 2005, Secrétariat du Conseil de la science et de la technologie.
23. OCDE, *L'économie fondée sur le savoir*. 1996, Organisation de coopération et de développement économiques: Paris. p. 6-7.
24. Peters, M., *Education and the knowledge economy*. Knowledge policy: Challenges for the 21st century, 2008: p. 27.
25. UNESCO, *Vers les sociétés du savoir*. 2005, Organisation des Nations Unies pour l'éducation, la science et la culture: Paris.
26. Välimaa, J. and D. Hoffman, *Knowledge society discourse and higher education*. Higher Education, 2008. **56**(3): p. 265-285.
27. Hearn, G. and D. Rooney, *Conclusion: Towards integrated knowledge policy*, in *Knowledge policy: Challenges for the 21st century*. 2008, Edward Elgar Pub. p. 252.
28. Morrison, K., et al., *Industry policy as innovation policy*. Knowledge Policy: Challenges for the 21st Century. Cheltenham, UK and Northampton, MA (Edward Elgar), 2008: p. 163-175.
29. Fischer, B. and M. Zigmond, *The Essential Nature of Sharing in Science*. Science and Engineering Ethics, 2010: p. 1-17.
30. Piwowar, H., et al., *Towards a data sharing culture: recommendations for leadership from academic health centers*. PLoS medicine, 2008. **5**(9).
31. Kaye, J., et al., *Data sharing in genomics re-shaping scientific practice*. Nature Reviews Genetics, 2009. **10**(5): p. 331-335.
32. Teeters, J., et al., *Data sharing for computational neuroscience*. Neuroinformatics, 2008. **6**(1): p. 47-55.
33. Caulfield, T. and B. Knoppers, *Consent, Privacy & Research Biobanks*. 2010.
34. Foster, M. and R. Sharp, *Share and share alike: deciding how to distribute the scientific and social benefits of genomic data*. Nature Reviews Genetics, 2007. **8**(8): p. 633-639.
35. UNESCO, *International Declaration on Human Genetic Data*. 2003, Organisation des Nations Unies pour l'éducation, la science et la culture.
36. OCDE, *Guidelines on Human Biobanks and Genetic Research Databases*. 2009, Organisation de coopération et de développement économique.
37. Knoppers, B., M. Abdul-Rahman, and K. Bedard, *Genomic databases and international collaboration*. Kings College Law Journal, 2007. **18**(2): p. 291.

38. Auray-Blais, C. and J. Patenaude, *A biobank management model applicable to biomedical research*. BMC Medical Ethics, 2006. **7**(1): p. 4.
39. *Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains*. 1998 Instituts de recherche en santé du Canada, Conseil de recherches en sciences naturelles et en génie du Canada, Conseil de recherches en sciences humaines du Canada, .
40. CAI. *Énoncé de mission de la Commission d'accès à l'information du Québec*. 2010 [cited 2010 8 mai]; Available from: <http://www.cai.gouv.qc.ca/>.
41. *Directives relatives à la gestion des renseignements personnels et du matériel biologique recueillis dans le cadre de projets de recherche impliquant des sujets humains [Version électronique]*. 2005 [cited 2010 20 avril].
42. Godard, B., J. Marshall, and C. Laberge, *Community engagement in genetic research: results of the first public consultation for the Quebec CARTaGENE project*. Public Health Genomics, 2007. **10**(3): p. 147-158.
43. Joseph, J.W., et al., *Empirical data about womens attitudes toward a biobank focused on pregnancy outcomes*. American journal of medical genetics. Part A, 2008. **146**(3): p. 305.
44. Helft, P.R., et al., *Cancer patients' attitudes toward future research uses of stored human biological materials*. Journal of Empirical Research on Human Research Ethics, 2007. **2**(3): p. 15-22.
45. Alon, B.N., et al., *Empirical data about women's attitudes towards a hypothetical pediatric biobank*. American Journal of Medical Genetics Part A, 2008. **146A**(3): p. 297-304.
46. Cambon-Thomsen, A., *The social and ethical issues of post-genomic human biobanks*. Nature reviews. Genetics, 2004. **5**(11): p. 866-873.
47. Hansson, M.G., *Combining efficiency and concerns about integrity when using human biobanks*. Studies in History and Philosophy of Biological & Biomedical Sciences, 2006. **37**(3): p. 520-532.
48. Hirtzlin, I., et al., *An empirical survey on biobanking of human genetic material and data in six EU countries*. European Journal of Human Genetics, 2003. **11**(6): p. 475-488.
49. Capron, A.M., et al., *Ethical Norms and the International Governance of Genetic Databases and Biobanks: Findings from an International Study*. Kennedy Institute of Ethics Journal, 2009. **19**(2).
50. Mukamurera, J., F. Lacourse, and Y. Couturier, *Des avancées en analyse qualitative: pour une transparence et une systématisation des pratiques*. Revue de l'association de la recherche qualitative, 2006. **26**(1): p. 110-138.
51. Dépelteau, F., *La démarche d'une recherche en sciences humaines: de la question de départ et la communication des résultats*. 2000: De Boeck Université. 226.
52. Strauss, A. and J. Corbin, *Basics of qualitative research: Grounded theory procedures and techniques*. 1990: Sage publications Newbury Park, CA.
53. Guillemette, F., *L'approche de la Grounded Theory; pour innover*. Recherches qualitatives, 2006. **26**(1): p. 32-50.
54. Paillé, P. and A. Mucchielli, *L'analyse qualitative en sciences humaines et sociales*. 2003, Paris: Armand Colin.

55. Poupart, J., *Approches et techniques de recherche*, in *La recherche qualitative; Enjeux épistémologique et méthodologiques*, J. Poupart, et al., Editors. 1997, Gaëtan morin editeur: montréal. p. 173-206.
56. Olivier, C. and E. Smith, *Rapport des travaux de Recherche présenté au Groupe de Recherche sur les bases de données et les banques de matériel du Programme VINCI*. 2010, Université de Montréal: Montréal. p. 119.
57. Smith, E., C. Olivier, and M. Bergeron, *Researchers' Perceptions on the Valorization of University Databases and Material Banks*. Review of Higher Education, 2010 (In review).
58. Fortin, S., et al., *Access Arrangements for Biobanks: A Fine Line between Facilitating and Hindering Collaboration*. Public Health Genomics, 2010.
59. Helft, P., et al., *Cancer patients' attitudes toward future research uses of stored human biological materials*. Journal of Empirical Research on Human Research Ethics, 2007. **2**(3): p. 15-22.
60. Nelson, B., *Empty archives*. Nature, 2009. **461**(7261): p. 160-163.
61. Campbell, E.G., et al., *Data Withholding in Academic Genetics: Evidence From a National Survey*. Journal of the American Medical Association, 2002. **287**(4): p. 473-480.
62. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2010.
63. Blumenthal, D., et al., *Data withholding in genetics and the other life sciences: prevalences and predictors*. Academic Medicine, 2006. **81**(2): p. 137-145.
64. ICMJE. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship*. 2009 [cited July 6th, 2010; Available from: http://www.icmje.org/ethical_1author.html].
65. Rasmussen, E., *Government instruments to support the commercialization of university research: Lessons from Canada*. Technovation, 2008.
66. Crespo, M. and H. Dridi, *Intensification of university-industry relationships and its impact on academic research*. Higher Education, 2007. **54**(1): p. 61-84.
67. Lebeau, L., et al., *The effect of university-industry collaboration on the scientific impact of publications: the Canadian case, 1980-2005*. Research Evaluation, 2008. **17**(3): p. 227-232.
68. Cauchy, C., *La crise financière secoue aussi les universités québécoise*, in *Le Devoir*. 2009: Montréal.
69. Aboelela, S.W., et al., *Defining interdisciplinary research: Conclusions from a critical review of the literature*. Health Services Research, 2007. **42**(1 Pt 1): p. 329.
70. Gössling, T., *Proximity, trust and morality in networks*. European Planning Studies, 2004. **12**(5): p. 675-689.
71. Miller, K., *Beyond the frontstage: Trust, access, and the relational context in research with refugee communities*. American Journal of Community Psychology, 2004. **33**(3): p. 217-227.

72. Solomon, J., *Programmers, Professors, and Parasites: Credit and Co-Authorship in Computer Science*. *Science and Engineering Ethics*, 2009. **15**(4): p. 467-489.
73. *Law on Cultural Property; regulations on archaeological research in B-4*.
74. Haddow, G., et al., *Tackling community concerns about commercialisation and genetic research: a modest interdisciplinary proposal*. *Social Science & Medicine*, 2007. **64**(2): p. 272-282.
75. Hall, M.A., et al., *Biobanking, consent, and commercialization in international genetics research: the Type 1 Diabetes Genetics Consortium*. *Clinical Trials*, 2010. **7**(1 suppl): p. S33.
76. Annas, G.J., L.H. Glantz, and P.A. Roche, *Drafting the Genetic Privacy Act: science, policy, and practical considerations*. *The Journal of Law, Medicine & Ethics*, 1995. **23**(4): p. 360-366.
77. Skrikerud, A., *The Dubious Uniqueness of Genetic Information*. *The Ethics of Research Biobanking*, 2009: p. 57-67.
78. CIHR. *Executive Summary*. Draft Policy Guidelines 2004 [cited 2011 May 2]; Available from: <http://www.cihr-irsc.gc.ca/e/22096.html>.
79. Johnson, P., *OECD Global Science Forum : Second Activity on Policy Issues Related to Scientific Research Collections*, in *Final Report on Findings and Recommendations*. 2008: Washington DC. p. 22.
80. Mitchell, R. and C. Waldby, *National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue*. *Science, Technology & Human Values*, 2010. **35**(3): p. 330.
81. National Institutes of Health, *Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)*, National Institutes of Health (NIH), Editor. 2007.
82. National Science Foundation, *Data Management for NSF SBE Directorate*, National Science Foundation (NSF), Editor. 2010.
83. Canadian Institutes of Health Research, *Draft Policy on Access to CIHR-funded Research Outputs*, Canadian Institutes of Health Research, Editor. 2007.
84. Wu, S. and C. Neylon, *Open Science: Tools, approaches, and implications*. 2008.
85. Giffels, J., S.H. Vollmer, and S.J. Bird, *Editors Overview: Topics in the Responsible Management of Research Data*. *Science and Engineering Ethics*, 2010: p. 1-7.
86. Lunshof, J.E., et al., *From genetic privacy to open consent*. *Nature Reviews Genetics*, 2008. **9**(5): p. 406-411.
87. Kaye, J., et al., *Data sharing in genomics - re-shaping scientific practice*. *Nature Reviews Genetics*, 2009. **10**(5): p. 331-335.
88. Petrini, C., *"Broad" consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose*. *Social Science & Medicine*, 2010. **70**(2): p. 217-220.
89. Newton, I. *Letter to Robert Hooke*. 1676 [cited 2011 July 4]; Available from: http://www.quotationspage.com/quotes/Isaac_Newton/.
90. Miller, T.R., et al., *Epistemological pluralism: reorganizing interdisciplinary research*. *Ecology and Society*, 2008. **13**(2): p. 46.

91. ESDS Qualidata. *About ESDS Qualidata*. 2010 [cited 2011; Available from: <http://www.esds.ac.uk/qualidata/about/introduction.asp>.
92. de Wolf, V., et al., *Part I: What is the requirement for data sharing?* IRB, 2005. **27**(6): p. 12-16.
93. Joshi, M. and S.S. Krag, *Issues in Data Management*. Science and Engineering Ethics, 2010: p. 1-6.
94. Kleppner, D. and P. Sharp, *Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age*. 2009: National Academies Press.
95. Piwowar, H., R. Day, and D. Fridsma, *Sharing detailed research data is associated with increased citation rate*. PLoS One, 2007. **2**(3): p. 308.
96. Rahman, L. and S.K. Muirhead-Allwood, *How many orthopedic surgeons does it take to write a research article? 50 years of authorship proliferation in and internationalization of the orthopedic surgery literature*. Orthopedics, 2010. **33**(7).
97. Levsky, M.E., et al., *A descriptive analysis of authorship within medical journals, 1995-2005*. Southern Medical Journal, 2007. **100**(4): p. 371.
98. Baethge, C., *Publish Together or Perish: The Increasing Number of Authors per Article in Academic Journals Is the Consequence of a Changing Scientific Culture. Some Researchers Define Authorship Quite Loosely*. Deutsches Arzteblatt International, 2008. **105**(20): p. 380.
99. Smith, E. and B. Williams-Jones, *Authorship and Responsibility in Health Sciences Research: A Review of Procedures for Fairly Allocating Authorship in Multi-Author Studies*. Science and Engineering Ethics, 2011: p. 1-14.
100. Merton, R.K., *The sociology of science: Theoretical and empirical investigations*. 1979: University of Chicago Press.
101. Chadwick, R. and K. Berg, *Solidarity and equity: new ethical frameworks for genetic databases*. Nature Reviews Genetics, 2001. **2**(4): p. 318-321.
102. Forsberg, J.S., M.G. Hansson, and S. Eriksson, *Changing perspectives in biobank research: from individual rights to concerns about public health regarding the return of results*. European Journal of Human Genetics, 2009. **17**(12): p. 1544-1549.
103. Schroeder, D., *Benefit sharing: it's time for a definition*. Journal of Medical Ethics, 2007. **33**(4): p. 205.
104. Advisory Committee on Access to Research Outputs, *Draft Policy on Access to CIHR-funded Research Outputs*, Canadian Institutes of Health Research, Editor. 2007: <http://www.cihr-irsc.gc.ca/e/32326.html>.
105. Social Sciences and Humanities Research Council of Canada, *Research Data Archiving Policy*, Social Sciences and Humanities Research Council of Canada, Editor. 2010: http://www.sshrc-crsh.gc.ca/funding-financement/policies-politiques/edata-donnees_electroniques-eng.aspx.
106. Human Genome Organisation. *Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing*. 1996 [cited 2011 June 30]; Available from: http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml.
107. Shamoo, A.E. and D.B. Resnik, *Responsible conduct of research*. 2009, New York: Oxford University Press.

108. Department of Health and Human Services, *Protection of Human Subjects*, in 45 CFR 46, Department of Health and Human Services, Editor. 2009.
109. Stair, T., et al., *Variation in institutional review board responses to a standard protocol for a multicenter clinical trial*. Academic Emergency Medicine, 2001. **8**(6): p. 636-641.
110. Hebert, P. and R. Saginur, *Ethique de la recherche: l'examen doit se faire une seule fois et bien se faire*. Canadian Medical Association Journal, 2009. **180**(6): p. 598.
111. Hernandez, R., et al., *Harmonisation of ethics committees' practice in 10 European countries*. Journal of Medical Ethics, 2009. **35**(11): p. 696-700.
112. Santos, N., K.P. Gummadi, and R. Rodrigues. *Towards trusted cloud computing*. 2009: USENIX Association.
113. Zwart, H., *Challenges of Macro-ethics: Bioethics and the Transformation of Knowledge Production*. Journal of Bioethical Inquiry, 2008. **5**(4): p. 283-293.
114. Kalra, D., et al., *Confidentiality and consent in medical research: Confidentiality of personal health information used for research*. BMJ: British Medical Journal, 2006. **333**(7560): p. 196.
115. Resnik, D., *Genomic research data: open vs. restricted access*. IRB, 2010. **32**(1): p. 1.
116. Health, N.I.o. *Modifications to Genome-Wide Association Studies (GWAS) Data Access*. 2008 [cited 2011 july 14]; Available from: <http://gwas.nih.gov/pdf/Data%20Sharing%20Policy%20Modifications.pdf>.
117. Beauchamp, T. and J. Childress, *Principles of biomedical ethics*. Fifth Edition ed. 2001: Oxford University Press, USA.
118. Caulfield, T., et al., *Research ethics recommendations for whole-genome research: consensus statement*. PLoS Biol, 2008. **6**(3): p. e73.
119. Hoeyer, K., et al., *The ethics of research using biobanks: reason to question the importance attributed to informed consent*. Archives of internal medicine, 2005. **165**(1): p. 97-100.
120. Elger, B., *Consent and use of samples*. 2008: Aldershot: Ashgate.
121. Hansson, M.G., et al., *Should donors be allowed to give broad consent to future biobank research?* The Lancet Oncology, 2006. **7**(3): p. 266-269.
122. Hofmann, B., *Broadening consent - and diluting ethics?* British Medical Journal, 2009. **35**(2): p. 125-129.
123. Hansson, M.G., *Need for a wider view of autonomy in epidemiological research*. BMJ, 2010. **340**.
124. Paul, H., *Research ethics review: Do it once and do it well*. CMAJ: Canadian Medical Association Journal, 2009. **180**(6): p. 597.
125. Chokshi, D.A., M. Parker, and D.P. Kwiatkowski, *Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration*. Bulletin of the World health Organization, 2006. **84**: p. 382-387.
126. Heller, M.A. and R.S. Eisenberg, *Can patents deter innovation? The anticommons in biomedical research*. Science, 1998. **280**(5364): p. 698.
127. Caulfield, T., et al., *Evidence and anecdotes: an analysis of human gene patenting controversies*. Nature biotechnology, 2006. **24**(9): p. 1091-1094.

128. Lei, Z., R. Juneja, and B.D. Wright, *Patents versus patenting: implications of intellectual property protection for biological research*. *Nature biotechnology*, 2009. **27**(1): p. 36-40.
129. Tutton, R. and O.P. Corrigan, eds. *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*. 2004, Routledge: London. 27.
130. Vogeli, C., et al., *Data withholding and the next generation of scientists: results of a national survey*. *Academic Medicine*, 2006. **81**(2): p. 133.
131. Gordon, R. and B.J. Poulin, *Cost of the NSERC science grant peer review system exceeds the cost of giving every qualified researcher a baseline grant*. *Accountability in Research*, 2009. **16**(1): p. 13-40.
132. Merton, R.K., *The Normative Structure of Science*. *The Sociology of Science*, 1942: p. 267-278.
133. Resnik, D.B., *Openness versus Secrecy in Scientific Research*. *Episteme* (Edinburgh), 2006. **2**(3): p. 135.
134. Williams, G., *Bioethics and large-scale biobanking: individualistic ethics and collective projects*. *Genomics, Society and Policy*, 2005. **1**(2): p. 50-66.
135. Salvaterra, E., et al., *Banking together. A unified model of informed consent for biobanking*. *EMBO reports*, 2008. **9**(4): p. 307.
136. Solbakk, J.H., *The ethics of research biobanking*. 2009: Springer Verlag.
137. Gottweis, H. and G. Lauss, *Biobank governance in the post-genomic age*. *Personalized Medicine*, 2010. **7**(2): p. 187-195.
138. Shickle, D., M. Griffin, and K. El-Arifi, *Inter-and intra-biobank networks: classification of biobanks*. *Pathobiology*, 2010. **77**(4): p. 181-190.

Annexe 1 – Participants de VINCI

Le programme VINCI est une initiative de Valorisation des Innovations et du Capital Intellectuel qui regroupait 10 établissements (Université de Montréal, Polytechnique, École des Hautes Études Commerciales; Centre Hospitalier de l'Université de Montréal; Institut de cardiologie de Montréal; Hôpital Sainte-Justine; Hôpital Sacré-Cœur de Montréal; Hôpital Maisonneuve-Rosemont; Centre de Recherche Interdisciplinaire en Réadaptation du Montréal métropolitain; Institut Universitaire de Gériatrie de Montréal), 2 sociétés de valorisation (Univalor et CRÉA) et 6 partenaires (Centre d'entrepreneurship, Centre de Liaison sur l'Intervention et la Prévention Psychosociales; Centre Interuniversitaire de Recherche en Analyse des Organisations; Centre Francophone d'Informatisation des Organisations; Centre de Transfert pour la Réussite Éducative du Québec; le centre Formation et Expertise en Recherche en Administration des Services Infirmiers regroupant l'Université de Montréal, l'Université Laval et l'Université McGill. Le Centre d'Études et de Formation en Enseignement Supérieur y a contribué également afin de fournir au Regroupement un accès aux ressources pédagogiques appropriées et de faciliter l'intégration des technologies de l'information.

Annexe 2 – Certificat d'éthique



COMITÉ D'ÉTHIQUE DE LA RECHERCHE DE LA FACULTÉ DES ARTS ET DES SCIENCES (CÉRFAAS)

CERTIFICAT D'ÉTHIQUE

Le Comité d'éthique de la recherche de la Faculté des arts et des sciences, selon les procédures en vigueur, a examiné le projet de recherche intitulé :

« Évaluation de l'intérêt des chercheurs universitaires pour la valorisation des bases de données et banques de matériel constituées à des fins de recherche »

subventionné par : *CRSNG, IRSC, CRSH (programme MPI)*

et soumis par : *Michel Bergeron, éthicien, Bureau Recherche-Développement-Valorisation*

Le Comité a conclu que la recherche proposée respecte les règles d'éthique énoncées à la « Politique sur la recherche avec des êtres humains » de l'Université de Montréal.

Tout changement anticipé au protocole de recherche doit être communiqué au CÉRFAAS qui devra en évaluer l'impact au chapitre de l'éthique afin de déterminer si une nouvelle demande de certificat d'éthique est nécessaire.

Toute interruption prématurée du projet ou tout incident grave devra être immédiatement signalé au CÉRFAAS.

Annexe 3 – Formulaire de consentement

Titre de la recherche : Évaluation de l'intérêt des chercheurs universitaires pour la valorisation des bases de données et banques de matériel constituées à des fins de recherche

Chercheur :

- Michel Bergeron, éthicien au Comité universitaire d'éthique de la recherche (CUÉR), responsable du Groupe de travail sur les banques et les sous-produits de la recherche, programme VINCI, Université de Montréal.

Cochercheurs :

- Jean Perrault, Directeur général adjoint, Centre de Liaison sur l'Intervention et la Prévention Psychosociales (CLIPP);
- Michelle Stanton-Jean, chercheure invitée, Centre de recherche en droit public (CRDP);
- Cynthia Chassigneux, agente de recherche, Centre de recherche en droit public (CRDP);
- Anne-Marie Bourret, conseillère en transfert de technologie, École Polytechnique;
- Johanne Dupuis, directrice administrative, Centre de recherche de l'Institut Universitaire de Gériatrie de Montréal (IUGM);
- Marc Elhage, conseiller juridique, Univalor.

A) RENSEIGNEMENTS AUX PARTICIPANTS

1. Objectifs de la recherche.

Ce projet de recherche vise à sonder l'intérêt des chercheurs de la communauté universitaire pour la valorisation des bases de données et des banques de matériel constituées à des fins de recherche. À travers cette consultation, l'équipe de recherche veut connaître, d'une part, la volonté des chercheurs à valoriser leur propre bases de données ou banques de matériel et, d'autre part, cerner les principales problématiques qui se posent en matière de valorisation de telles bases/banques.

Soutenue par le Bureau Recherche-Développement-Valorisation de l'Université de Montréal dans le cadre du programme de **Valorisation de l'INnovation et du Capital Intellectuel (VINCI)**, cette recherche cherche plus spécifiquement à comprendre les difficultés conceptuelles et pratiques associées à la valorisation des banques et à identifier les types de banques présentant un potentiel de valorisation. La valorisation se définit ici comme étant un « processus de transfert des connaissances développées dans les milieux universitaires vers un milieu d'utilisateurs, effectué dans un but d'ajouter une valeur aux résultats de la recherche. ». Ce processus de valorisation ne se limite donc pas qu'à la commercialisation ou à l'ajout d'une valeur monétaire ou commerciale aux résultats de recherche.

2. Participation à la recherche

Votre participation à cette recherche consiste à prendre part à un entretien semi-dirigé d'une durée approximative de 60 minutes avec un agent de recherche. Cet entretien sera enregistré sur support audio pour retranscription

3. Confidentialité

Les renseignements que vous nous donnerez demeureront confidentiels. Les questionnaires utilisés et les supports audio seront identifiés à l'aide d'un code afin de ne pas les associés directement au nom du participant. La retranscription des entrevues fera également fi des informations nominatives divulguées lors de l'enregistrement. Cependant, l'appartenance départementale ou le champ de recherche étant essentiel à l'analyse des informations recueillies, il y a un risque potentiel d'identification du participant par ses pairs (p. ex. un chercheur qui travaille sur tel type de banque dans tel département) lors de la communication des résultats de recherche. L'équipe de recherche s'engage cependant à minimiser cette éventualité dans la communication de ses résultats et invite le participant à lui faire savoir quelles informations sensibles il préfère ne pas voir divulguées.

De plus, les renseignements seront conservés dans un classeur sous clé situé dans un bureau fermé. Aucune information permettant de vous identifier d'une façon ou d'une autre ne sera publiée. Ces renseignements personnels seront détruits 7 ans après la fin du projet. Seules les données ne permettant pas de vous identifier seront conservées après cette date.

4. Avantages et inconvénients

En participant à cette recherche, vous pourrez contribuer à l'avancement des connaissances sur la valorisation de la recherche universitaire et l'utilisation de banques de données et de matériel en recherche. Plus spécifiquement, cette initiative de consultation de la communauté universitaire fournira des informations essentielles à la mise sur pied d'une politique d'encadrement des banques de données et de matériel par l'Université.

Votre participation à cette recherche ne vous fait pas courir de risque plus grand que les risques de tous les jours.

5. Droit de retrait

Votre participation est entièrement volontaire. Vous êtes libre de vous retirer en tout temps par avis verbal, sans préjudice et sans devoir justifier votre décision. Si vous décidez de vous retirer de la recherche, vous pouvez communiquer avec le chercheur, au numéro de téléphone indiqué à la dernière page de ce document. Si vous vous retirez de la recherche, les renseignements qui auront été recueillis seront détruits, sauf les données irréversiblement anonymisées.

6. Déclaration de conflit d'intérêts

Bien que le Groupe de travail jouisse du support administratif du Bureau Recherche-Développement-Valorisation (BRDV) de l'Université de Montréal, il n'en demeure pas moins une entité indépendante dont les activités de recherche sont complètement séparées de la fonction de gestion du BRDV. Aussi, le Groupe s'engage-t-il à ne divulguer aucune information potentiellement compromettante qui lui est révélée aux administrateurs, à la direction du BRDV ou de l'Université.

B) CONSENTEMENT

Je déclare avoir pris connaissance des informations ci-dessus, avoir obtenu les réponses à mes questions sur ma participation à la recherche et comprendre le but, la nature, les avantages, les risques et les inconvénients de cette recherche.

Après réflexion, je consens librement à prendre part à cette recherche. Je sais que je peux me retirer en tout temps sans préjudice et sans devoir justifier ma décision.

J'accepte que cet entrevue soit enregistrée sur support audio : OUI NON

Signature : _____ Date : _____

Nom : _____ Prénom : _____

Je déclare avoir expliqué le but, la nature, les avantages, les risques et les inconvénients de l'étude et avoir répondu au meilleur de ma connaissance aux questions posées.

Signature du chercheur _____ Date : _____
(ou de son représentant)

Nom : _____ Prénom : _____

Pour toute question relative à la recherche, ou pour vous retirer de la recherche, vous pouvez communiquer avec Michel Bergeron, éthicien au Comité universitaire d'éthique de la recherche (CUÉR), au numéro de téléphone suivant : (514) 343-6111, poste 5520 ou à l'adresse courriel suivante : [REDACTED]

Toute plainte relative à votre participation à cette recherche peut être adressée à l'ombudsman de l'Université de Montréal, au numéro de téléphone (514) 343-2100 ou à l'adresse courriel [REDACTED] (L'ombudsman accepte les appels à frais virés).

Un exemplaire du formulaire de consentement signé doit être remis au participant

Annexe 4 - Grille d'entrevue

Évaluation de l'intérêt des chercheurs universitaires pour la valorisation des banques de données et de matériel constituées à des fins de recherche

Définitions

Base de données : Ensemble de données qui est organisé ou non selon une structure conceptuelle décrivant les caractéristiques de ces données ainsi que les relations entre leurs entités correspondantes et destinées à un ou plusieurs domaines d'application.

Banque de matériel : Collection structurée d'échantillons de matériel, incluant ou non les données y étant associées

Valorisation : Processus de transfert des connaissances développées dans les milieux de recherche vers un milieu d'utilisateurs, effectué dans un but d'ajouter une valeur aux résultats de la recherche.

Questions

Bloc A : Définition du contexte de recherche et de création des bases ou banques de données ou de matériel.

1. Dans quel domaine de recherche travaillez-vous? Et depuis combien de temps êtes-vous dans ce domaine de recherche?

2. Détenez-vous un poste cadre au sein de votre département ou institution d'attache?

Oui Non

3. Avez-vous été amené lors de vos recherches à créer une ou des bases de données ou banques de matériel?

Oui Non

NB : La réponse à cette dernière question sera déterminante quant au contexte de poursuite de l'entrevue (axée vers un administrateur d'unité ou de département de recherche ou vers un chercheur possédant une base de données ou banque de matériel).

Bloc B : Identification des types de bases de données ou banques de matériel caractérisant les domaines de recherche (objectif 1)

4. Dans vos recherches ou votre domaine de recherche, quel sont les types de bases de données ou banques de matériel utilisées?

À titre indicatif voici quelques balises que l'équipe de recherche pourra utiliser afin d'identifier le types de bases de données ou banques de matériel dont il est question, et ce afin de répondre à l'objectif 2 du projet de recherche :

A) Informatique; c'est-à-dire obtenues par traitement informatique (données statistiques, imagerie, modélisation...)

B) Médecine; c'est-à-dire obtenues auprès de patients atteints de pathologies données

C) Sciences expérimentales; c'est-à-dire obtenues lors d'expérimentation à l'aide de matériel organique ou inorganique ne constituant pas des organismes entiers

D) Sciences appliquées; c'est-à-dire obtenues lors d'expérimentation à l'aide de matériel organique ou inorganique constituant des organismes ou constituants entiers

E) Sciences humaines (ou sociales) quantitative; c'est-à-dire obtenues auprès d'individus correspond à une caractéristique recherchée dans le but de quantifier/qualifier un fait ou comportement humain

F) Sciences humaines (ou sociales) qualitative; c'est-à-dire obtenues auprès d'individus correspond à une caractéristique recherchée dans le but de qualifier un fait ou comportement humain

G) Autre : _____

5. Quel type d'informations ou d'échantillons est majoritairement contenu dans ces bases de données ou banque de matériel?

A) Informations (données) confidentielles sur des individus

B) Informations (données) anonymisées sur des individus

C) Matériaux (tissus humains, échantillons biologiques, etc) confidentiels

D) Matériaux (tissus humains, échantillons biologiques, etc) anonymisés

C) Autre : _____

6. Les informations ou échantillons constituant ces bases ou banques proviennent-elles?

A) De recherches individuelles

B) De collaborateurs ou collègues provenant de la même institution d'attache

C) De collaborateurs ou collègues provenant d'une autre institution

D) De collaborateurs ou collègues provenant d'une autre province ou d'un autre pays

Bloc C : Évaluation de l'intérêt de la communauté universitaire pour les questions de valorisation des bases de données et banques de matériel (objectif 2)

7. Selon vous, qui est propriétaire des bases de données ou banques de matériel constituées?

A) Les chercheurs

B) Les institutions d'attache

C) Les sujets (ou participants)

D) Autre : _____

8. Dans le cas de bases de données ou de banques de matériel ayant été constituées à partir de participants de recherche humains, est-il envisageable de transférer les base ou banques avant ou en absence de l'obtention de l'accord du participant?

- A) Avec des étudiants
- B) Avec des collaborateurs sur le même projet
- C) Avec d'autres collaborateurs
- D) Avec tout autre chercheur qui en fait la demande (de la même ou d'une institution différente)

9. Dans le cas de bases de données ou de banques de matériel ayant été constituées à partir de participants de recherche humains, est-il envisageable de transférer les base ou banques après l'obtention de l'accord du participant?

- A) Avec des étudiants
- B) Avec des collaborateurs sur le même projet
- C) Avec d'autres collaborateurs
- D) Avec tout autre chercheur qui en fait la demande

10. Qui devrait avoir un droit de regard sur une base de données ou banque de matériel créée dans un contexte de recherche issue de votre domaine de recherche/ votre recherche?

- A) Personne
- B) L'université à laquelle vous êtes affilié
- C) Votre centre de recherche
- D) Les comités d'éthique de la recherche
- E) Les partenaires industriels qui ont subventionné en tout ou en partie les recherches
- F) Les participants ou les communautés qui constituent l'essentiel des échantillons ou données

11. Croyez-vous que les bases ou banques caractérisant votre domaine de recherche/ votre recherche ont une valeur utilitaire pour d'autres chercheurs travaillant sur des thématiques connexes aux vôtres?

- Oui Non

12. Croyez-vous que les bases ou banques caractérisant votre domaine de recherche/ votre recherche sont valorisables (bénéficieraient d'un encadrement de partage puisque s'avérant d'une utilité pour d'autres chercheurs)?

- Oui Non

13. Seriez-vous intéressés à un accès aux bases de données de chercheurs travaillant sur des thématiques connexes aux vôtres ?

- Oui Non

Bloc D : Identification des modalités et difficultés de la valorisation des bases de données ou banques de matériel (objectif 3)

14. Quels sont les principales difficultés à surmonter afin de rendre le partage des bases de données ou banques de matériel possible?

15. Croyez vous que votre établissement devrait faciliter la valorisation des bases de données ou banques de matériel?

Oui Non

Si oui, comment?

Par exemple, en créant

- a) un répertoire de toutes les bases/banques de recherches existantes à l'Université?
- b) un répertoire de certaines bases de données telle la liste de sujets volontaires de recherche

16. Quels sont les responsabilités et/ou droits de l'établissement concernant l'ensemble des bases et banques de données de leurs chercheurs ?

- A) Aucun droit
- B) Le droit de donner les informations
- C) Le droit de vendre les banques
- D) Le droit de détruire de l'information ou du matériel

17. Croyez-vous pouvoir détruire vos bases ou banques de données?

Oui Non

18. Croyez-vous pouvoir conserver cette base ou banque de données si vous quittez votre institution ?

Oui Non

Annexe 5 – Demande d'autorisation de rédiger par articles

1. **Identification de l'étudiante:** Elise Smith, SMIE28588408
2. **Nom de l'unité académique:** Médecine sociale et préventive, Faculté de Médecine
3. **Nom du programme:** Programmes de bioéthique – maîtrise
4. **Liste des articles proposés:**
 - a. Smith, E. Olivier C. Bergeron, M. *Researchers' Perceptions on the Valorization of University Databases and Material Banks*. Review of Higher Education, soumis pour publication.
 - b. Smith, E. *The limits of sharing: an ethical analysis of the arguments for and against the sharing of databases and material banks*. Accountability in Research, soumis pour publication.
5. **Signature et déclaration de l'étudiant**
 - a. Elise Smith et Catherine Olivier ont contribué à toute les étapes de la recherche intitulé *Researchers' Perceptions on the Valorization of University Databases and Material Banks*. La contribution d'Elise Smith lors de la rédaction fut nettement plus grande que ses collaborateurs. Michel Bergeron a dirigé ce projet.
 - b. Elise Smith est la seule auteure de l'article *The limits of sharing: an ethical analysis of the arguments for and against the sharing of databases and material banks*.

Signature : [REDACTED] Date : 19 mai, 2011

6. **Avis et signature du directeur de recherche**
 - a. **Commentaires : aucun**

Nom du directeur de recherche: Bryn Williams-Jones

Signature : [REDACTED] Date : 19 mai, 2011

7. **Décision ou recommandation et signature du directeur de programme**

Nom du directeur de programme : Bryn Williams-Jones

Signature : [REDACTED] Date : 19 mai, 2011