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Qualitative Insights into Good Practice Guidelines for Human Biological Material Holdings

FINAL REPORT

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EKOS RESEARCH ASSOCIATES INC.
March 31, 2005

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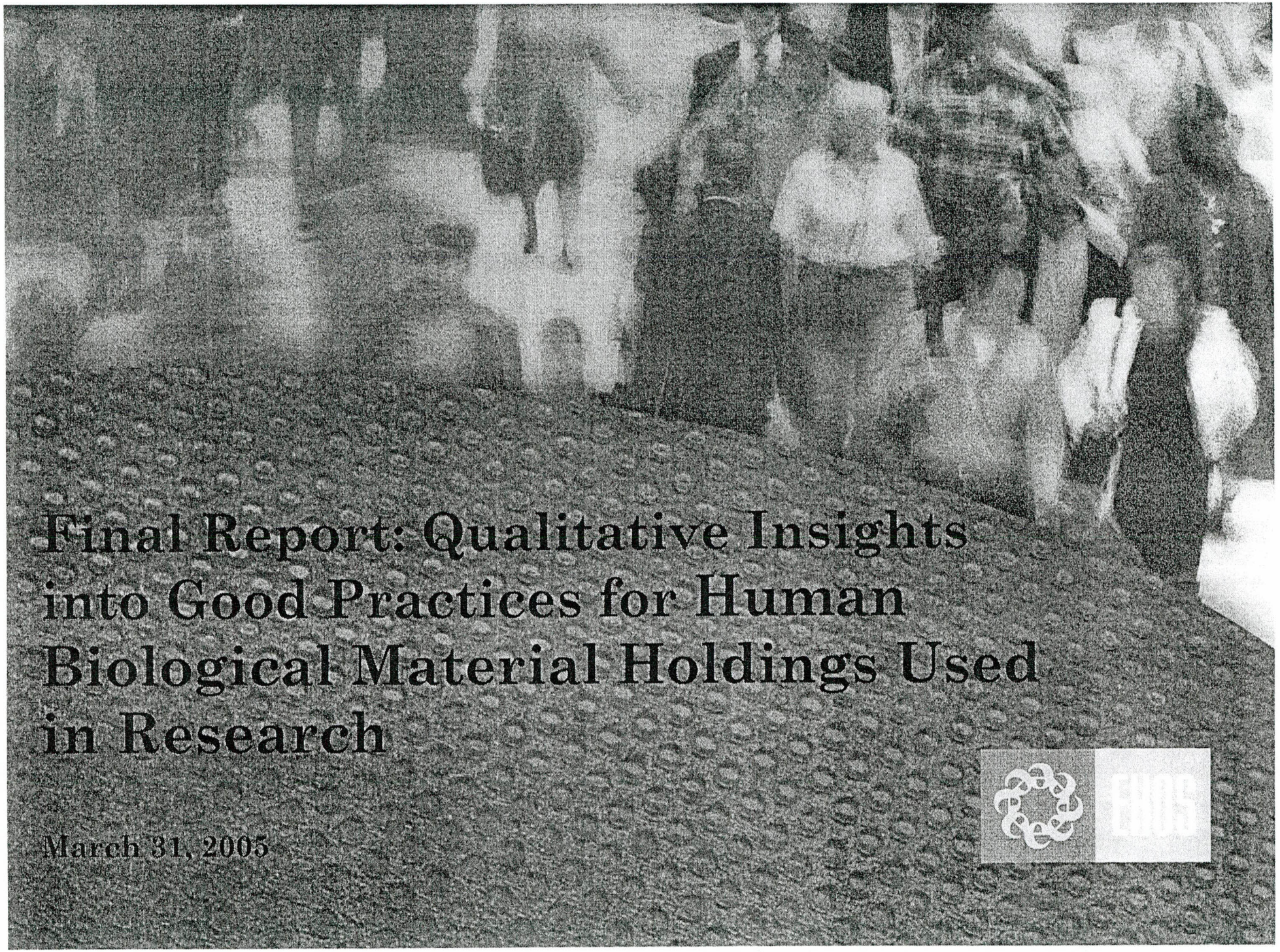

Final Report: Qualitative Insights into Good Practices for Human Biological Material Holdings Used in Research

March 31, 2005

Introduction

- HSPD seeking to articulate current good practices on key issues surrounding research using HBM

- Builds upon policy research already conducted to gather existing policy, regulations, provincial law, guidelines and good practices. Sought input from officials within the Federal Health Portfolio to help guide the process. The intention was not to attempt to answer questions or provide solutions, but rather to gather information to move the project forward.

- These findings were based on 20 anonymous, voluntary interviews conducted in January/February 2005. Participants were randomly selected from a list of 40 individuals from the science and policy groups at Health Canada and The Public Health Agency of Canada. Respondents received an information package of background information prior to being interviewed.

- As this was purely a qualitative policy research study of only 20 participants, it is impossible to extrapolate individual comments as representative of Health Canada or the federal health portfolio.

- The interview guide as well as a pre-interview briefing package are included as Annexes to this report.

Macro Level Views

- Respondents enthusiastic/welcoming about a single guidance instrument
- Some see as offering guidance that is not currently available
- Others suggest that this is mainly a codification of existing practice

Opportunities/Benefits

- Amount of research using HBM seen as on the rise/clear benefits of going to stored samples versus new collection in some cases (e.g. for public health research)
- Necessary to bank biological materials and no single articulation exists that consolidates storage, use and collection
- Issues face ethics boards such as samples where it is unknown if the donor is alive or dead/what kind of consent was given — ethics boards left to make decisions case by case
- An articulation of good practices useful to sort issues out inside HC, and to set a standard of best practices for other researchers outside of government
- Good to have protocol for how scientists could and should deal with HBM of uncertain provenance (e.g. samples that have been stored for a long time, consistency of disposal in terms of timing, processes to follow, etc.)
- Also better address issues such as privacy and cultural sensitivities in a consistent manner
- Get ahead of the curve/guard against future challenges
- Could serve as a basis for educating new employees and those facing unique situations

Challenges/Risks

- Interviewees offer a host of cautions/warnings (but still opt to move forward!)
- Discussion/debate has potential to be volatile (some feel especially with charged issues such as genetics), and advise guarding against knee-jerk versus rational, balanced analysis
- Government involvement in bio-banking "amps up the volume" on the issue, need to manage challenge of public opinion
- Sense that no one really knows the scope – exactly how much HBM is there, and under what conditions, with what levels of consent and ethics oversight, given the length of time some of these samples have been stored
- Potential for increase in delays in approval of research (already an irritant) with developing new guidelines and potential impact of harsh limitations or cumbersome regulations
- Contentious issues and need for broad consultation could lead to divergent (entrenched?) opinions/difficult to steer to a productive conclusion (need for consultation, especially with those on the "front line")
- Competing interests for access to samples (question if this is an ethics board decision, or can we make policy decisions in some areas?)

Reaction to Proposed Components/ Infrastructure Needs

- Proposed components (see Annex) meet with essentially universal approval

- Infrastructure needs:
  - Staff to interpret and enforce it
  - Infrastructure for security and storage of specimens
  - Resources to help researchers follow good practices (e.g., carry out privacy impact assessments)

Issue Areas

- Largely seen as the right areas

- Perhaps more emphasis on genetic testing and information good practices, unique sensitivities and ethical/legal/social issues

- Some see all issue areas as intrinsically linked/difficult to prioritize

- Others suggest hiving off technical/scientific issues from ethical/legal issues (easier to resolve, allows team to gain some wins/maintain momentum/not bogged down in contentious issues)

Some issues that need to be addressed are...

- Can samples collected for one purpose be used for another without new consent? If yes, then under which circumstances?
- Can you use information collected for one purpose for another? If yes, when?
- Who owns the HBM (the sampled individual, the province, the fed govt)?
- What can be done with specimens without consent or with partial consent (issues similar to those raised by unused embryos from in vitro fertilization)
- Role for Office of Chief Scientist
- Public Health Agency of Canada (PHAC) ethics board or continue to work with HC's?

Consulting/Engaging

- Seek advice from academic and industry researchers
- Public Advisory Committee
- Possibly other research related bodies such as the NSRC and SSHRC
- Uncertainty on how best to proceed with public consultation
- Useful References:
  - Tri-Council Policy Statement
  - Opinion piece from German National Ethics Council (May 2004)
  - Work underway by CIHR on Privacy Best Practices

Bottom Line

- "Not revolutionary but long overdue"
- "Our people are ethical but some issues are under discussed or taken for granted"
- "Will enable scientists to have confidence in their lab practices"

Annex

Annex A
Briefing Package

Internal Consultation on Developing Good Practice Guidelines for Research Using Human Biological Materials

Preamble:

Health Canada holds the majority of human biological materials (HBM) in the Canadian Federal Government. While we use several different regulatory, professional and policy documents to guide our actions, there is no single governance instrument that bundles and articulates our good practices. To this end, the Health Sciences Policy Division of Health Canada has initiated a project to coordinate the development of guidelines related to research using human biological materials. The initial focus for this project is internal to the federal health portfolio and we are consulting within the department, the Public Health Agency of Canada, the Canadian Institutes of Health Research and the Interagency Panel on Research Ethics, which is tasked with revising the Tri-Council Policy Statement on Research Involving Humans.

To facilitate your input and participation in this initiative, we have contracted EKOS to conduct interviews within the scientific and policy community to determine the following:

1) your general sense of this initiative;
2) key challenges;
3) the key elements of a guidance document;
4) the areas or issues around which guidelines might be developed and their priority;
5) potential impacts of this initiative on your centre;
6) useful guidelines that may be referenced, incorporated or pointed to; and,
7) other input that you find important to move forward.

The results of the interviews will inform the planning stages of a 1 ½ day workshop (February 28 and March 1, 2005) where we will discuss the overall good practice guideline document and three or four issue areas for guideline development in breakout sessions.

The following page contains background information that may help prepare you for the interview. This e-mail also includes a draft of a life cycle from sample intake to disposal.

Please remember that this exercise is entirely voluntary and confidential. Participants might be randomly selected from a larger list, and it should take no more than 30 minutes of your time. If you have questions, please feel free to contact me, Lori Engler-Todd, at (613) 948-2615.

ANNEX B
INTERVIEW GUIDE

INTERVIEW GUIDE

HBM GUIDELINES

JANUARY 13, 2005

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1. INTRODUCTION

- Confirm that interviewees have received package from Lori Engler-Todd and re-send if not.
- Purpose of the interview
  - Health Sciences Policy Division seeking to coordinate/codify/develop guidelines on key issues surrounding research using HBM. Before taking this further they are seeking input from officials within the Federal Health Portfolio to help guide the process. This is very much a preliminary consultation exercise; nothing is yet cast in stone. Additional information about this exercise was provided in the background document sent to you.
- Explanation of format
  - Discussions are being audio taped for the purposes of writing a report —comments will remain confidential, no attributed remarks/no names in report.
- Participant: Brief description of role, how long with Health Canada.

9. Are there some that are higher priority items that merit special attention or that should be addressed before others? What would your top 4 or 5 items be? Are there some that are lower priorities?

4. Wrap-Up

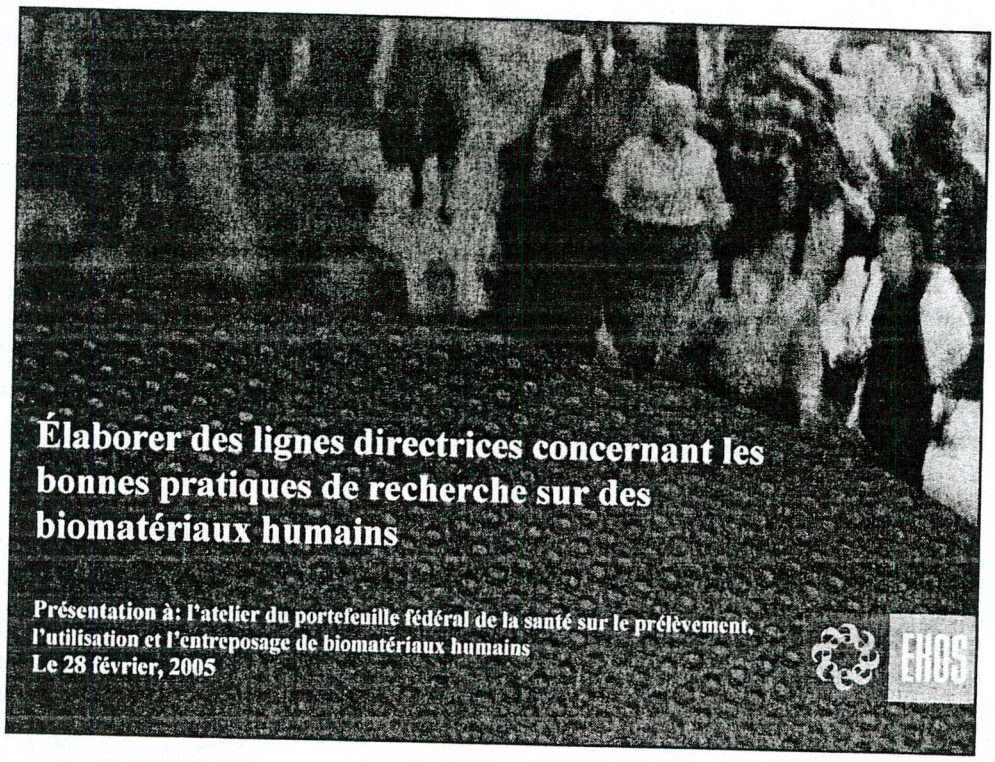
10. All in all, how would you characterize this initiative — is it a dramatic change in the way research with HBM takes place or more of a formalizing of existing practices?

11. What impacts do you think this initiative will have on your area? Probe positive/negative, means of mitigating less desirable impacts?

12. Are there any other things the HSPD needs to consider as it moves ahead with this initiative? Any other thoughts on engaging the research community? Thoughts on broader engagement?

13. Is there anything else you would like to say before we end the discussion? I'll also provide you with my contact information in case you think of anything else that you want to ensure is included in a report.

Thank you very much for your participation



Introduction

- La Division des politiques en sciences de la santé veut coordonner/codifier/élaborer des lignes directrices sur les grandes questions qui entourent la recherche sur des biomatériaux humains.
- La Division a demandé l'avis de responsables du portefeuille fédéral de la santé afin d'orienter le processus.
- Les résultats qui suivent proviennent de 20 entrevues menées en janvier-février 2005.

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Opinions au macro-niveau

- Les répondants sont enthousiastes/en faveur d'un code ou d'un ensemble de lignes directrices.
- Certains voient cela comme offrir des directives qui n'existent pas en ce moment.
- D'autres suggèrent surtout une codification des pratiques en cours.

Possibilités/avantages

- On croit que le volume de recherche sur les biomatériaux humains est en hausse/il y a de nets avantages à utiliser des échantillons entreposés au lieu d'en prélever de nouveaux.
- Il faut constituer des banques de biomatériaux, mais il n'y a pas de directives officielles écrites.
- Les comités d'éthique sont confrontés à des problèmes – par exemple, des échantillons de donneurs dont on ignore s'ils sont vivants ou morts/quel genre de consentement a été donné – les comités d'éthique doivent improviser.
- Des lignes directrices sont utiles pour faire le point à Santé Canada et établir des normes de pratiques exemplaires pour d'autres chercheurs.
- Il est bon d'avoir un protocole qui indique comment les scientifiques pourraient et devraient traiter les biomatériaux humains de provenance incertaine.
- Il faut aussi aborder des questions comme la protection des renseignements personnels et les enjeux culturels délicats.
- Il faut aller au-devant des coups/se prémunir contre les difficultés éventuelles.

Problèmes/risques

- Les personnes interviewées expriment une foule de mises en garde/d'avertissements (mais il faut quand même aller de l'avant!).
- La discussion/le débat risquent d'être volatils; analyse par à-coups plutôt que rationnelle et pondérée.
- La participation du gouvernement au dossier des banques de biomatériaux augmente la visibilité; il faut composer avec la problématique de l'opinion publique.
- On a l'impression que personne ne connaît vraiment toute l'étendue de la question – la quantité de biomatériaux humains qu'il y a, les conditions d'entreposage, les niveaux de consentement, et la surveillance de l'éthique.
- Les retards possibles d'approbation des travaux de recherche (déjà un irritant).
- Les questions litigieuses et la nécessité d'une vaste consultation pourraient entraîner des opinions divergentes (ancrées?)/difficile d'arriver à une conclusion fructueuse.
- Intérêts concurrentiels d'accès aux échantillons (on se demande si cette décision relève du comité d'éthique).
- Risque de limitations sévères ou de règlements difficiles à appliquer.

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Réaction aux éléments proposés/ Besoins d'infrastructure

- Il faut obtenir une approbation essentiellement universelle.
- Besoins d'infrastructure
  - Du personnel pour interpréter le code et l'appliquer.
  - Une infrastructure de sécurité et d'entreposage des échantillons.
  - Des ressources pour aider les chercheurs à suivre les lignes directrices (ex., exécution d'études d'impact au point de vue de la protection des renseignements personnels).

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Questions d'intérêt

- Considérées, dans l'ensemble, comme les bonnes questions.
- Peut-être insister davantage sur la génétique (question épineuse).
- Certains trouvent que les questions sont intrinsèquement liées/difficiles à classer par ordre de priorité.
- D'autres suggèrent de séparer les questions techniques/scientifiques des questions d'ordre éthique/juridique (plus facile à régler, permet à l'équipe de remporter quelques victoires/maintien de l'intérêt/pas enlisés dans des questions litigieuses).

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Quelques questions qu'il faut aborder

- Les échantillons prélevés à une fin donnée peuvent--ils servir à d'autres fins sans qu'il faille obtenir un nouveau consentement?
- L'information recueillie à une fin donnée peut-elle servir à d'autres fins?
- À qui appartiennent les biomatériaux humains (à l'individu duquel on a prélevé l'échantillon, à la province, au gouvernement fédéral)?
- Que peut--on faire avec des échantillons sans consentement ou avec un consentement partiel (questions semblables à celles que soulèvent les embryons inutilisés issus d'une fécondation in vitro) ?
- Rôle à jouer par le Bureau de l'expert scientifique en chef?
- Comité d'éthique de l'Agence de santé publique ou continuer de travailler avec celui de Santé Canada?

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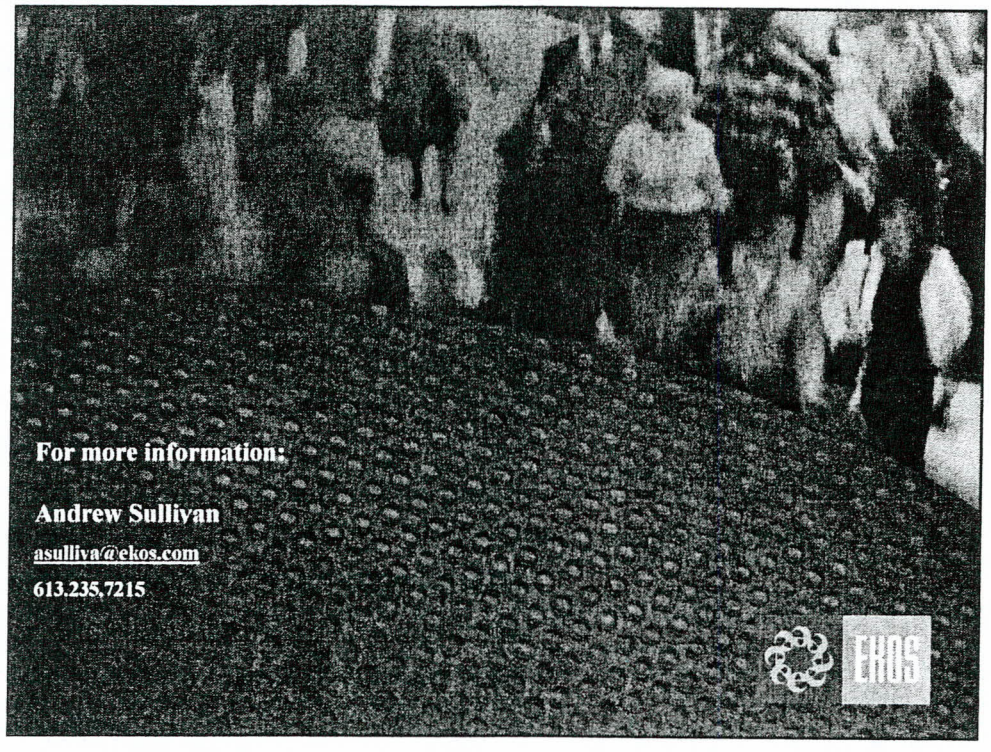
Consultation/Participation

- Obtenir l'avis des chercheurs universitaires et industriels.
- Comité consultatif public.
- Peut-être d'autres organismes de recherche, comme le Conseil de recherches en sciences naturelles et le Conseil de recherches en sciences humaines.
- Incertitude à propos d'une consultation publique, en termes d'ouverture et de reddition de comptes, mais cela pourrait aussi créer des problèmes difficiles à régler.
- Références utiles
  - Politique inter-conseils sur l'intégrité dans la recherche et les travaux d'érudition
  - Opinion du German National Ethics Council (mai 2004?)
  - Travaux en cours des Instituts de recherche en santé du Canada

Conclusions

- « Pas révolutionnaire, mais attendu depuis longtemps ».
- « Nos gens respectent l'éthique, mais certaines questions sont sous-étudiées ou tenues pour acquises ».
- « Permettra aux scientifiques d'avoir confiance dans leurs pratiques de laboratoire...ne craindront pas les pleins feux de la rétrospective s'il survient de la controverse ».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