EVALUATION REPORT

CONSULTATIONS
ON
CIHR DRAFT PRIVACY BEST PRACTICE GUIDELINES

Prepared for:
The Ethics Office of
The Canadian Institutes of Health Research (CIHR)

Prepared by:
One World Inc.
1206-1 Nicholas Street
Ottawa, Ontario
K1N 7B7

Phone: 613-562-4073
Fax: 613-562-4074
Email: info@owi.ca
Website: www.owi.ca

TABLE OF CONTENTS

APPENDICES

EVALUATION REPORT

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EXECUTIVE SUMMARY

The Ethics Office of the Canadian Institutes of Health Research (CIHR), with the advice of its Privacy Advisory Committee, has developed draft privacy best practice guidelines for addressing privacy, confidentiality and security concerns in the design, conduct and evaluation of health research. A public consultation process to obtain feedback on the draft guidelines was conducted from March to September, 2004. It was designed to test out the guidelines with a wide variety of stakeholders involved in various capacities in health research. It also included a limited consultation with citizens.

The consultation process had three complementary components:

1. Three multi-stakeholder sessions, each emphasizing a different research theme;
2. Small group dialogues with citizens; and
3. Written submissions, including an on-line questionnaire.

This process evaluation was conducted based on an evaluation framework agreed-upon before the consultation process began. There were three key sources of data: participant evaluation forms, interviews with members of the Privacy Advisory Committee and the involved CIHR staff, and documentation.

Overall, the evaluation concludes that the consultation process was very successful as assessed through the four areas of inquiry.

1. The process did largely fulfill the guiding principles of transparency, inclusiveness and critical dialogue. A contributing factor to the consultation's success was flexibility and CIHR's willingness to revise supporting documents and strategies as required.
2. The process was very effective in getting feedback on the guidelines. It should be noted that the complementarity of the three process components was important in achieving comprehensive feedback. Certainly, the multi-stakeholder sessions coupled with the opportunity for written feedback enhanced the possibilities for considered reflection and feedback.
3. The perspective of staff and PAC members, based on anecdotal information from others, is that visibility and interest in the guidelines was enhanced. Over 500 direct invitations were sent out to stakeholders. These were complemented by the website, the use of list-serves, announcements at conferences, etc.

4. From the comments of participants and the perspectives of PAC members, CIHR has clearly demonstrated the kind of national leaderships participants expect from it. The inclusive and yet pro-active style of leadership being demonstrated by CIHR was highly commended as were the staff people involved in this process.

This consultation process did most things right, and certainly features of it should be replicated in future consultations when appropriate. These features include:

1. A process design that encouraged small group work and productive dialogue;
2. A document or discussion paper that was clear and met the challenge of presenting complex and dense material in a format that could be readily used in consultation;
3. Good, professional facilitation that created an environment conducive to a respectful but frank exchange of ideas;
4. A proactive outreach strategy that helped ensure the desired diversity and calibre of participants; and
5. A multi-faceted consultation process with complementary strategies – in particular, in this instance, the combination of the multi-stakeholder sessions with the opportunity to make written submission.

Possible improvements for future consultations are:

1. Ensure that key documents are easily accessible on-line before the first invitations are sent out.

2. Allow more time between invitations and the deadlines or sessions. For example, the 2.5 weeks for the May session was very tight and did not allow time for word-of-mouth recruitment.

3. Allow more time when the invitation process is coordinated with partners

4. Send out invitations for written submissions earlier in the process and provide a longer period for feedback. Avoid having the summer period as the only time for written submissions.

5. Use an on-line feedback format that permits people to save their feedback and return to it at a later point in time.

6. Have a note-taker at each small break-out group, when overall resources permit.

7. Use the same key consultation document for all multi-stakeholder sessions. This is a general best practice to better ensure comparability of results.

8. Pilot-test consultation materials, such as the scenarios used in the small group dialogues.

9. Ensure that statistics are collected on the number of guidelines/invitations sent out.

EVALUATION REPORT

CONSULTATIONS
ON
CIHR DRAFT PRIVACY BEST PRACTICE GUIDELINES

1. CONTEXT

The Ethics Office of the Canadian Institutes of Health Research (CIHR), with the advice of its Privacy Advisory Committee, has developed draft privacy best practice guidelines for addressing privacy, confidentiality and security concerns in the design, conduct and evaluation of health research. A public consultation process to obtain feedback on the draft guidelines was conducted from March to September, 2004.

The Privacy Advisory Committee (PAC) for Best Practices in Health Research includes representatives from the following interested groups: Privacy Commissioners, Privacy Enhancing Technologies, Research Ethics Boards, Health Researchers, Voluntary Health Organizations, Patients/Consumers, Policy-makers, Data Producers, Law/Ethics, Aboriginal communities and Health Service Providers. Its mandate is to advise on the development of the Privacy Best Practice Guidelines and on a communication and knowledge translation strategy. At their first face-to-face meeting, the Privacy Advisory Committee (PAC) advised CIHR's Ethics Office to conduct a public consultation process to broaden input into the draft guidelines. A subcommittee of PAC members was subsequently established, chaired by CIHR, to advise on a consultation strategy. The Ethics Office also established an ad hoc group of CIHR staff associated with knowledge translation, partnerships, stem cell guidelines, Institutes, and communications, to provide advice as needed.

2. CONSULTATION PROCESS

The 2004 consultation process was designed to test out the guidelines with a wide variety of stakeholders involved in some capacity in health research. It also included a limited consultation with citizens.

The consultation objectives were:

1. Obtain feedback on the draft guidelines,
2. Obtain feedback on how and which guidelines might be most relevant for particular research areas, e.g. genetic research,
3. Heighten the visibility of the guidelines.

In addition, the consultation process needed to act in accordance with the Interagency Advisory Panel on Research Ethics (PRE) consultation principles of: transparency, inclusiveness and critical dialogue.

The consultation process had three components:

1. Multi-stakeholder workshops,
2. Small group dialogues with citizens, and
3. Written submissions, including an on-line feedback questionnaire.

A consultant, Jacquie Dale of One World Inc., was engaged to advise on the consultation process. She also designed and facilitated the multi-stakeholder and small group dialogue sessions.

Multi-stakeholder Workshops

There were three one-day facilitated workshops. Each targeted a different mix of stakeholders based on the particular theme being emphasized and each involved different so-sponsors. The table below provides the details:

Session Date and Place	Co-sponsors	Theme – How well do these draft guidelines address:
Ottawa, March 26	Health Canada	Genetic Privacy
Ottawa, May 20	Interagency Advisory Panel on Research Ethics (PRE)	Spectrum of research funded by federal granting agencies
Toronto, August 24	Heenan Blaikie LLP	Research involving the health care context

The workshops began with a presentation on the CIHR guidelines. This was complemented with one or two other presentations specific to the workshop theme. Participants then broke into small groups to discuss the various elements contained in the guidelines. They were able to choose which element they wished to work on in each of three rounds of discussion. After lunch and report-backs, the participants broke into pre-assigned groups to discuss the theme as well as ideas on how the guidelines should be implemented. The agendas (see Appendix A) provide the precise questions used in each workshop.

Small Group Dialogues

There were two three-hour facilitated dialogues. The first was held in Ottawa on June 19 and the second in Toronto on August 23. The sessions were conducted with a representative selection of citizens, including those who had participated in health research. The sessions were intended to test, in a qualitative and preliminary way, the acceptability to the general public of selected recruitment and informed consent "best practices" contained in the draft guidelines. Participants were seated in pre-assigned

groups. They were provided with a workbook that contained four scenarios, which were worked through systematically with report-backs after each scenario.

Written Submissions

Interested stakeholders were invited to send in written comments on the guidelines. The guidelines were available on the CIHR website. An on-line questionnaire was also developed based on the draft guidelines. It was made available on the website in early May.

3. EVALUATION METHODOLOGY

The purpose of the evaluation was to inquire, from a process perspective, about whether/how well the consultation process achieved its objectives and responded to the guiding principles for consultations. It is meant as a learning opportunity, to determine what worked well and what didn't and to make recommendations to improve future consultations. It is a short-term evaluation and does not attempt to assess longer-term questions.

The first step in the evaluation process was the development of the framework. This was done early in the design of the consultation process as previous experience has shown that clarity on evaluation helps ensure clarity on the consultation objectives themselves. The original framework had three areas of inquiry. A fourth area was added after the first workshop was conducted. The four areas of inquiry are:

1. Did the process fulfill the guiding principles of transparency, inclusiveness and critical dialogue?
2. Was the process effective in getting feedback on the guidelines?
3. Did the process heighten the visibility of the guidelines?
4. Does the initiative reflect the kind of national leaderships participants expect from CIHR?

The final framework, which follows the outline proposed in the 2004 Health Canada document on the evaluation of public involvement activities[1], is given in Appendix B.

Step 2 in the evaluation process was the creation of the tools for evaluation. Two types of tools were built:

1. Evaluation forms for participants to complete. There were forms for each of the consultation components. These are provided in Appendix C. Only 1 respondent

[1] *Evaluating Public Involvement Activities: A Framework and Resources for Health Canada*; Corporate Consultation Secretariat, Communications, Marketing and Consultations Directorate, 2004.

completed the on-line evaluation form and therefore the results are not included in this report.

2. Interview questions. Two group interviews were conducted with PAC members. These were conducted by teleconference and eights members participated. Those who could not attend were invited to respond in writing to the questions. A group interview was also held with the three relevant staff of the CIHR Ethics Office. The interview scripts are provided in Appendix D.

Step 3 was the compilation and analysis of the data obtained through the evaluation tools. A review of documentation was also conducted.

Step 4 was the preparation of the evaluation report for submission to CIHR. As the three components of the consultation process were designed to be complementary, the evaluation report is built on the areas of inquiry, rather than on the components themselves. However under each area of inquiry, there is generally explicit reference to each consultation component.

4. Area of Inquiry #1 – Did the process fulfill the consultation principles of transparency, inclusiveness and critical dialogue?

4.1 Transparency

Transparency relates to how easily someone can access clear information - in this case, for and about the consultation process. Principles like equal opportunity to access information, relevance and timeliness are important.

The selected indicators for transparency were:

- explanation of the process and its objectives;
- all stages of the consultation process are documented; and
- workshop documentation was received in a timely fashion.

The invitation letters and registration forms sent to potential participants for the multi-stakeholder sessions and the written feedback process clearly stated the objectives of the process and the particular session, if face-to-face, that participants were invited to. Within each session, the explanation of the process, both for the session and the overall consultation process, was clear. Four participants commented that the presentation on the guidelines made at the beginning of a session was too brief.

On the evaluation form for the multi-stakeholder sessions, participants provided the following average response to the statement related to transparency:

Statement: I received the materials in time to review it before the session.	March 26	May 20	August 24
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.	2.47	1.62	1.53

In the May and August meetings, participant received their materials in a timely fashion. However for March there was less agreement with this statement. The difference seems to be that for the March session the document was not yet available on the website. For May and August, the materials were available from the website and the website address was provided on the invitation itself. In March, the draft guidelines had to be sent to each individual and there were at least six of the 25 participants who did not receive them in a timely fashion.

The version of the draft guidelines used in the March session was not the same as the one used in the May and August sessions or for the written feedback. With hindsight, the March session occurred prematurely in the consultation process, even though it fitted within the original consultation timeframe. Pressure to have the session in March came from year-end budgeting requirements. However one must conclude that there was a minor negative effect in terms of transparency.

For the small group dialogues, there were no advance materials disseminated and the process was purposely designed this way. At the start of each session, there was a presentation to explain the objectives, the sponsors and the process. This seemed to be acceptable to participants.

For those providing written feedback, including responding on-line, there is an indication that the documentation was not always easy to find on the website even though it was up from early May to the end of August.

The documentation on the consultation process is clear and thorough, with the exception that the actual vs. intended timeframes for invitations, etc. is not always clear.

Conclusion

The consultation largely lived up to the principle and intent of transparency. Improvement could be achieved by:

1. Ensuring that key documents are available on-line before the first invitations are sent out.

4.2 Inclusiveness

The principle of inclusiveness relates to the breadth of participation as well as its quality. The selected indicators are:

- participants represent a broad cross-section of stakeholders; and

- participants are able to express their views.

Outreach is the first crucial step in inclusiveness. In this consultation, the outreach process to solicit written feedback and multi-stakeholder participation was extensive and an inventory of all activity was maintained. Invitation lists were developed with input from others, including the partners involved in each session. PAC members actively solicited within their networks. This ensured that the invitations spread through-out and beyond Canada. It also meant that often the process was being championed regionally rather than being seen just as an "Ottawa" process. Over 200 invitations were sent out to solicit written feedback and other avenues such as list-serves, announcements at conferences, etc. were also used.

The total number of participants was 195. The number in each component of the consultation process was:

Multi-stakeholder sessions Total = 91 participants			Written Feedback Total = 68 responses		Small Group Dialogues Total = 36 participants	
March 26	May 20	August 24	Email/Mail/Fax	On-line	June 19	August 23
25 people	20 people	46 people	54 respondents	14 respondents	21 people	15 people

Multi-stakeholder Sessions

While the total number of participants was lower than hoped for, there is a consensus that those who came were from diverse backgrounds and perspectives. For example, participant responses on the evaluation forms indicate substantial agreement with the following statement related to diversity.

Statement: Participants represented a good cross-section of stakeholders interested in this issue.	March 26	May 20	August 24
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.	1.61	2.69	1.83

Their written comments also indicate a strong appreciation for the diversity of backgrounds, ideas and perspectives present.

> *The cross-section of participants was very helpful in providing many different perspectives. It forced us to think about some tough issues and consider many viewpoints.*
>
> Session participant

The May meeting was not rated as highly as the other two sessions. This may be because it had the smallest number of participants and yet was on the full spectrum of

federally-funded research. For this session, the development of the invitation list was decentralized to some extent through coordination with CIHR Institutes and PRE, SSHRC[2] and NSERC[3]. Working collaboratively with these partners was important for obtaining an adequate outreach to a mix of researchers across disciplines. However, as it took considerable time to develop an invitation list, the first invitations did not go out until May 3, leaving only 2.5 weeks before the session itself. This tight timeline meant that there was not enough time for CIHR staff to proactively fill any perceived gaps in participation after people registered. (Filling gaps in registration was important in achieving a broader mix in the other two sessions.) Nevertheless, this smaller session of 20 participants provided solid feedback on the guidelines, particularly those relating to qualitative research and population and health services research. In addition, post-session, NSERC undertook to put a notice of the consultations on their website to increase the visibility of the initiative to their community, and CIHR sent a one-page flyer and display copies of the guidelines to the Canadian Federation of the Humanities and Social Sciences Congress, May 29 – June 6.

For those PAC members interviewed, people felt that a good cross-section of participation had been achieved. They expressed full confidence in the results. When asked if there were any gaps of concern to them, a few people noted they would have liked to have seen more participation from Research Ethics Boards, clinical physicians also engaged in research, qualitative and social science researchers, and the international epidemiology community.

Small Group Dialogues

For the small group sessions, the original outreach was through patients and health groups. However this did not yield results quickly enough and was time-intensive. Therefore the decision was taken to use professional services, who recruited a small sample of citizens based on selected demographics. This approach was successful and the resulting mix of people was diverse in terms of age, ethnicity, occupation, income, education and experience in health research.

Participants agreed and gave an average rating[4] of 1.31 (June) and 1.66 (August) to the statement: *Participants represented a good cross-section of people.*

Written Submissions

While the outreach strategy for written feedback was extensive, the actual invitations soliciting feedback were sent out rather late in the process. The first mail-out was June 28, with response requested by the end of July. A number of participants noted that summer was not an ideal time for consultations. On request, the deadline for

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[2] SSHRC – Social Sciences and Humanities Research Council

[3] NSERC- Natural Sciences and Engineering Research Council of Canada

[4] Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.

comments was extended into August, and comments were accepted as late as mid-October. Clearly, an earlier invitation process and/or a definitive and longer deadline would have been preferable, both to give respondents more time and to foster more word-of-mouth communications. However, as noted later in this report, the number of respondents and the quality of the feedback was, despite the timing, ample.

The number of respondents choosing to complete the on-line questionnaire was less than anticipated. One potentially discouraging factor noted by staff (and echoed by the one person who completed the on-line evaluation form) was that it was not possible for a respondent to save their responses and return to it at a later time to finish. One had to send what one had before logging out. Therefore while people could return to the site any number of times, they would not have access to what they had previously written. Another comment received indicated that it was difficult to access the on-line questionnaire – that "there were too many screens" one had to go through to get to it. In addition, the sole respondent to the evaluation also indicated that it was a time-consuming process, taking three hours to complete.

The second part of inclusiveness relates to how well the process allowed people to express their views. Participant feedback from both types of face-to-face sessions was very positive. The average response to the statement: *The process allowed me to express my views and ideas with respect to the guidelines* (or for the small group dialogues, *with respect to the selected privacy issues*), are given below.

Multi-stakeholder Sessions			Small Dialogue Groups	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.				
March – 1.11	May – 1.23	August – 1.43	June – 1.29	August – 1.27

I liked the flexibility of being able to go to the topic of my choice in the morning.

Session participant

People's written comments echoed these results with several remarking on the frankness of the discussion, on the respect that all comments received, and on the freedom people had in the multi-stakeholder groups to choose the groups they wished to work in during the morning sessions.

Conclusion

The consultation process rates very highly in terms of inclusiveness, both in terms of the diversity of participants and its openness to participant views. The outreach strategy was extensive and coordinated, and should be replicated in future consultations. It is also noteworthy that flexibility was important. When the first approach to recruitment for the small group dialogues did not work, a quick decision was taken to try another approach which was successful. Finally the process design for both the multi-stakeholders sessions and small group dialogues facilitated a good sharing of perspectives.

Possible improvements might be achieved by:

1. Allowing more time between invitations and the deadlines or sessions. The 2.5 weeks for the May session was very tight and did not allow time for word-of-mouth recruitment. By comparison, the time frame of the August meeting was almost 3 months, not unreasonable given that it spread over the summer months.

2. Allowing more time when the invitation process is coordinated with partners. For example, for the May session which involved two partners, the development of the invitation lists began at the end of March but invitations were not sent out until 5 weeks later.

3. Sending out invitations for written submissions earlier in the process and providing a longer period for feedback. Avoid having the summer period as the only time for written submissions.

4. Using an on-line feedback format that permits people to save their feedback and return to it at a later point in time would perhaps encourage more participation. The on-line questionnaire also needs to be easy to find.

4.3 Critical Dialogue

For the purposes of the evaluation, critical dialogue was seen as the extent to which the process enabled an interesting exchange between participants that enriched their own thinking. Since it relies on exchange, it was not an applicable evaluation indicator for the written feedback component and no data was collected.

From both the participant questionnaires and the interviews with staff and PAC members, it is clear that the quality of dialogue generated at both the multi-stakeholder sessions and the small group dialogues was very high. There were two evaluation statements that relate to this indicator. The ratings received are provided below:

Statement	Multi-stakeholder Sessions			Small Group Dialogues	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.					
The process allowed for an interesting exchange between participants that added to my own thinking about the issues.	March – 1.06	May – 1.31	August - 1.20	June – 1.31	August – 1.20
The facilitator kept us on track but did not stifle participants.	March – 1.11	May – 1.31	August - 1.47	June – 1.24	August – 1.47

> *'The discussions were excellent and very conducive to open and frank dialogue.*
>
> Session participant

These are consistently high ratings and are bolstered by the written comments of participants: *The process forced us to think about tough issues and consider many viewpoints; Very interactive; Everyone could contribute; Terrific facilitation; Good use of*

ground rules. These reflections were echoed by the commentary from PAC members: *Extremely rich discussion; Sensational; Collaborative and yet divergent views were clearly heard; Very educative; This is as good as it gets.*

Conclusion

The face-to-face components of the consultation process clearly lived up to the principle of critical dialogue. It would appear there were four essential components that helped achieve this and should be considered in subsequent consultations:

1. A process design that encouraged small group work and productive dialogue. Features like the ground rules which set the tone for the group interaction and the freedom participants in the multi-stakeholder groups had to choose the group they wished to work in for the morning break-out helped set the foundation for good interaction;

2. A document or discussion paper that was clear and met the challenge of presenting complex and dense material in a format that could be readily used in consultation;

3. Good facilitation that created an environment conducive to a respectful but frank exchange of ideas; and

4. The diversity and high calibre of participants.

A few people commented that the one-day multi-stakeholder session was too short. They would have liked more time to work through the issues together.

5. Area of Inquiry #2 – Was the process effective in getting feedback on the guidelines?

There were two relevant evaluation issues: the quality of materials and the support systems (e.g. meeting facilities).

5.1 Adequate Resources

Multi-stakeholder Sessions

The principle document used in the multi-stakeholder sessions was the draft guidelines. As mentioned earlier, the version used for the March workshop was a preliminary version. While there is no evidence that this affected the feedback provided, good practise recommends using the same consultation documents for comparability purposes whenever possible.

For the May and August sessions, as well as for the written feedback, the version used was: Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research: Best Practices, Consultation Draft, April 2004. The document was well-written and the information clearly laid-out for consultation purposes. This is a significant accomplishment given the density and complexity of the material.

In addition, worksheets were designed to enable small break-out groups to record their feedback. Participant ratings of the materials are high as the responses to the two related evaluation statements indicate.

Statement	Multi-stakeholder Sessions		
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.			
The draft guidelines were presented in a useful and understandable manner.	March – 1.83	May – 1.77	August – 1.83
The worksheets were a useful was to record participants' feedback.	March – 1.44	May – 1.38	August – 1.73

PAC members were similarly satisfied with the draft guideline document and commented that it is seen as breaking new ground from a content perspective. The main challenge noted was the development of a set of guidelines that was relevant to the broad range of researchers involved in health research, particularly those involved in qualitative research.

There were a few comments from participants and one PAC member about whether the worksheets adequately captured the richness of the conversations in small break-out groups. While there were two CIHR staff present taking notes in break-out groups and the plenary, there were not sufficient note-takers to assign one to each small group.

Small Group Dialogues

Participants in the citizen dialogues were presented with scenarios that explored issues around recruitment and informed consent. Feedback was collected through the use of worksheets in small group and plenary report-backs.

The preparation of the materials for the small groups was done quite rapidly, as the main consultation document – the draft guidelines – was very time-consuming. As a result, there was not sufficient time to pilot test the materials. Thus the scenarios were first used in the June session and the constructive feedback of participants on the scenarios themselves was well-appreciated and made good use of in revising the material. The improvement in materials is documented by the feedback from participants as illustrated in the following table:

Statement	Small Group Dialogue	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.		
The scenarios were presented in a useful and understandable manner.	June – 1.95	August – 1.53
The worksheets were a useful way to record participants' feedback.	June – 1.83	August – 1.53

The revisions to the scenarios were ones that added clarity to the scenario and task. They did not alter the nature of the questions being asked.

The support systems for all the face-to-face sessions were viewed positively as noted in the following table:

Statement	Multi-stakeholder Sessions			Small Group Dialogues	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.					
The facilities and refreshments helped to make for a productive session.	March – 1.65	May – 1.15	August – 1.24	June – 1.45	August – 1.27

Participants in the Toronto multi-stakeholder session were particularly complimentary about the quality of the space and the food, both of which were provided by Heenan Blaikie LLB.

Written Submissions

Fewer than 10 people commented that they had difficulty accessing the materials via the website. As noted earlier, some people had trouble finding the document and for some the on-line questionnaire itself posed some challenges. Staff noted that there was a significant learning curve for them in preparing the on-line questionnaire. The timeframe was short and a survey platform was used for the on-line questionnaire. With hind-sight, a more flexible platform, that would have allowed people to save their input and return to it later, would have been preferred,.

Conclusion

The materials were adequate to the task, with improvements made along the way to improve them as required. Indeed the draft guideline consultation document was much more than adequate and deserves praise for meeting the challenge of presenting complex and dense material in a format that could be readily used in consultation.

The question of how well participant feedback was captured is an important one. Improvements could have been achieved by:

1. Having a note-taker at each small break-out group, when overall resources permit.

2. Using the same key consultation document for all multi-stakeholder sessions. This is a general best practice to better ensure comparability of results.

3. Pilot-testing consultation materials, such as the scenarios used in the small group dialogues.

However in this instance, given the combination of face-to-face and written comments, both PAC and staff are confident in the quality of feedback obtained through the

process. As noted by at least one PAC member, continuing to get quality feedback as the guidelines move into their next phase will be crucial. One idea suggested was to send out a questionnaire to all those who try using the guidelines as they prepare their research plans.

5.2 Suitable Process

Confidence in the quality of the feedback provided in the face-to-face sessions is shared by the participants, as indicated in the table below:

Statement	Multi-stakeholder Sessions			Small Group Dialogues	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.					
The process allowed me to express my views and ideas with respect to the guidelines (with respect to the selected privacy issues, for small group dialogues).	March – 1.11	May – 1.23	August – 1.43	June – 1.29	August – 1.27
The discussions provided solid feedback to CIHR (or, in the case of the small group dialogues – The discussion provided solid feedback on the selected privacy issues).	March – 1.56	May – 1.46	August – 1.53	June – 1.67	August – 1.53

Interviews with PAC and staff reinforce the view that the feedback from both the face-to-face sessions and written submissions was more than adequate to move forward with. People were very impressed with both the quality and extent of the feedback received.

The written feedback was varied in it specificity and depth. Some written submissions were comprehensive. Others focussed in on one or two aspects of the guidelines. There was consensus that the multi-stakeholder sessions and the written feedback components were very complementary as people could attend a session and then further their ideas through written submission.

Staff commented that small group dialogues were very important to the reworking of the guidelines as they made the issues of recruitment and informed consent very tangible. The citizen comments also provided good feedback to the stakeholders and for the August session, were fed into the stakeholder process as appropriate.

Stakeholders were asked to identify any issues they felt remained unfinished or needed further attention. The resulting comments were all content-oriented and included areas such as: issues around biomaterials; implications of genetic data for extended families, further reflection of the distinction between data collected for direct vs. secondary research; more operational details for Research Ethics Boards; more clarity about how these guidelines relate or could relate to others already in place.

Conclusion

The consultation process was effective in getting high-quality and comprehensive feedback on the guidelines. The complementarity of the face-to-face sessions and the written feedback was an important component of this and would be recommended for future consultations when possible. Improvements could be gained, as mentioned previously, by using an on-line questionnaire platform that provides more flexibility.

5.3 Participant Satisfaction

The overall satisfaction level with the face-to-face sessions was very high, as shown in the following table:

Statement	Multi-stakeholder Sessions			Small Group Dialogues	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.					
Overall I am pleased with the session and its output.	March – 1.42	May – 1.46	August – 1.48	June – 1.48	August – 1.40

Both staff and PAC commented that they had received consistently positive feedback on the sessions. This was reinforced by their own observations of participants at the multi-stakeholder sessions, with several PAC members noting the high energy level of participants and that people stayed and were engaged through to the end even though privacy issues were not necessarily their key area of interest. One person interviewed commented that the sessions had re-energized him as a PAC member.

There are countless considerations to be made... it is essential to view and reflect on the issues in order to make an informed decision.

Small group dialogue participant

Participants were asked to comment on features of the session they particularly liked. Many of these have already been noted: mix of stakeholders, small group work; quality of dialogue; facilitation; ground rules; food and venue, informative discussions. In terms of areas for improvement, comments included: earlier distribution of materials; greater clarity on guidelines; improved system of note-taking.

There was a resounding yes in response to the question: *Has the session contributed to your interest in the guidelines (or in the case of the small group dialogues, interest in privacy and confidentiality issues in health research)?* For those in the multi-stakeholder session, comments included: It helped me to reflect on my own work; Clarified issues for me; Raised new issues; Brought to my attention serious flaws in other guidelines; Good learning experience.

Conclusion

Participant satisfaction in the face-to-face sessions was very high. It would appear this is again due to the diversity of participants, the richness of the dialogue and the process design itself.

6. Area of Inquiry #3 - Did the process heighten the visibility of the guidelines?

The guidelines are intended to be of use to the broad health research community, with particular focus on health researchers, research ethics boards, and policy-makers. Therefore, nurturing buy-in to promote eventual uptake of the guidelines is a key objective of the overall process to develop the guidelines. As this stage, it is too early to anticipate buy-in. However, increasing visibility for the guidelines is a reasonable objective and a necessary step in achieving eventual buy-in and use.

Within this context, the priority at this stage is visibility with stakeholders. Therefore the objective was not applied to the small group dialogues and no information was collected relevant to this area of inquiry. The indicator for this area was the number of participants (or potential participants) who were sent the guidelines.

In total, 91 people attended one of the multi-stakeholder sessions. All invitees were sent the web link as part of the invitation. Due to the decentralized nature of some aspects of the invitation process it is not possible to determine the exact number of invitations that went out, but CIHR has a record of at least 328 invitations. In addition 201 invitations were sent out to solicit written feedback as well as invitations being made through list serves and conferences. Sixty-eight responded giving a reasonably high response rate of 34%.

Quantitative data was not always collected. For example, the number of guidelines sent out on request was not recorded.

Frequently, people being sent invitations were from interested organizations. Thus, it is reasonable to assume that one individual may pass on the information to others in their organization. Certainly this is confirmed by anecdotal information from Health Canada, where a team of people reviewed the guidelines.

Total number of website hits from May to September was 8416. The largest proportion of these hits (3659) was for the guidelines themselves. However it is hard to interpret these numbers as they are by hit, not by person. For example, one person could have accessed each section of the site and would have been counted as a hit each time. Nor do the numbers exclude staff or PAC members.

From the perspective of PAC and CIHR staff, people felt that the visibility of the guidelines had been considerably enhanced through the consultation process and that they were even gaining international recognition. CIHR staff also noted that the consultation process has increased the visibility of the guidelines within CIHR itself.

Conclusion

It would appear that visibility has been enhanced through the consultation process, although this is difficult to quantify. However the quality and scale of the outreach strategy as previously noted would reinforce this conclusion. Maintaining visibility will be essential in the next phases and the website will be a key tool to achieve this. Improvements could be made by:

1. Ensuring the key document is easily accessible on the website.

2. Ensuring that statistics are collected on the number of guidelines/invitations being sent.

7. Area of Inquiry # 4 - Does the initiative reflect the kind of national leadership participants expect from CIHR?

This area of inquiry was deemed to be relevant only for stakeholder participation as citizens' knowledge of CIHR would be limited. Therefore participant data is provided only for the multi-stakeholder sessions. Two indicators were examined:

1. whether participants' expectations for CIHR were met, and
2. extent of support for CIHR.

There were three statements in the evaluation form that relate to these indicators. These questions were only asked in the May and August meetings, as this area of inquiry was added after the March session. The responses are noted in the table below:

Statement	Multi-stakeholder Sessions	
Average Response on a scale from 1- 5, with 1 being strongly agree, 2 somewhat agree, 3 undecided, 4 somewhat disagree and 5 being strongly disagree.		
The development of privacy guidelines meets my expectations of what CIHR should be doing.	May – 1.46	August – 1.66
I think that privacy and confidentiality issues should be a priority for CIHR.	May – 1.46	August – 1.39
CIHR's leadership in the area of privacy and confidentiality is necessary and appropriate.	May – 1.46	August – 1.48

These are positive responses and clearly support the type of leadership that CIHR is demonstrating in this area. One PAC member characterized this leadership as being highly pro-active but also inclusive – so that people are "brought-along" in the process and can actively contribute. The PAC members interviewed were unanimous in their praise for the CIHR staff involved in this process.

Conclusion

The consultation process has clearly demonstrated the type of leadership participants expect from CIHR. The message is that CIHR's leadership is being appreciated and needs to continue. The importance of continuing to be pro-active and inclusive was reinforced. The need to keep stakeholders regularly informed with opportunity for ongoing feedback was frequently mentioned.

8. Conclusion and Summary of Recommendations

Overall this was a very good consultation process as assessed through the four areas of inquiry.

1. The process did largely fulfill the guiding principles of transparency, inclusiveness and critical dialogue. Certainly participants commented positively about the diversity of participants and the quality of dialogue obtained in the face-to-face sessions. Transparency could have been improved if written materials were sent out earlier and website documents were more accessible. The timelines (especially for the March session) were a challenge for this consultation process as they are for most. Preparing invitation lists and recruiting participation is always time-consuming.

   A contributing factor to the consultation's success was flexibility and the willingness to revise documents and strategies as required. Two examples of this were the change in the recruitment strategy for the small group dialogues and the revisions of the scenarios for these same sessions.

2. The process was very effective in getting feedback on the guidelines. Participants, as well as staff and PAC members, stated that the quality of feedback was extensive and provided what was needed to move forward with confidence. Improvements could have been made in the note-taking done for the face-to-face sessions and in the platform for the on-line questionnaire.

   It should be noted that the complementarity of the three process components was important in achieving comprehensive feedback. Certainly the multi-stakeholder sessions coupled with the opportunity for written feedback enhanced the possibilities for considered reflection and feedback.

3. The perspective of staff and PAC members, based on anecdotal information from others, is that visibility and interest in the guidelines was enhanced. The quantitative indicator (# of invitations) show that over 500 direct invitations were sent out to stakeholders to participate in one form or another. These were complemented by the website, the use of list-serves, announcements at conferences, etc.

4. From the comments of participants and the perspectives of PAC members, CIHR has clearly demonstrated the kind of national leaderships participants expect from it. The inclusive and yet pro-active style of leadership being demonstrated by CIHR was highly commended as were the CIHR staff people leading this process.

This consultation process did most things right, and certainly features of it should be replicated in future consultations when appropriate. These features include:

1. A process design that encouraged small group work and productive dialogue. Features like the ground rules which set the tone for the group interaction and the freedom participants in the multi-stakeholder groups had to choose the group they wished to work in for the morning break-out helped set the context for good interaction.

2. A document or discussion paper that was clear and met the challenge of presenting complex and dense material in a format that could be readily used in consultation;

3. Good, professional facilitation that created an environment conducive to a respectful but frank exchange of ideas;

4. A proactive outreach strategy that helped ensure the desired diversity and calibre of participants; and

5. A multi-faceted consultation process with complementary strategies – in particular in this instance the combination of the multi-stakeholder sessions with the written submission opportunity.

Finally, there is always room for improvement. Possible improvements for future consultations are:

1. Ensure that key documents are easily accessible on-line before the first invitations are sent out.

2. Allow more time between invitations and the deadlines or sessions. The 2.5 weeks for the May session was very tight and did not allow time for word-of-mouth recruitment. By comparison, the time frame of the August meeting was almost 3 months, not unreasonable given that it spread over the summer months.

3. Allow more time when the invitation process is coordinated with partners. For example, for the May session, the development of the invitation lists began at the end of March but invitations were not sent out until 5 weeks later.

4. Send out invitations for written submissions earlier in the process and provide a longer period for feedback. Avoid having the summer period as the only time for written submissions.

5. Use an on-line feedback format that permits people to save their feedback and return to it at a later point in time. The questionnaire also needs to be easy to find.

6. Have a note-taker at each small break-out group, when overall resources permit.

7. Use the same key consultation document for all multi-stakeholder sessions. This is a general best practice to better ensure comparability of results.

8. Pilot-test consultation materials, such as the scenarios used in the small group dialogues.

9. Ensure that statistics are collected on the number of guidelines/invitations sent out.

APPENDIX A
AGENDAS FOR MULTI-STAKEHOLDERS SESSIONS

CIHR's Consultations on Draft Privacy Best Practice Guidelines
Multi-stakeholder workshop – Theme: *How well do these draft guidelines address genetic privacy issues?*

March 26, 2004 (08:00 – 16:30)
Ottawa Marriott, 100 Kent St., Ottawa - York Salon

AGENDA

08:00 –08:30	***Canadian Breakfast***	*Albert Salon*
08:30 – 09:30	Welcome and Introductions. • Context Setting and overview of the guidelines (CIHR) (15 minutes) • Presentation on the theme of the day (Health Canada) (15 minutes)	*York Salon*
09:30 – 12:00 including 15 min. break	Discussion of Guidelines in small groups. 1) Does the GENERAL PRINCIPLE apply well to genetic data? 2) In the context of genetic data, is this BEST PRACTICE workable?	
12:00 – 13:00	***Lunch***	*Albert Salon*
13:00 – 13:30	Question and answer period, based on questions arising from morning discussions.	York Salon
13:30 – 15:30 ***including 15 min. break***	Afternoon discussion in assigned small groups and plenary on: 1) Generally, how well do CIHR's privacy guidelines apply to genetic research? Are there any gaps/potential problems? 2) A) Are there unique issues relating to the collection and banking of human biological materials that cannot be adequately covered by the guidelines? B) If so, what complementary instrument could be used? 3) How enforceable should the guidelines (and whatever complementary instrument) be? A) Voluntary guidelines? B) Mandatory funding criteria? C) Regulatory policy? Why?	
15:30 – 16:00	Final plenary.	
16:00 – 16:30	Synthesis of key ideas emerging from the groups. Closing remarks.	

Consultations on CIHR Draft Privacy Best Practice Guidelines

Multi-stakeholder Workshop

Co-funded by the Interagency Advisory Panel on Research Ethics (PRE) and CIHR

Theme: How well do these draft guidelines apply across the spectrum of research funded by federal research granting agencies?

Thursday, May 20, 2004 8:30 am – 4:30 pm (Breakfast from 8:00 am)
Crowne Plaza Ottawa Hotel, 101 Lyon St., Ottawa - Joliet and Richelieu Rooms

AGENDA

08:00 –08:30	***Canadian Breakfast***	*Joliet Room*
08:30 – 09:30	Welcome and Introductions. (Jacquie Dale, Patricia Kosseim) • Context setting and overview of the guidelines (CIHR) (15 minutes) • Evolution of the Tri-council Policy Statement: Mandate of the Interagency Advisory Panel on Research Ethics (PRE- Derek Jones) (10 minutes) • Overview of privacy and confidentiality issues from a SSHRC perspective (Dr. McGinn) (15 minutes) • Questions and Answers	*Richelieu Room*
09:30 – 12:00 ***including 15 min. break***	Discussion of the Guidelines in small groups. 3) Does the GENERAL PRINCIPLE apply well across the spectrum of research funded by federal granting agencies? Any ideas for improvement? 4) Is this BEST PRACTICE workable in different research contexts? Any ideas for improvement?	*People choose their groups according to which element they wish to discuss, resulting in a mixture of research perspectives at each table.*
12:00 – 13:00	***Lunch***	
1:00 – 1:30	Question and answer period, based on questions arising from morning discussions.	
1:30 – 3:30	Afternoon discussion in assigned small groups and plenary on:	*People who work in similar research contexts*

including 15 min. break	1. **Generally, how well do CIHR's privacy guidelines apply to the research contexts represented at your table?** What might be the positive implications of the guidelines on these research contexts? Are there any possible negative implications to be concerned about? If so, what are these? 2. **Are there substantial differences or similarities in how privacy and confidentiality issues need to be handled across various research contexts?** If there are substantial differences, can the guidelines accommodate these? If so, how? If not, why not? What are the alteratives? **How should the guidelines be implemented?** Should these guidelines provide voluntary guidance or should they become mandatory criteria for federal research funding such as by eventual incorporation, in some form, into the Tri-council Policy Statement (TCPS)?	*(methodologies, paradigms, etc.) are pre-assigned to groups, allowing for in-depth discussion from similar contexts.*
3:30 – 4:00	Final plenary.	
4:00 – 4:30	Synthesis of key ideas emerging from the groups. Closing remarks.	*Evaluation forms completed.*

Heenan Blaikie LLP and the Canadian Institutes of Health Research

Consultations on CIHR Draft Privacy Best Practice Guidelines
Multi-stakeholder Workshop

Theme: How well do these draft privacy guidelines apply to research involving the health care context?

Date/Time: August 24, 2004 8:30 am – 4:30 pm (Breakfast from 8:00 am)
Site: Heenan Blaikie, Suite 2600, Royal Bank Plaza, South Tower, Toronto M53 2J4

Tel: (416) 360-3559 Fax (866) 553-4339.

AGENDA

Facilitator: Jacquie Dale, One World Inc.

08:00 –08:30	***Breakfast***	
08:30 – 09:30	Welcome and Introductions. Presentations: • CIHR draft privacy guidelines: Overview and Context (CIHR) (15 minutes) • Highlights of Ontario's new privacy Bill-31 with respect to research (Heenan Blaikie) (10 minutes) • Canadian Medical Association's Health Information Privacy Code and privacy enhancement tools for physicians (CMA) (15 minutes) • Questions and Answers	
09:30 – 12:00 ***including 15 min. break***	Discussion of the Guidelines in small groups. 5) Does the GENERAL PRINCIPLE apply well to research involving the health care context? Any ideas for improvement? 6) Is this BEST PRACTICE workable? Any ideas for improvement?	*People choose their groups according to which element they wish to discuss, resulting in a mixture of perspectives at each table.*

12:00 – 13:00	***Lunch***	
1:00 – 1:20	Question and answer period, based on questions arising from morning discussions.	
1:20 – 3:45	Breakout into small pre-assigned groups to discuss: **1. Generally, how well do CIHR's privacy guidelines apply to research involving the health care context?** What might be the positive implications of the guidelines for patients and research participants, health care providers, clinician /researchers, other researchers, sponsors, others? Are there any possible negative implications to be concerned about? If so, what are these? **2. Are there unique privacy and confidentiality issues for research involving the health care context?** If there are unique issues, can the guidelines accommodate these? If so, how? If not, why not? What are the alternatives (e.g. other policies, laws, additional modules for the guidelines)?	*People from similar perspectives are pre-assigned to groups, allowing for in-depth discussion from similar viewpoints.*
2:30–2:45 Break	Plenary Session for report- backs from groups. Return to breakout groups, to discuss: **3. How should the guidelines be implemented?** Should these guidelines provide voluntary guidance or should they become mandatory criteria for federal research funding such as by eventual incorporation, in some form, into the Tri-council Policy Statement (TCPS)?	
3:45 – 4:30	Final plenary. Synthesis of key ideas emerging from the groups. Closing remarks.	*Evaluation forms completed.*

APPENDIX B
EVALUATION FRAMEWORK

CIHR PRIVACY BEST PRACTICE GUIDELINES
EVALUATION FRAMEWORK FOR THE CONSULTATION PROCESS

Multi-stakeholder Workshops, On-line Questionnaire and Small Group Citizen Dialogues

Context:
CIHR, with the advice of its Privacy Advisory Committee, has developed draft privacy best practice (PBP) guidelines for health research. A public consultation process to obtain feedback on the draft guidelines is planned for the period March –September, 2004.

The consultation process will have three components:
1. Multi-stakeholder workshops
2. Small group dialogues
3. Individual submissions and feedback (electronic and written)

Consultation Objectives:
1. Obtain feedback on the draft guidelines.
2. Heighten the visibility of the guidelines.
3. Obtain feedback on how and which guidelines might be most relevant for the particular topic area: e.g. genetic privacy.

In addition, the consultation process needed to act in accordance with the Interagency Advisory Panel on Research Ethics (PRE) consultation principles of:
- Transparency
- Inclusiveness, and
- Critical dialogue (e.g. by avoiding a top-down approach).

Areas of Inquiry:
Taking into consideration, the objectives, guiding principles and the pedagogy, the following areas of inquiry will be explored;
1. Did the process fulfill the guiding principles?
2. Was the process effective in getting feedback on the guidelines?
3. Did the process heighten visibility of the guidelines?

The evaluation framework is provided on the next pages. One table includes the multi-stakeholder sessions and the on-line questionnaire. A second table provides the framework for the citizen dialogues.

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
Did the process fulfill the guiding principles?	Transparency	Explanation of the process and the objectives			Review of presentation material and other documentation, e.g. Letter of invitation			Review of website
		All stages of the consultation process are documented.			Review of documentation.			Review of documentation
		Workshop documentation was received in a timely way.	Q. I received the materials in time to review it before the session.		Dates materials were sent out.			Length of time the on-line feedback process was on the web-site.
	Inclusivity	The participants represent the broad cross-section of stakeholders.	Q. Participants represented a good cross-section of the stakeholders interested in this issue.	Q. Do you think that the participants represented a good cross-section of stakeholders interest in this issue? Q. Were there any gaps in representativeness that concern you?	Review outreach strategy and results.	Q. In which stakeholder category would you put yourself?	Q. Do you think that the participants represented a good cross-section of stakeholders interest in this issue? Q. Were there any gaps in representativeness that concern you?	Review outreach strategy and results.

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
		Participants are able to express their views	Q. The process allowed me to express my views and ideas with respect to the guidelines.			Q. Responding on-line allowed me to express my views and ideas with respect to the guidelines.		
	Critical dialogue	Quality of participation	Q. The process allowed for an interesting exchange between participants that added to my own thinking about the issues.	Q. Did the process foster a critical dialogue, i.e. allow participants to express their views, exchange perspectives with others, etc?		(Not applicable for on-line)	(Not applicable for on-line)	(Not applicable for on-line)
		Facilitator's Role	Q. The facilitator kept us on track but did not stifle participants.			(Not applicable for on-line)	(Not applicable for on-line)	(Not applicable for on-line)
Was the process effective in getting feedback on the principles?	Adequate resources	Quality of materials	Q. The draft guidelines were presented in a useful and understandable manner. Q. The worksheets were a useful way to record participants'		Review of documentation	Q. The draft guidelines were presented in a useful and understandable manner. Q. Using the online feedback process was a useful way to provide my feedback on the		Review documentation

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
			feedback.			guidelines.		
		Support systems	Q. The facilities and refreshments helped to make for a productive day.			Q. Did you run into any difficulties on the website? If so, what were these? Did you request any help, and if so, was it satisfactory?		Review of any complaints/problems documented
	Suitable process	Feedback	Q. The process allowed me to express my views and ideas with respect to the guidelines. Q. The discussions provided solid feedback to CIHR Q. What issues remain unfinished or neglected in your view, and need further attention?	Q. Do you feel the quality of feedback will be useful? Adequate?		Q. Responding on-line allowed me to express my views and ideas with respect to the guidelines. Q. What issues remain unfinished or neglected in your view, and need further attention? Q. The on-line feedback process allowed me the flexibility I needed to comment as little or as much as I wanted and to focus on the areas that I thought were important.	Q. Do you feel the quality of feedback will be useful? Adequate?	

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
	Participant Satisfaction	Participants' expectations were met.	Q. Overall I am pleased with the workshop and its output. Q. What are some features of the day that you particularly liked? Q. What are some aspects you would suggest changing or improving?	Q. Did you hear any comments from participants in terms of their satisfaction with the session they attended? Q. Any observations you would like to share from attending a session, e.g. people's energy levels, degree of involvement?		Q. Overall I am pleased with the on-line feedback process. Q. Approximately, how long did it take for you to give your feedback? Did you do this all at one time or in multiple sittings? Q. The length of time it took me to give my feedback was reasonable. Q. What are some aspects of the on-line feedback process you would suggest changing or improving, if any?	Q. Did you hear any comments from participants in terms of their satisfaction with the functionality of providing on-line feedback?	
		Extent of support/buy-in	Q. Has the workshop contributed to your interest in the guidelines? Why or why not?			Q. Has the on-line feedback process contributed to your interest in the guidelines? Why or why not?		

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
Did the process heighten visibility of the guidelines?	Quantitative	Number of participants (or possible participants) sent the guidelines.	Note: This area of inquiry was not applicable to the small group dialogues.	Q. Do you feel the process succeeded in enhancing the visibility of the guidelines? Why or why not?	Number of participants (or possible participants) sent the guidelines.		Q. Do you feel the process succeeded in enhancing the visibility of the guidelines? Why or why not?	# of hits # of participants who sent the link on to another # of individuals who provided feedback
Does this initiative reflect the kind of national leadership participants' expect from CIHR?	Participant satisfaction with CIHR.	Participants' expectations for CIHR were met.	The development of privacy guidelines meets my expectations of what CIHR should be doing.	Q. Does the initiative reflect the kind of national leadership you would expect from CIHR?		The development of privacy guidelines meets my expectations of what CIHR should be doing.	Q. Does the initiative reflect the kind of national leadership you would expect from CIHR?	
			I think that privacy and confidentiality issues should be a priority for CIHR.			I think that privacy and confidentiality issues should be a priority for CIHR.		
		Extent of support for CIHR	CIHR's leadership in the area of privacy and confidentiality is necessary and appropriate.			CIHR's leadership in the area of privacy and confidentiality is necessary and appropriate.		

Area of Inquiry	Evaluation Issue	Indicators	Data Collection –Multi-stakeholder Sessions			Data Collection – On-line		
			Participants	PAC	CIHR	Participants	PAC	CIHR
			Other comments?	Q. Overall were you satisfied with the consultations?			Q. Overall were you satisfied with the consultations?	
				Q. Based on this experience, what recommendations would you have for future consultations?			Q. Based on this experience, what recommendations would you have for future consultations?	
				Q. Any comments on the role and participation of PAC?			Q. Any comments on the role and participation of PAC?	
				Q. Any other comments you would like to make?			Q. Any other comments you would like to make?	

Small Group Citizen Dialogues

Area of Inquiry	Evaluation Issue	Indicators	Data Collection – Citizen Dialogues		
			Participants	PAC	CIHR
Did the process fulfill the guiding principles?	Transparency	Explanation of the process and the objectives			Review of presentation material and other documentation, e.g. Letter of invitation
		All stages of the consultation process are documented.			Review of documentation.
		Workshop documentation (invitation) was received in a timely way.			Dates invitations were sent out.
	Inclusivity	The participants represent a good cross-section of people.	Q. Participants represented a good cross-section of People	Q. Do you think that the participants represented a good cross-section of people? Q. Were there any gaps in representativeness that concern you?	Review outreach strategy and results.
		Participants are able to express their views	Q. The process allowed me to express my views and ideas with respect to the guidelines.		
	Critical dialogue	Quality of participation	Q. The process allowed for an interesting exchange between participants that added to my own thinking about the issues.	Q. Did the process foster a critical dialogue, i.e. allow participants to express their views, exchange perspectives with others, etc?	

Area of Inquiry	Evaluation Issue	Indicators	Data Collection – Citizen Dialogues		
			Participants	PAC	CIHR
		Facilitator's Role	Q. I am pleased with the manner in which the facilitation conducted the session.		
Was the process effective in getting feedback on the principles?	Adequate resources	Quality of materials	Q. The scenarios were presented in a useful and understandable manner. Q. The worksheets were a useful way to record participants' feedback.		Review of documentation
		Support systems	Q. The facilities and refreshments helped to make for a productive morning/evening.		
	Suitable process	Feedback	Q. The process allowed me to express my views and ideas with respect to the selected privacy issues. Q. The discussions provided solid feedback on the selected privacy issues.	Q. Do you feel the quality of feedback will be useful? Adequate?	
	Participant Satisfaction	Participants' expectations were met.	Q. Overall I am pleased with the session and its output. Q. What are some features of the morning/evening that you particularly liked? Q. What are some aspects you would suggest changing or improving?	Q. Did you hear any comments from participants in terms of their satisfaction with the session they attended?	

Area of Inquiry	Evaluation Issue	Indicators	Data Collection – Citizen Dialogues		
			Participants	PAC	CIHR
		Extent of support/buy-in	Q. Has the workshop contributed to your interest in privacy and confidentiality issues in health research? Why or why not?		
Did the process heighten visibility of the guidelines?	Quantitative	(Not applicable)	(Not applicable)	(Not applicable)	(Not applicable)
Does this initiative reflect the kind of national leadership participants' expect from CIHR?		(Not applicable)	(Not applicable)	(Not applicable)	(Not applicable)

APPENDIX C
EVALUATION FORMS

CANADIAN INSTITUTES OF HEALTH RESEARCH (CIHR)
PRIVACY BEST PRACTICE GUIDELINES

EVALUATION FORM – Multi-stakeholder Session - August 24, 2004

Thank you for taking the time to complete this questionnaire. All responses will be treated confidentially.
Please check one response for each statement.

MATERIALS

1. I received the materials in time to review them before the session.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

2. The draft guidelines were presented in a useful and understandable manner.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

3. The worksheets were a useful way to record participant feedback.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

PROCESS

4. The process allowed for an interesting exchange between participants that added to my own thinking about the issues.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

5. The facilitator kept the dialogue on track, but did not stifle participants.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

The discussions provided solid feedback on the guidelines.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

6. The process allowed me to express my views and ideas with respect to the guidelines.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

OTHER

7. Participants represented a good cross-section of the stakeholders interested in this issue.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

8. The facilities and refreshments helped to make for a productive day.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

9. Overall I am pleased with the workshop and its output.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

CIHR'S ROLE

10. The development of privacy guidelines meets my expectations of what CIHR should be doing.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

11. I think that privacy and confidentiality issues should be a priority for CIHR.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

12. CIHR's leadership in the area of privacy and confidentiality is necessary and appropriate.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

13. Has the workshop contributed to your interest in the guidelines? Why or why not?

_____

_____

_____

_____

14. What are some features of the day that you particularly liked?

_____

_____

_____

_____

15. What are some aspects you would suggest changing or improving?

_____

_____

_____

_____

16. What issues relating to the guidelines remain unfinished or neglected in your view, and need further attention?

Other Comments:

Thank you.

THE CANADIAN INSTITUTES OF HEALTH RESEARCH
PRIVACY BEST PRACTICE GUIDELINES

EVALUATION FORM - SMALL GROUP DIALOGUES

Thank you for taking the time to complete this questionnaire. All responses will be treated confidentially. Please check one response for each statement.

MATERIALS

1. The scenarios were presented in a useful and understandable manner.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

2. The worksheets were a useful way to record participant feedback.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

PROCESS

The process allowed for an interesting exchange between participants that added to my own thinking about the issues.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

3. I was pleased with the manner in which the facilitator conducted the session.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

The discussions provided solid feedback on the selected privacy issues.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

4. The process allowed me to express my views and ideas with respect to the selected privacy issues.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

OTHER

5. Participants represented a good cross-section of people.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

6. The facilities and refreshments helped to make for a productive morning.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

Overall I am pleased with the session and its output.

Strongly Agree	Somewhat Agree	Undecided	Somewhat Disagree	Strongly Disagree
❒	❒	❒	❒	❒

7. Has the session contributed to your interest in privacy and confidentiality issues in health research? Why or why not?

_____

_____

_____

8. What are some features of the morning that you particularly liked?

_____

_____

_____

_____

9. What are some aspects you would suggest changing or improving?

_____

_____

_____

_____

10. Other Comments:

_____

_____

_____

APPENDIX D
INTERVIEW QUESTIONS

Evaluation Questions for CIHR Staff Team
CIHR PRIVACY BEST PRACTICE GUIDELINES – CONSULTATION PROCESS

Areas of Inquiry:

The evaluation, as outlined in the evaluation framework, focuses on three areas of inquiry. These are:

1. Did the consultation process fulfill the guiding principles of transparency, inclusiveness and critical dialogue?
2. Was the consultation process effective in getting feedback on the guidelines?
3. Did the process heighten the visibility of the guidelines?

When reflecting on the consultation process, please consider its three components: multi-stakeholder workshops, the citizen dialogues and the on-line feedback. Some questions below specifically ask about only one component.

1. Transparency

1.1. When considering the multi-stakeholder sessions, what are your reflections on the invitation process and the subsequent dissemination of the materials? For example, did the time frame for the multi-stakeholder sessions allow materials to be sent out in advance to all participants in sufficient time for them to review them? If not, why not?

1.2. What recommendations would you have for future processes?

2. Inclusivity

2.1. Do you think that the participants represented a good cross-section of stakeholders interested in this issue?

2.2. Do you feel that the consultation process measured up to the principle of inclusivity? Were there any gaps in representativeness that concern you?

3. Critical Dialogue

3.1. Did the face-to-face processes foster a critical dialogue, i.e. allow participants to express their views, exchange perspectives with others, etc?

4. Adequate Resources

4.1. How well did you feel the on-line process worked? Were people able to access the documents? Were queries or technical difficulties responded to in a timely manner?

4.2. Were there any resource issues that affected participation in the face-to-face sessions, e.g. food, facility, etc?

4.3. What recommendations would you have for future processes?

5. Suitable Process

5.1. Do you feel the quality of feedback will be useful? Adequate?

5.2. Was the mixture of the three components in one consultation process useful? Why or why not?

5.3. What recommendations would you have for future processes?

6. Participant Satisfaction

6.1. Did you hear any comments from participants in terms of their satisfaction with the session they attended?

6.2. Any observations you would like to share from attending a session(s), e.g. people's energy levels, degree of involvement?

7. Visibility

7.1. Do you feel the process succeeded in enhancing the visibility of the guidelines? Why or why not?

7.2. If yes, what were some of the most successful elements for increasing visibility?

8. CIHR Leadership

8.1. Anything you'd like to share in terms of reactions (positive or negative) within CIHR to the consultations?

9. Other

9.1. Overall were you satisfied with the consultations?

9.2. Based on this experience, are there any other recommendations you would have for future consultations?

9.3. Any other comments you would like to make?

Thank you!

Evaluation Questions
CIHR PRIVACY BEST PRACTICE GUIDELINES – CONSULTATION PROCESS

As members of the Privacy Advisory Committee, we would like to gather your reflections as part of the evaluation process. To achieve this, CIHR is organizing a 30 minute teleconference which will focus on the questions provided below. For those of you, who are unable to make this conference call, please email your responses to the questions to the evaluator: Jacquie Dale at jdale@owi.ca. She will require your feedback by October 29, 2004.

Areas of Inquiry:
The evaluation, as outlined in the evaluation framework, focuses on three areas of inquiry. These are:

4. Did the consultation process fulfill the guiding principles of transparency, inclusiveness and critical dialogue?
5. Was the consultation process effective in getting feedback on the guidelines?
6. Did the process heighten the visibility of the guidelines?

When reflecting on the consultation process, please consider its three components: multi-stakeholder workshops, the citizen dialogues and the on-line feedback.

Questions

1. Guiding Principles

1.1. Do you think that the participants represented a good cross-section of stakeholders interested in this issue?
1.2. Were there any gaps in representativeness that concern you?
1.3. Did the process foster a critical dialogue, i.e.; allow participants to express their views; exchange perspectives with others, etc?

2. Feedback on the Guidelines

2.1. Do you feel that the quality of feedback will be useful? Adequate?
2.2. Did you hear any comments from participants in terms of their satisfaction with the session they attended or the functionality of providing on-line feedback?
2.3. Any observations you would like to share from attending a session, e.g. people's energy levels, degree of involvement?

3. Visibility of the Guidelines

3.1. Do you feel the process succeeded in enhancing the visibility of the guidelines? Why or why not?

4. CIHR Leadership

4.1. Does the initiative reflect the kind of national leadership you would expect from CIHR?

5. Other Areas/Comments

5.1. Overall were you satisfied with the consultations?

5.2. Based on this experience, what recommendations would you have for future consultations?
5.3. Any comments on the role and participation of PAC?
5.4. Any other comments you would like to make?

Thank you for your feedback.