

## ISSUES FOR BREAKOUTS

From the replies received to the Options Paper, the Task Force has identified a number of issues about which it would like some comments from those attending the workshop. These issues have been placed in four groups. The comments will be developed by small panels of attendees in four breakout sessions, one for each group of issues. Each attendee has been assigned to a breakout panel of from 10-15 members. The panels will each consider the same group of issues simultaneously. Thus, by the end of the conference, every attendee will have had an opportunity to develop responses to all of the issues.

### **Issues Group A: The interests of stakeholders**

*Any successful accreditation program relies heavily on the involvement of stakeholders. In the current case, the number of stakeholders can be quite large. It includes potentially several national organizations, governments with their departments and organizations, teaching and research institutions, sponsors of research including industry, research subjects and participants, the public, etc. We would like you to help us answer the following questions:*

1. Who are the stakeholders in an organization responsible for accrediting a human research protection programme, and how are they identified?
2. If the accreditation entity is to be connected in some way to NCEHR, which is a Council composed of individuals, how can the interests of stakeholder organisations be expressed in the governance of the accrediting entity within NCEHR? Similarly, how can the interests of the public and research participants be expressed?
3. If the governing body for accreditation includes representatives of stakeholder organisations, how can potential conflicts of interest be managed?
4. How should accountability for the accreditation entity and process be expressed, and to whom?

### **Issues Group B: Adding accreditation to NCEHR's current responsibilities**

*The responses to the options paper indicated that some were concerned about the way the different functions of an NCEHR organization with the addition of accreditation would be organized. In particular, questions were raised about how educational activities would be organized. We would like you to help us answer the following questions:*

5. How can the conflicts of interest that might arise from NCEHR accepting responsibility for accreditation while continuing its current responsibilities in education, identifying emerging issues and providing informal advice be managed?
6. Does the educational component of the accreditation process replace the program of educational site visits presently carried out by NCEHR?

### **Issues Group C: Maintaining flexibility in the accreditation process**

*As accreditation would be offered to all types and sizes of human research protection programs, questions have been raised about how it could be made flexible enough to meet the*

*particularities of smaller organizations and especially of those involved essentially with social science and humanity research. In addition, some jurisdictions have developed mechanisms that need to be taken in consideration as an accreditation program would come to complement what is already in place. We would like you to help us answer the following questions:*

7. What mechanisms would best meet the needs of small organisations?
8. What mechanisms would best recognise the requirements of the social sciences and humanities, particularly the qualitative approaches often used in these disciplines? It is important to keep in mind that we are seeking advice on the accreditation process to be employed.
9. What mechanisms should be used to avoid duplication of or interference with systems already in place in some jurisdictions, particularly in Quebec?

#### **Issues Group D: Standards and evaluation**

*Standards development is an important and complex task. However, those standards cannot be set in isolation and need to benefit from the input of stakeholders. They also need to be tested at some point to ensure they can be applied in a meaningful way in real situations. In addition, a wish was clearly expressed to see an evaluation component built in the overall project. We would like you to help us answer the following questions:*

10. At what stages in the evolving process of standards setting and maintenance should input be sought from the stakeholders?
11. If there is to be an ongoing evaluation of the accreditation process, how should this be put in place? What are the questions? How is effectiveness measured?
12. The standards will need some testing. At what stage of development should pilot studies be undertaken, and what should be the nature of such tests?