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## Report of Second Meeting

The Task Force held its second meeting on 4 June, 2004 at the Crowne Plaza Washington Airport in Washington, DC.

The Task Force heard a presentation from Dr Marjorie Speers on the experience of the Association for the Accreditation of Human Research Protection Programs in establishing and operating an accreditation program. Among the relevant points to emerge from the presentation and discussion were the following:

- The demand for accreditation emanated from the institutions (primarily universities) in the wake of a number of incidents that resulted in the temporary cessation of government research funding
- The AAHRPP accreditation program is a non-profit entity, designed to be self-supporting and relying on fees from the institutions seeking accreditation
- The initial start up has relied on a line of credit supported by stakeholder organizations, such as the Association of American Medical Colleges, the Association of American Universities, the Consortium of Social Science Associations
- The major pharmaceutical corporations are also financial guarantors, but at their request, they do not appear on the website as sponsors.
- AAHRPP was incorporated in April of 2001 and has a Board of Directors with 21 members.
- The standards were developed rapidly and are based on US federal regulations, ICH guidelines and "common sense"
  - There were pre-existing standards developed under the auspices of PRIM&R, with an evaluation by the Institute of Medicine
  - These standards were further developed by a committee with guidance from a law firm beginning in May, 2001
  - The standards were released for public comment in October, 2001
- Pilot site visits began in December 2001, with program officially launched in February of 2002
- The standards are flexible in order that they can be applied to:
  - Different types of research organizations
  - Different disciplines

- Accreditation is valid for three years and is conferred by a “Council on Accreditation” on the advice of a site visit report and may be in one of the following categories:
  - Full Accreditation;
  - Qualified accreditation;
  - Accreditation pending;
  - Accreditation withheld.

The Task Force also addressed the organization of the entity that would undertake the accreditation process, working from a discussion paper provided by the Ken Davey, and a paper provided by Marianne Vanderwel outlining her method of assessing the performance of an REB. During the lively discussion, four processes were identified as essential to accreditation:

- The setting of standards;
- The process of assessment, assumed to involve self-assessment plus a site visit;
- The certification process;
- Feedback to the policy forming entities.

It was also important to recognize that there was a background of assumptions held by the community at large that would need to be addressed. First, there is the assumption that the entity will in some way represent the interests of the “stakeholders”, a group of organizations that has yet to be defined. The number of possible organizations that may self-identify as stakeholders is likely to be large. Second, there is the widely held perception that NCEHR will “do” accreditation. That perception that may be naïve or misplaced, but it needs to be addressed. Third, the entity will want to be able to undertake contracts, and to protect itself from liability, suggesting that it should be a formally incorporated entity.

The Task Force identified a total of 5 possible options.

### **Organizational Option I—An entirely independent entity**

Under this option a new entity, independent of NCEHR, would be established as, for example, a “Council on Accreditation of Human Research Protection Programs”. CAHRPP would exist as an independent incorporation, modeled after the Canadian Council on Animal Care. It might have a self-identifying membership of stakeholder organizations with a smaller Board elected from the membership. The major issue would revolve around credibility. Would a new and entirely independent organization composed of stakeholders in a community that can sometimes be fractious be able to establish the credibility that would lead to wide acceptance? This body would be responsible for all four of the functions outlined above.

### **Organizational Option II—NCEHR transforms itself into the accrediting entity**

In this model, NCEHR would convert itself from an organization based on individuals into one based on stakeholder organizations, specifically to undertake accreditations. NCEHR as it currently exists would thus disappear, the argument being that the educational activities for which NCEHR is best known could be subsumed by the reconfigured NCEHR. Thus the reconfigured NCEHR would continue to undertake its current responsibilities, but add accreditation as a major (and likely pre-occupying)

activity. It would retain the name, but alter its membership. This entity would also be responsible for all of the functions identified above.

The major consideration in this model is whether a Council composed of stakeholders rather than individuals is capable of undertaking the current responsibilities, including the analysis of emerging issues. Would the development of a program of accreditation remove the necessity for such analyses? (For example, the two task Forces on Accreditation are the product of such analyses).

### **Organizational Option III—The accrediting entity retains a connection to NCEHR**

In this model, the new entity, very like CAHRPP in option I, would be established as a subsidiary of NCEHR. The closeness of the relationship could vary in a number of ways, but the essence of the model would be that CAHRPP would undertake the accreditation process, and would recommend that accreditation be granted. NCEHR would itself then issue the accreditation. In addition, NCEHR might also oversee the establishment and continuing review of standards, thus arranging for that process to be at some distance from the assessment process. Such a separation is a feature of some of the accreditation programs that the Task Force has examined. This maneuver would confer credibility on the process by ensuring NCEHR's continuing involvement, at least in the early years of the process.

The interaction between the two very different bodies might take the form of mutual representation on the Boards, and joint membership on the various committees established by each Council.

If there is a need for the continued existence of NCEHR as currently configured (composed of individual members selected for their expertise and interest), then this option is probably not viable.

### **Organizational Option IV— Contract the Process to an Existing Organisation**

Under this option, an existing organization from another country might be invited to establish a program of accreditation in Canada. Thus AAHRPP could adapt its standards to recognize TCPS, the Health Canada regulations and the proliferating provincial requirements. There could be variations on such an arrangement ranging from AAHRPP simply offering its service within Canada either on a short term or more permanent basis, to AAHRPP establishing a Canadian organization. (AAHRPP has expressed its willingness to explore such arrangements). Under this arrangement, the entity could perform all four functions associated with accreditation

### **Organizational Option V—An Agency of the Federal Government**

In this option, an agency of the federal government would be established by legislation to carry out the functions. This would provide authority and recognition. However, apart from the delay in establishing such an arrangement, it does not obviously conform to one of the basic tenets of an accreditation process, that it be operated by peers.

The Task Force also considered briefly a second paper prepared by Ken Davey on the process for setting the standards. It agreed on the following statement.

In identifying some of the issues that need to be considered in developing models for setting the standards for accreditation, there are some conflicting considerations in the background. It is widely assumed that standards will be set by the stakeholders. But a little reflection reveals that standard setting requires two sorts of expertise. Obviously there is expertise required in art of establishing standards language. Equally, however, there is expertise required in the practical matters of the ethics of research on humans. These two talents are not likely to be resident in the same individuals, and it will often be the case that neither will be resident in many of the stakeholder organizations. The challenge becomes one of involving the stakeholders while at the same time ensuring that the task is completed quickly and efficiently. In addition, standards setting is a continuous task, and the process will have to be institutionalized in the organization associated with accreditation.

Given that background, two broad models present themselves.

### **Standards Option I— Leave it to the professional standards organisations**

In this model, a professional standards setting organization, such as the Canadian Standards Council, would be contracted to establish the standards. As part of their service, such organizations would develop standards from existing documents, and present them to stakeholders for consideration and comment, refining the standards after each iteration until agreement is achieved. It is reputed to be expensive, and could be slow. Given the relative lack of expertise among many of the stakeholders there might be too ready acceptance of inadequately considered standards. A second consideration is whether such a process would be accepted by the academic community.

### **Standards Option II—Do it yourself**

This model would involve the advice of an expert in standard setting who might undertake some preliminary work based on the existing documents, but the standards would be established by Standards Committee, composed of experienced and knowledgeable individuals in human ethics. The standards that emerged would still be presented to the stakeholders for consideration and comment, but there might be greater confidence in their utility if they had been developed under the guidance of experienced and knowledgeable individuals. The membership of the committee would be crucial. It should be based on individuals rather than on constituencies, but that membership is most likely to be found among NCEHR site visitors and experienced members of CAREB. Such a committee could begin work relatively soon, in order to begin the process of developing a model set based on some sections of TCPS.

Neither of these options has considered the issue of whether the standards setting body should be coincident with the assessment, although the Task Force has received advice from some experienced individuals that the two processes, while closely connected, ought to be independent. Since the standards are based on documents, none of which are under the control of the accrediting body, this may not be a relevant issue.

The Task Force also considered a provisional work plan and budget. It noted that without a source of significant funding, it probably could not proceed further.