

The background of the slide features a series of stylized, 3D human figures in a light blue color, holding hands in a line. The figures are rendered with a slight shadow, giving them a three-dimensional appearance against the solid blue background. The overall aesthetic is clean and modern.

**“Harmonization” and Human Ethics
Review
in British Columbia**

Harmonization



- Harmonization does not mean one review or centralized review, it means working together, with all voices / instruments having a say

Background



- Michael Smith Foundation for Health Research
- Workshop October 2007
- Report on Proceedings November 2007
- Feasibility RFP June 2009
- Report from Feasibility Study December 2009
- Formal RFP by MSFHR January 2010
- Response filed May 7, 2010

Background



- Peer review panel discussion in June, 2010
- Project was approved in July 2010
- Request to refine and narrow the proposal was made and submitted with a final award issued July 28th.

RFP Original Elements



- Shared IT platform and tools for submission review and tracking of applications
- Creation of a common (one and only one) application form
- Consortium reciprocity agreements
- Shared Educational resources

Ultimate Response to the RFP



“Steering Committee”

University of Victoria, Simon Fraser
University, University of British Columbia

\$1 Million over Five Years

(with request for in kind contributions)

(and with an annual assessment to see if
funding will continue)

Ultimate Response to the Request

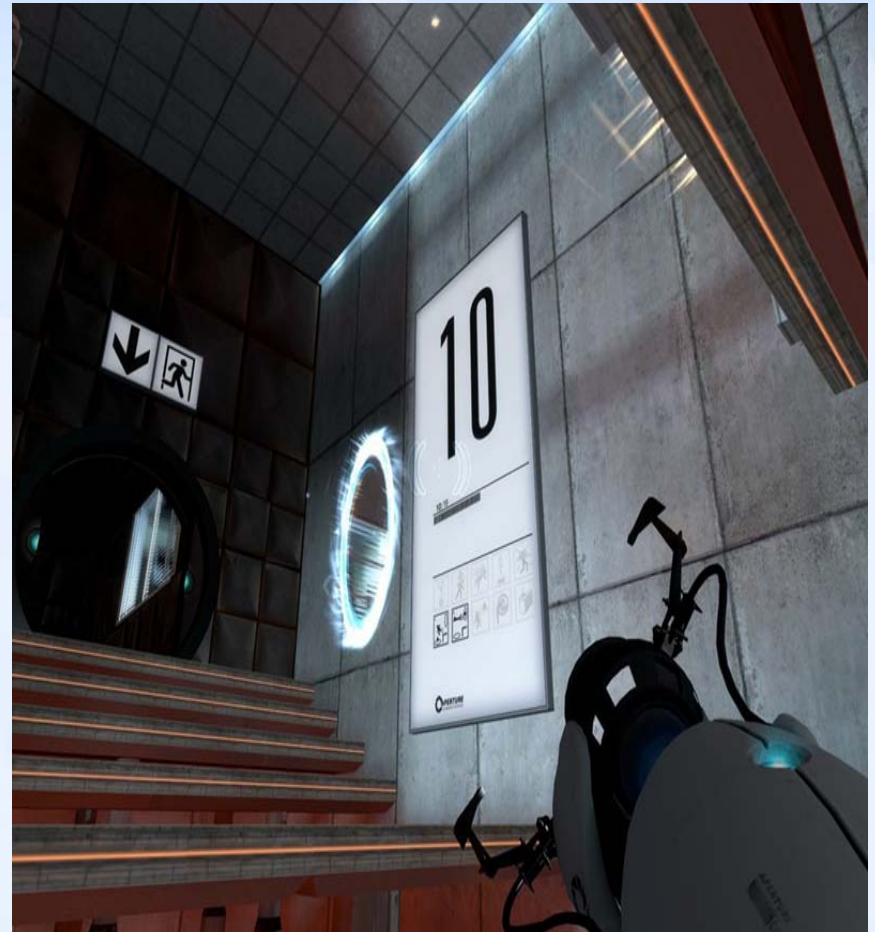


- RFP response is akin to submitting a bid in response to a tender.
- Obligates the responders to deliver what they promise.
- **Ultimate response significantly scaled back from the “required” RFP elements.**
- Covers only the initial year (nine months) funding period
- Longer term “vision” was articulated

Ultimate Response: Two Pronged Approach



- 1) Development of an Ethics Exchange Portal (EEP) that could be used by all REBs in the Province
- 2) **Pilot Projects involving clinical trials, health services and public health research studies**



Proposed Four Main Working Groups



- Establish four main working groups to focus on:
 - 1) Forms and Templates (rationalization)
 - 2) Education and Best Practices
 - 3) **Reciprocity / Collaboration**
 - 4) Design of the **EEP** (needs assessment etc.)

Ethics Exchange Portal (EEP)



- Combination web application and data warehouse usable and accessible by all REBs in the Province of BC.
- House / library of useful educational material, information, resources, sample forms, agreements etc.
- Provide communication mechanisms such as list-serve, blog's, discussion forums etc.

EEP Document Repository

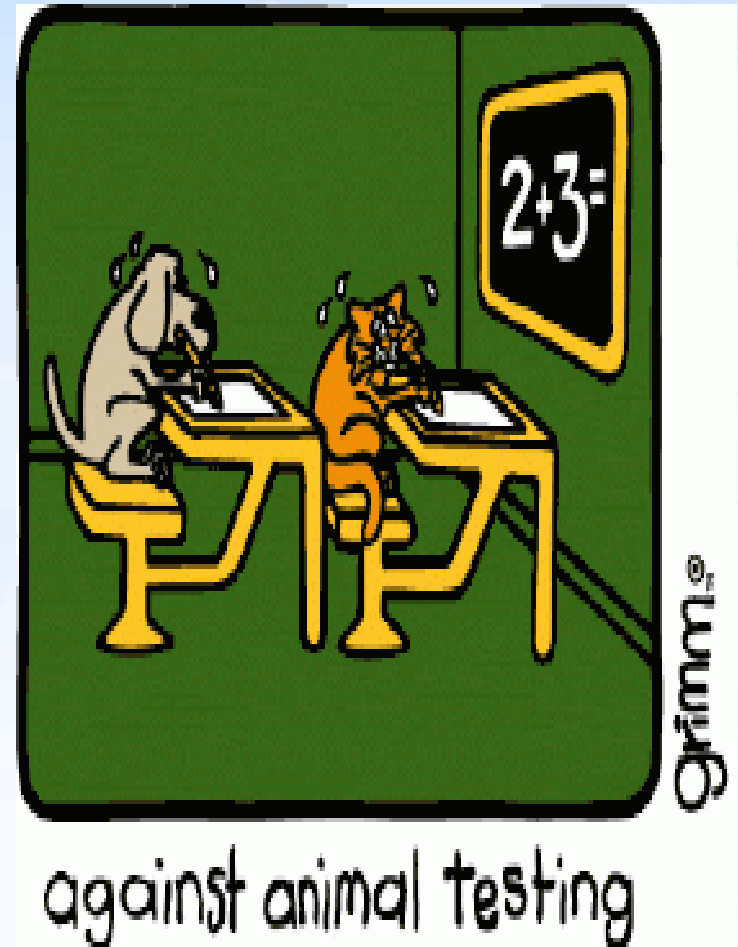


- Proposed “viewing” capacity for authorized individuals / representatives from REBs involved in the same study
- Initial concept is to at least allow other boards who are reviewing the same study, to “look” at what another board reviewing the same study had in the way of concerns, suggestions, etc.

Education and Best Practices



- Create education and best practices working group(s) that will start by compiling an accessible library of resources and ultimately by creating and offering training programs in research ethics



Rationalization of Forms



- Working group to analyze content commonalities
- Rationalize questions
- Suggest common templates for informed consent forms etc.



Reciprocity and Collaboration



- Proposal is to have a main working group focusing on this issue. Investigate various options, accumulate template agreements, consider what works and what doesn't.
- **Have a sub-committee consisting of a pilot project working group to actually propose, conduct and evaluate a number of pilot projects for collaborative or central review.**

Pilot Projects



- In areas of clinical trials, health services and public health research
- Have already been some initial discussions between UBC and the Health Authorities and UBC and U of Victoria



Pilot Projects



- Idea is to coordinate with the newly created BC Clinical Research Infrastructure Network
- Leverage off of UBC's current secure, on-line, web-based platform
- Negotiate arrangements for collaborative review of studies that are multi-site
- Possible disease specific (cancer?)
“central” review pilot project

Pilot Projects



- Create a **guest** reviewer role in UBC's on-line system
- Allow representatives from other sites to view all documentation and provide review comments *prior* to formal review by UBC
- Possible participation in the actual review



Pilot Projects



- **Assess** what works and what doesn't
- Develop and build **trust** amongst key REBs in health research in BC
- **Voluntary** participation
- **Option** to adopt review or not
- Recognition that particularly in ethics review, "one size" or "**one solution**" will not necessarily work for all.



Pilots



- If successful, possibly build a new IT system or license a current system that would allow key REBs to have systems that accommodate “guests” or



Pilots



- Possible “multi-institution” REB for health research involving multiple sites in B.C.
- Hope is that a “snowball effect” will be created in relation to capacity to trust other board’s reviews.....



What Was Accepted



- The steering committee's scaled back response was accepted, but we were requested to further narrow the focus
- All of the proposed areas and working groups were acknowledged as important and worthwhile, including the EEP.
- Pilot projects considered the most achievable within the budget, timeline, and given what MSFHR considered to be the primary "problem" areas.

What was Accepted



- Initial focus will be on health related research, primarily clinical trials and population based / epidemiological research.
- First steps will be to get the pilot projects off the “ground”.
- Hiring of a Project Manager is virtually completed
- Initial Stakeholders meeting will be held on September 17th, 2010

Initial Stakeholders: Pilots



- UBC
- Simon Fraser
- University of Northern BC
- University of Victoria
- Vancouver Island Health
- Northern Health
- Interior Health
- Fraser Health
- Vancouver Coastal Health
- Provincial Health

Can You Help?



- If you have a study that you think would be a good candidate for a pilot project, let us know about it
- As you are completing your UBC ethics application, try as best you can, to take the time to identify where possible, any other BC (or Canadian) Institution that is also participating in the same study
- The more we know about what multi-site studies are being done, and by whom, the more informed we will be around how to minimize duplication of review.

Thanks



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