CONSENSUS BUILDING AND SUMMING UP

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Biobanks

- New and evolving field with several unique considerations

- Issues to consider:

  - Consent – different options, broad vs. specific
  - Different and unique types of harm
  - Privacy and anonymity
  - Feedback to study participants, their families and the public
  - Stewardship and governance

- Considerations for the DoH revision:
  - How to deal with the unique and rapidly evolving field in the current revision
  - Whether to mention “Biobanks” specifically or try and capture important considerations within the current text
  - Introduce the topic here and elaborate in the next version?

Insurance/compensation/protection

- Currently addressed in Paragraph 14 of the DoH
- Wording needs to be strengthened
- WG currently working on this issue, will need to decide how specific and directive the language should be versus providing general guidance
- Include the word “insurance” specifically or does this set too high a threshold in some locations?

- Local circumstances vary considerably
- Difficult to capture all options and types of protection/ compensation in one document

Resource poor settings and post study arrangements

- Need to clarify and strengthen current provisions on post trial access during the current revision of the DoH

- Unique issues and considerations in resource poor settings
  - Limited access to medication for the average patient – special type of vulnerability
  - Reliance on trials to get access to medications and supplies (patients, doctors and hospitals)
  - Disposal of research drugs and materials
  - Access to qualified REC's

Vulnerable groups

- We all agree that vulnerability is difficult to define (is it like art?)
- Researchers need to be acutely aware of the possibility of exploitation in the name of science
- Protection of vulnerable subjects requires a balanced view and clearly enunciated principles

- India represents an excellent example of the challenges of doing important research in vulnerable populations and the very real possibilities of exploitation
- Sponsors, regulators and investigators all have a role to play in the protection of vulnerable subjects
- The DoH needs to be able to provide clear principles in this area

Research Ethics Committees

- Points to consider in revision process:
  - Relationship between DoH and REC's
  - International research and dual approval
  - Membership of REC's
  - Training for chairs and members
  - Quality assurance

- Challenge: Balance between high level guidance for REC's versus specific proscriptions or requirements that will not be implementable locally


The bioethical review
will approve your proposal.

Thank you!

- The Working Group very much appreciates your expertise and input on these important issues
- This is very valuable for our subsequent discussions and work on the next draft of the DoH