Consensus building/summing up

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General

- Document should be better organized for ease of use and readability
- Should have universal applicability
- Basic ethical principles and standards that can be applied worldwide

Vulnerable groups

- Clarify and strengthen existing language
- Build on current paragraphs
- Don’t try and develop comprehensive lists

Biobanks

- Need to clarify consent requirements
- Open consent versus wide consent with the right to withdraw
- Whether to address the issue of disclosure of incidental findings (specific to biobanks or in general)
- Don’t need specific paragraph on the topic

Post study arrangements

- DoH needs to continue to address this issue
- Importance of continuity of care from the research to the community setting
- Burden of providing access should be shared (and agents should be identified)
- Benefits to host communities should be fair and not restricted by responsiveness requirement

Research Ethics Committees

- Important role for DoH in presenting basic principles and minimum standards
- Balance this with being too specific/proscriptive
- Clarification of role of local REC compared to remote REC's when study sponsor is not local or trial is multi-national

Enhancement

- Consensus that, while important, issue is either sufficiently captured by relevant current articles or may even fall outside of the framework of the DoH

Positions of international organizations

- Important role of DoH as high level principle-driven international standard

- Need to continue to strive for balance between sufficient detail to assist researchers and others versus too much detail that would undermine local circumstances

- Important role of REB's, need to also involve them in discussions of post trial access and benefits
- Post trial access must be made transparent and described prior to approval
- Responsible agents must be identified

- No consensus on best approach to use to determine most appropriate post trial benefits/access

- Any additions or changes to the DoH should only be made where there is a sound and compelling ethical rationale for doing so

- Should only revise provisions that create problems

Insurance/compensation/protection

- Paragraph 14 may not be strong enough
- Should consider a more definitive commitment to some form of protection and allowances for “fair compensation” in the case of complications or adverse outcomes
- May benefit from a separate paragraph

Unproven interventions/off label use

- Paragraph 35 – complex issue
- Delete paragraph? Part of paragraph? First sentence?
- Important distinction between “unproven” and “off-label”
- Strengthen requirement to tie it to research and more clearly reflect the purpose of the paragraph
- Move up in document (Para 4/5)?

Broad consent – Paragraph 25

- Broad/general consent is acceptable to most subjects
- “Broad consent is ethically acceptable”
- Option of tiered consent
- Need for last sentence?
- Change “reuse” to “single or multiple uses”; timeline?; “future uses”

Research in children

- No consensus on need to include children separately in the DoH
- Concepts of assent/dissent/cognitive abilities (Para 28)
- Encourage research in populations under-represented in research (Para 5)