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Comments on 'Multi-jurisdictional review'

Change sentence : "*Researchers **are** the first to consider participant protection as they design..." to "Researchers **must be** the first to consider participant protection as they design..."* as this better reflects the responsibility of researchers, not that they are inherently flawless, and segues with the following sentences better.

Note that in section 3.4 the process as stated is confusing; you state that "*Timelines should be established by the REB of record for researchers to provide the necessary documents, and for local REBs to provide their acknowledgement."* Where in the next paragraph you state that it is the responsibility of the researcher to "*...send that decision and associated final approved materials to the local REBs **from all institutions involved in the research**."* Does this mean that all acknowledgments of all the sites need to be sent to all the other sites? Or only to the site of Record and each site just receives a site of Record approval?

Also, it would be useful to state in section 3.4 that REB's should establish a process whereby substantive and local issues that are raised in multi-jurisdictional research reviews can be managed should they be the REB of record. Simply stating that REB's should talk to each other does not provide much guidance when the timeline being set here is 3 weeks for turn-around. I have seen situations where substantive issues existed in minimal risk studies related to consent and it can take many days to sort out between REB's and researchers. It should also be noted that some REB's do have different interpretation of the Guidelines. Research participants should be assured that the most proper standards of review are being applied to all research that they may participate in.

Comments on 'Broad Consent'

Section 5.0 this sentence just does not make sense when you are talking about obtaining consent for a repository: "*The repository is an important part of the shared responsibility to protect participants."* Suggest deleting as it seems to have no context.

This sentence should also be deleted

"However, it must be acknowledged that not all participants are interested in the details of a repository's governance and their inclusion in the consent form may distract from information that is more relevant to the participant at the time of initial consent."

as it 1) does not segue with the fact that Section 5.4 provides appropriate limited details on what should be provided, 2) 5.4 is the largest subsection for information that should be provided and 3) governance is important for people to make a decision about something that is essentially a long-term investment of their own blood/tissue and they should have at least the same sort of information that is provided for financial investments. In theory, a researcher could put only a website on a consent form and be absolved of providing anything else since all information could be found there. The importance of providing consent for this type of repository research should reflect the respect and consideration that should be shown to people who choose to do this. Shortening or overly simplifying this type of consent could lead to seeing people only as a means to an end, which is not appropriate.

Comments on 'cell line exemptions'

Section 8, suggest inserting a link to the NIH agreement for use of the HeLa cell line.

Comments on Chapter 12.

It is unclear why consent should be sought again for donated gametes once a research idea is generated if consent has been provided for the donation to research already; would the concept for Broad Consent also apply to this section 12.12 (understanding that the broad consent section is also new)?

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