WHO CAN BE AN HRP REVIEWER?

Background

As part of the process for an IRB to consider an Exception from Informed Consent (EFIC) for a research study, the IRB must review and approve a Community Consultation (CC) Plan for each site engaging in the research.

When the University of Utah is the single IRB (SIRB) for a study that plans to employ EFIC, we employ the Human Research Protection (HRP) program or office to help us determine whether the site investigator's CC plan is appropriate for your local population. We provide the HRP Reviewer with a copy of the CC plan, the study protocol, and we ask the HRP Reviewer to provide feedback and recommendations to the SIRB regarding the plan for their community.

Selecting an HRP Reviewer for Your Site

We rely on the HRP representative(s) at each site to select an appropriate HRP Reviewer for the EFIC CC Plan. Your HRP Reviewer should be someone very familiar with the FDA requirements relating to EFIC and community consultation. In addition, the HRP Reviewer can be someone who:

- Is very familiar with the local community under study
- Is willing to provide prompt and detailed feedback on whether or not the CC plan is appropriate for your site, including suggestions/recommendations for improvements/enhancements to the plan
- Works for or has significant experience working with the IRB at the site
- Has experience serving as an advocate for research participants
- Has served on an IRB as a scientist or non-scientist representative, preferably one familiar with the state laws and requirements of the participating site
- Feels comfortable representing/advocating for the interests of the participating community

Points to Consider

There are several things we will ask the HRP Reviewer to provide feedback on relating to the EFIC protocol. Some of the items to consider include:

1. Does the CC plan appropriately provide information to the majority of the community under study? Are there other or better ways to reach the subject pool?
2. Have all appropriate groups/populations been considered for outreach?
3. Are there conversational methods of consultation included that will allow the investigator(s) to hear and respond to the community?
4. If applicable, is there an appropriate method employed in which individuals who wish to be excluded from the research may do so (e.g. opt-out mechanisms)?
5. Will the consultation methods planned be adequate and effective for reaching the target community?
6. Are the consultation methods feasible at your institution or in your community? Can they be effectively deployed as described in the CC plan?
7. Will the proposed plan satisfy the requirements for community consultation as described in FDA guidance?

What about Public Disclosure?

In most cases, a robust and appropriate CC plan will provide the SIRB with enough insight into how to engage the site community that a Public Disclosure (PD) plan can be assessed without detailed input from sources outside the study team. However, if the HRP Reviewer has suggestions or recommendations regarding the PD plan for their local community, please feel free to send those along with your CC plan review.

REFERENCES

"Exception from Informed Consent Requirements for Emergency Research, Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors", Version April 2013. *Accessed online 11/18/2019.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research

Exception from Informed Consent (EFIC) & Planned Emergency Research https://irb.utah.edu/guidelines/fda-requirements/planned-emergency-research.php

Informed Consent Requirements in Emergency Research. *Accessed online 11/18/2019.* https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html

21 CFR 50.24 Exception from informed consent requirements for emergency research. *Accessed online 11/18/2019.* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24