

AAHRPP Emails & Website

IRB In-Service
12-2-19

Training Materials
Training materials for the program

Training Sessions
Training Sessions

Questions of the Week
Knowledge and Application of AAHRPP
Human Research Protection Accreditation Standards

Updated Policies
Changes to policies

AAHRPP REVIEW

- ### What training & educational opportunities are provided to IRB members?
- IRB Member Webpage
 - Human Subject Protection
 - New Member Orientation
 - IRB Mentor
 - CITI - I Have Agreed to be an IRB Community Member. Now What?
 - IRB In-Service
 - Presentations at meetings
 - Regional Human Subject Protection Conference
 - Special topic presentations
-
- AAHRPP REVIEW

- ### Who on the IRB represents special perspectives or populations?
- Representatives:
- Prisoners
 - Pregnant women, fetuses, neonates
 - Children
 - Individuals with impaired consent capacity
 - Other vulnerable populations
- Non-scientist
 - Unaffiliated
- Do other IRB Members listen to your concerns?
- AAHRPP REVIEW

What the Community Member may offer that is not met by other Members?

- Voice for the research participant
- Provide balance to pro-research view
- Provide unbiased perspective
- Represent values of the community, public, patients, etc.



7

Does ORI have resources for potential participants?

Research Participants

Research involving human subjects is based on a combination of scientific methods, knowledge, and understanding, and can involve cultural diversity. Researchers, administrators, government and private institutions participate in their research involving human subjects for many reasons. For example, an institution may wish to address an issue or identify a health problem in their patients, or address public health or environmental health concerns with the existing human population. (https://www.fda.gov/oc/ohrt/faq.html)



Participants

What to consider before you agree to participate in a research study and other resources.

Learn more

Social & Behavioral Health Research

- Information About Participating in Research
- What is a Clinical Trial?
- For Parents and Kids
- Information on Research - an Essential
- What is an Institutional Review Board (IRB)?
- What does Full Accreditation by AAHRPP say About ORI?



8

Who do participants call....

- 📞 Injury? Investigator
- 📞 Concern regarding rights? ORI Director
[hint: toll-free # on every consent form]
- 📞 If international study or non-English Speaking? Determined case-by-case basis
- 📄 Online Anonymous Form-
<https://redcap.uky.edu/redcap/surveys/?s=iB2Nfm>



9

Have you reviewed a study recruiting educationally or economically disadvantaged, and if so what safeguards did you consider?

Inclusion

Exploitation

Undue Influence

Informed Consent

Guidance - www.research.uky.edu/uploads/ori-d1390000-research-involving-economically-or-educationally-disadvantaged-persons

"under the right circumstances leads to better generalizability of research and a more equitable distribution of the potential benefits of research"
Moira Keane, MA, HR Consultant



10

Informed Consent Document

- How do you evaluate whether consent form
 -
 - is understandable,
 - is concise, or
 - Provides Key Information that meets the reasonable person standard?



11

Informed Consent Process

- How do you evaluate the researcher's consent process?
- What suggestions have you made to improve a researcher's process?



12

Informed Consent

- A researcher requests a waiver of informed consent to review existing patient records.
- What criteria do you consider?



13

Consent Waiver Criteria:

- (i) Minimal Risk;
- (ii) Could Not Practicably be Conducted;
- (iii) Identifiable Private Information or Identifiable Biospecimens necessary;
- (iv) Not Adversely Affect Rights & Welfare of Subjects; &
- (v) Whenever Appropriate provide Additional Pertinent Information After Participation.



Waiver of Documentation

Now 3 options:

- Sensitive research
- Minimal risk (on-line, phone, mailed surveys)
- Cultural concern



15

FEEDBACK



How is IRB Performance Evaluated?
Are you given feedback?
Is your workload evaluated?



16

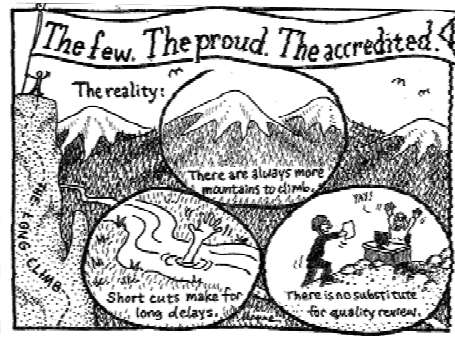
FEEDBACK



Annual Performance Evaluation Questionnaire
Aggregate results provided by email.
ORI runs reports to assess scope, volume, approval times, etc. and makes adjustments as needed.



17



Cartoon © 2008 by JRC. Permission granted for non-commercial reproduction with attribution; all other rights reserved. www.cartoonist.com



18