REACCREDITATION 2020

Document review

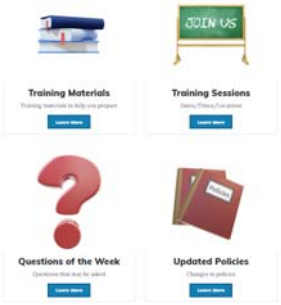
Interviews

Human Research Protection Program (HRPP)

3

AAHRPP Emails & Website

IRB In-Service 12-2-19



4

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

5

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

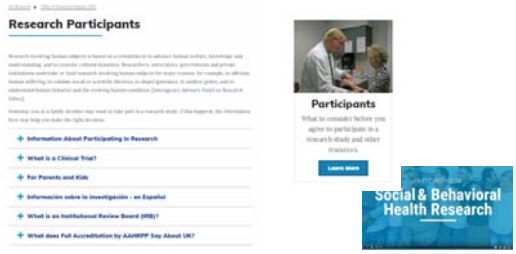
6

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?



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=jB2Nfm

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

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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?

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

FEEDBACK

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

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.