Human Research Protection Program (HRPP) Reaccreditation

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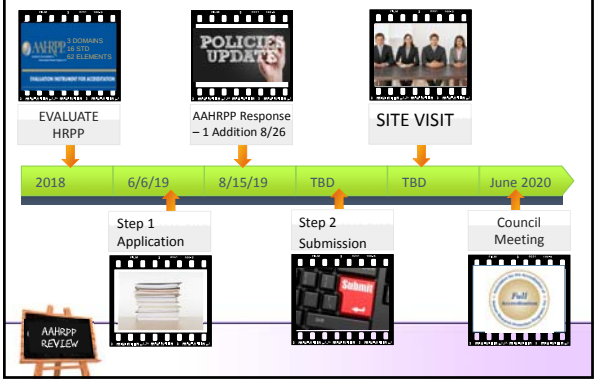
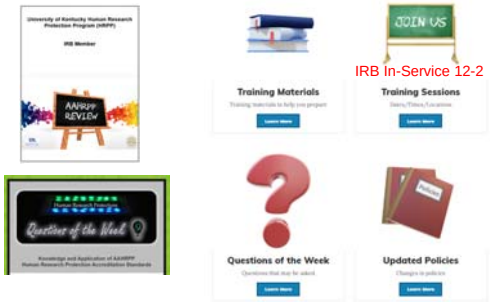
Human Research Protection Program Re-Accreditation Process



AAHRPP Emails & Website



IRB In-Service 12-2

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Key Points

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Quality Assurance / Quality Improvement Reviews

- Administrative
- Directed
- Abbreviated (Wellness Check)

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Researcher Outreach

Office of Research Integrity (ORI) Office Hours

Meet with ORI staff in an informal setting and get immediate feedback and advice on any IRB-related questions.

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How did UK Transition to Revised Common Rule?

- Based on date of submission
- Follow old rule through completion. Transitioning to new rule would require closing existing and opening new protocol.
- Under Revised Rule

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IRB Authority

- How is authority communicated to the research community?
- Can an IRB decision be overturned by the institution?
- Can the intuition disapprove research that has been IRB approved?

HRPP Comprehensive Plan
www.research.uky.edu/uploads/2018-university-kentucky-human-research-protection-program

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Vote: Who has authority to approve revisions?

- Minor Vote 2- (point to who reviews)
- Minor revisions must be Directive or Non Substantive.
- Major Vote 3 or 4- (point to who reviews)
- Revisions tied to regulatory criteria

AAHRPP REVIEW

What's New with Expedited Review?

- Revised Rule no longer required Continuing Review for Post 2019 Expedited
- Non-FDA Regulated Expedited research will undergo an Annual Administrative Review (AAR) instead of a Continuing Review (CR)

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Transition to Single-IRB

- NIH policy went into effect January 2018
- ORI Reliance Team (Jessica & Joe) >100 Agreements since January 2019
- 1-20-2020 Revised Common Rule will require Single-IRB review for most federally-funded collaborative research.

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Abbreviated Application (AA)

- As of October 1, 2019, investigators submitting a Reliance Request will be asked to submit an "Abbreviated Application (AA)" in E-IRB for their ceded research project.
- Provide prompts and links to requirements or processes handled locally, not by the external IRB (COI, HIPAA, Biosafety)

AAHRPP REVIEW

Educationally or Economically Disadvantaged, What safeguards do 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

Informed Consent Document

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

Informed Consent Process

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

PROCESS is described in the Research Description

- Who:
  - PI may delegate to authorized personnel but ultimately responsible
- When:
  - Ample time for participant
  - Key Information FIRST
  - Prior to research activity
  - Ongoing throughout
- How:
  - Minimize coercion, undue influence, therapeutic misconception
  - Use of visuals, aids, verbal concepts, demos, or learning tools
  - Methods to assess understanding

Who is required to sign the informed consent document at UK?

What do federal regulations state about re-consent?

Federal human subject research regulations do not reference the term "re-consent."

…when appropriate, participants will be provided with significant new findings that develop during the research which may relate to their willingness to continue participation (45 CFR 46.116(c)(5)).

Communicating New Information

See Reconsent Notification Guidance for Considerations and Criteria for Determining Communication Method/Process

www.research.uky.edu/uploads/ori-d1000000-would-you-ever-need-re-consent-research-participant-pdf

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PRIMARY IRB REPORTING:

- To regulatory agencies or appropriate officials

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What does ORI/IRB Promptly Report to AAHRPP?

- Any negative actions taken by a government oversight office (OHRP Determination Letters, FDA Warning Letters or restrictions);
- Any lawsuits (i.e., litigation, arbitration, or settlements initiated) related to human subject research protections; or
- Press coverage (TV, newspaper, online publications) of negative nature regarding the UK HRPP.

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