HUMAN SUBJECT RESEARCH

Update on IRB Activities and Guidance for Researchers

March 10, 2022

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Agenda

- IRB activities since September 2021
- Key policy changes
- Improvements to the Cayuse IRB application for new studies
- Tips to help researchers prepare IRB applications
- New process for studies that involve external institutions

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IRB Activities Since September 2021

- New IRB chair: Julia Boehm
- New IRB committee members from Chapman: Jo Armour-Smith, Ian Barnard, and Mary Kennedy
- New experts on the IRB committee: Cheryl Byers and Lisa Rooney
- IRB member training: more robust and use of reviewer checklist
- Re-reviews of federally-funded and select higher risk studies

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Policy Changes

- Human research protection program policy
- Legacy studies (i.e., studies originally submitted before 2018 outside of Cayuse IRB)
  - Starting April 1, legacy studies will need to be resubmitted in Cayuse IRB as a **new study** before their current expiration date
  - Ensures compliance with current regulations and institutional policies
  - Allows expedited studies with expiration dates to be reviewed and approved under the revised Common Rule, which no longer requires annual review

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Updated IRB Application in Cayuse

- Improved IRB application for new studies launched in February
  - Removed unnecessary questions
  - Added required questions
  - Clarified questions, expanded guidance, and provided more context
- Updated IRB applications for renewals and modifications launched in March
- The checklist used by the IRB reviewers is available on the IRB website so researchers can do their own pre-review

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Updated IRB Application: Personnel

- Include only people who are “engaged” in research
- People who are “engaged” obtain:
  - data about participants through intervention or interaction, or manipulation of the participants’ environment
  - identifiable private information or biological specimens from any source
  - the informed consent of human participants for research

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Updated IRB Application: Personnel

- Collaborative Institutional Training Initiative (CITI) training
  - All researchers: “Social and Behavioral Research” or “Biomedical Research”
  - For clinical trials only: “Good Clinical Practices in Social and Behavioral Research” and/or “Good Clinical Practices for Clinical Investigators of Devices”
  - Faculty can link to CITI training, all others attach PDFs
  - Remove expired and duplicate attachments

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Updated IRB Application: Conflicts of Interest

- Expanded definition of conflicts of interest (COI) in human research beyond just financial conflicts
- All research team members are asked to disclose any relationships with an outside entity that:
  - funds the study
  - provide data and other materials for the study
  - could be impacted by the results of the study
- New Human Subjects COI Disclosure Form is submitted for any COI

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Updated IRB Application: Research Description

- Streamlined background information
- Research procedures
  - Clinical trials (i.e., humans prospectively assigned to an intervention to assess health-related biomedical or behavioral outcomes)
  - Devices (e.g., EEG, EMG, motion capture systems, smartphone apps)
    - Evaluating the safety and effectiveness of a device or submitting to the FDA requires more details
- Sample size justification
- Screening: how, when, and with what measure

Updated IRB Application: Risks

- Social risks
  - e.g., reputation or social standing in one's community, family, or peer group
- Legal risks
  - e.g., criminal prosecution for illegal activities
  - Certificates of Confidentiality (CoC)
- Economic risks
  - e.g., employability or financial standing
- Full board review and data and safety monitoring plan (DSMP) when risk is greater than minimal

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Updated IRB Application: Research Documents

- Nearly all documents are uploaded in one section
- Upload **unprotected PDF files** only (no files with track changes)
- File names should indicate type of document and date
- Additional documents (e.g., screening and debriefing materials, translation certificate and translated materials) have dedicated space

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Updated IRB Application: Informed Consent

- Abbreviated consent form (i.e., information sheet) for exempt studies
- Waiver of documentation of consent (i.e., signature)
- Waiver of informed consent in its entirety (e.g., in the context of secondary data analysis)
- Alteration of informed consent (e.g., in the context of deception)
- Parental permission and child assent

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Updated IRB Application: Confidentiality

- Clarity about identifying information (e.g., names, e-mails), de-identified data (e.g., use of codes to link data to identifiers), and anonymous data (i.e., no one can identify individuals)
- Data recording and storage

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Overall Guidance for Researchers

- Answer all relevant questions completely
- Pay attention to detail and be consistent
- Carefully read the exempt and expedited categories before submitting your research to the IRB
- Faculty advisors should review student-led research carefully and thoroughly before submission
- In modifications and when responding to reviewer comments, make changes in the original description of the study itself
- IRB approval does not mean Chapman has the institutional capacity for all research

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Single IRB Review

- Updating policy and procedures for single IRB review
  - **Single IRB review** – a legal arrangement that allows one IRB to review the research on behalf of other engaged institutions
  - **IRB of record** – the IRB that reviews and makes the required regulatory determinations (i.e., the reviewing IRB)
  - **Relying institution** – the institution that cedes IRB responsibilities to the IRB of record (i.e., the relying IRB)
  - **Reliance agreement** (also called an IRB authorization agreement) – a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB
- Incorporating reliance agreements into Cayuse

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Reliance Agreement Considerations

- Local researcher needs to contact the IRB to request permission to be the single IRB of record
  - Each institution will have its own specific process and will want different information to help them decide to be the IRB of record
  - Check with local IRB office for rules related to ceding review and required documents
- A reliance agreement needs to be negotiated between institutions
- All required local ancillary reviews for the sites need to be completed
- Local IRB grants formal permission ("acknowledgment") for collaborating researcher to begin work under a single IRB
- Local researcher must provide participating site's materials related to the local context, consent, conflict of interest training and disclosures, CITI training, policies and procedures, etc.

Questions?

- IRB (irb@chapman.edu)
- Director of Research Integrity, Michael Briggs (mibriggs@chapman.edu)
- IRB Chair, Julia Boehm (jboehm@chapman.edu)

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