HUMAN SUBJECT RESEARCH

Update on IRB Activities and Guidance for Researchers

March 10, 2022
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
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
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
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
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
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
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
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
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
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
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
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
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
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)