Cayuse IRB

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Cayuse IRB

Chapman uses Cayuse IRB for submission and review of human subject research studies in accordance with institutional, federal, ethical, and regulatory standards. Cayuse IRB is an enterprise software program for preparing, submitting, and reviewing studies for IRB approval.
All information is stored in the online Cayuse IRB system and can be accessed securely from any location. Multiple users can simultaneously view and access study documents. Additionally, study submissions can smoothly proceed from study creation to IRB approval, as users receive electronic notifications whenever they need to complete required tasks.

**Exempt Review**
For research to qualify as "Exempt" from the Code of Federal Regulations pertaining to the Protection of Human Subjects (45 CFR 46 full text), the research must be considered minimal risk. Additionally, human subject involvement must fall within one of eight categories listed in 45 CFR 46.104.

Research qualifying for exempt status must be in accordance with the University's ethical standards and training requirements.

The Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations define some research as exempt from IRB review. However, depending on the potential risks subjects may experience, the IRB may require a higher level of review either through the expedited process or by the IRB at a convened meeting. PIs who feel their research exactly fits one of the categories for exemption may submit an Exemption application. Upon receipt, the IRB Administrator, in consultation with the IRB Chair, if needed, will evaluate all requests for exemption and determine whether or not the research is eligible for exempt status. PIs will be informed of the results of the evaluation by letter. PIs are not allowed to make the final determination of exemption. PIs are not authorized to begin until this letter is received.

Modifications that affect the exempt category or the criteria for exempt determination must be submitted as an amendment.

**Criteria to Determine that Subjects of Exempt Research are Protected**
Although exempt research is not covered by the federal regulations, it is not exempt from institutional ethical considerations. The individual making the exempt determination will assure the research meets the criteria of one of the categories for exemption and that ethical standards are met regarding risks, equitable selection of subjects, privacy and confidentiality, and informed consent.

More details about each of the categories is available in the [U.S. Department of Health & Human Services website](https://www.hhs.gov).
the research:

1. All research personnel are trained in ethical principles, relevant federal regulations, and institutional policies governing human subjects research.
2. All subjects are provided pertinent information (e.g., risks and benefits, contact information for investigators and IRB), are selected equitably, and voluntarily consent to participate.
3. Information or unanticipated problems that may increase the risk to the subjects and cause the category of review to be reclassified as expedited or full committee review are immediately reported to the IRB.
4. Complaints from subjects regarding their risks and benefits are immediately reported to the IRB.
5. The privacy of the subjects and confidentiality of the research data will be maintained appropriately to ensure minimal risks to subjects.
6. Reporting, by submission of an amendment request, any changes in the research study that alter the level of risk to subjects.

**Expedited Review**

For research to qualify for "Expedited" review, the research must present no more than minimal privacy, psychological, and/or physical risk to human subjects, and involve only procedures listed in one or more of the nine expedited categories.

NOTE: The expedited categories describe research that is eligible for expedited review. However, full committee review may be required if determined by the IRB.

If a protocol has been determined to be minimal risk it may be considered for expedited review provided that it fits one of the categories authorized by 45 CFR 46.110 for expedited review.

**Studies involving fMRI/MRI scans**

fMRI/MRI studies may be expedited if no contrast is being used and the overall study is minimal risk and all other procedures fit into the expedited categories. The designated reviewer should have the appropriate imaging background and expertise. If the study does utilize radioactive tracers the study will be sent to Full Committee for review. Please note: An External IRB with the appropriate expertise and experience may be necessary for imaging studies involving a radioactive tracer or contrasting agent.
• Make sure that the risks section of the consent, contains the following information:
  o A warning that the subject should not participate if they have any type of metallic object implanted in their body. The MRI may cause these objects to move or heat up.
  o The loudness of the machine (subjects are usually given earplugs)
  o The machine requires the subject to be in an enclosed space for a prolonged duration of time. If the subject is claustrophobic they may wish to opt out of the study. (language may be altered for open MRI)

• The incidental findings language from fMRI-MRI Consent must be included verbatim in every study that utilizes an fMRI or MRI for research purposes only, in either the risk section or its own section called “Incidental Findings”

Please note
• A clinical trial with research scans added that are not done as standard of care may need to add incidental findings language to the consent form.

More details about each of the categories is available in the U.S. Department of Health & Human Services website.

The expedited review proposal may be reviewed and approved by the IRB Chair, IRB Administrator, or IRB designated reviewer.

**Submission and Review Schedule**
Protocols submitted for expedited review may be submitted at any time. There is no timeframe or submission deadlines. At least one IRB member or chair reviews the complete protocol, including any protocol modifications previously approved by the IRB.

**Submission Requirements/Materials Reviewed**
If the protocol meets all requirements for expedited review, the following must be electronically submitted:
1. A completed IRB application, with an electronic signature of the PI.
2. A research proposal describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information.
3. An informed consent document.
4. Verification of training in human subjects research.
5. Recruitment materials (e.g., flyers, posters, web-pages, email messages).
   If applicable:
6. Copies of all instruments if the study involves the use of interviews,
questionnaires, surveys, or similar instruments.

7. Letters of support for external sites.
8. Institutional Biosafety Committee (IBC) approval documentation, if required.
10. Copy of the HHS grant application - Human subject section.

Assignment of Expedited Reviewer
Upon processing, the IRB Administrator(s) will verify the protocol is appropriate for expedited review. They will work with the PI to assure that all required documentation has been uploaded and the application is complete. The research protocols are then presented to the IRB Chair, or other IRB designated reviewer. Designated reviewers will be experienced IRB members, defined as having served on the IRB for at least one year. The IRB Administrator will assure that reviewers do not have a conflict of interest.

Reviewer Considerations
Protocols undergoing expedited review are reviewed to assure:

1. The research meets all applicability criteria and falls into one or more categories of research eligible for review using the expedited procedure. 45 CFR 46.110
2. The regulatory criteria for approval are met.
3. Investigators and their research staff have appropriate and sufficient qualifications, expertise, and training.

Applicability Criteria
The following criteria should be considered for research undergoing expedited review:

1. The research procedures present no more than minimal risk to subjects.
2. The identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
3. The research is not classified.

Criteria for IRB Approval of Research
In order to approve research, the IRB will provide ethical and scientific/scholarly review of all human subjects research to determine that all of the requirements of 45 CFR 46.111 criteria for IRB approval of research are satisfied.

Protocols that may be minimal risk but are not included on the list of activities that may undergo expedited review are reviewed at a convened meeting of the IRB. The IRB may then designate that a protocol is minimal risk and determine that the protocol may undergo an expedited review process during its subsequent reviews for continuation.
Scientific/Scholarly Review
The IRB relies upon the IRB Administrator to assure that submissions contain appropriate information to facilitate IRB review. The IRB is ultimately responsible for the scientific/scholarly and ethical review of the research. The IRB may evaluate methods to the extent that the research design impinges upon the consideration of risk and benefit to the participants and may provide advice or make recommendations on methods even in instances where an evaluation of methods does not affect approvability.

Length of Approval Period for Full Committee Review
The interval for continuing review will be at least once per year (not to exceed 365 days; 366 days during a leap year) but may be shorter. If the protocol was approved or approved with explicit conditions, the expiration date is calculated from the date of review and approval by the IRB Chair or designated reviewer. Protocols that have not undergone continuing review will expire at midnight on the expiration date. Research activities may not continue after midnight of the expiration date. A new submission will be required if the research need to continue.

Reporting of Expedited Review to the IRB
The protocol number, title, PI name, and the category of research for which each protocol that was approved using an expedited review procedure is reported to the IRB at the next scheduled meeting.

Full Committee Review
If the research does not qualify as Exempt or Expedited based on the above research category descriptions, the research will require full committee review.

The following is required to be electronically submitted and included in the submission package:
1. A completed IRB application with an electronic signature of the PI.
2. A research narrative describing the rationale for the study, research questions to be answered, information that allows the IRB to determine whether selection of participants will be equitable, methods, procedures, data analysis plan, and other required information that will allow the IRB reviewer(s) to conduct an analysis of the risks and potential benefits.
3. An informed consent document.
4. Verification of training in human subjects research.
5. Recruitment materials (e.g., flyers, posters, web-pages, email messages).
6. Copies of all instruments if the study involves the use of interviews, questionnaires, surveys, or similar instruments.

If applicable:
7. Letters of support for external sites.
8. Review/confirmation from the Institutional Biosafety Committee (IBC) or other committee as needed.
9. Sponsor protocol (and the Investigator's Brochure, when one exists).
10. Data use agreements.
11. Letter to verify accurate translations of non-English forms.
12. Copy of the Health & Human Services (HHS) grant application - Human subjects section.

**Assignment of Primary and Secondary Reviewers**
The IRB Administrator will assign each protocol to IRB members who, as primary and secondary reviewers, will review the protocol in detail and act as a liaison between the IRB and the PI. Primary and secondary reviewers are assigned, as closely as possible, according to their expertise with the research being proposed and/or the subject population(s) being enrolled and their appropriate scientific or scholarly expertise to review the protocol. Protocols are not assigned to reviewers who have a conflict of interest (COI) or who have academic appointments in the same administrative unit as the PI. The primary and secondary reviewers may contact the investigator, co-investigators, other IRB members, or outside sources as necessary to ensure a thorough evaluation of risks and benefits of the proposed research.

At times, the IRB may not have the appropriate expertise to review the study for scientific or scholarly validity. In those cases, the IRB Chair will consider who in the University faculty or community has the appropriate scientific expertise to serve as an expert consultant to perform an in-depth review of the study. Consultants will disclose any COI prior to performing the review and those with a COI will not be used for protocol review.

**Distribution of Submitted Materials to IRB Members**
Meeting documents will be accessible to the IRB members 5-10 days prior to the scheduled meeting. The primary and secondary reviewers are expected to review all materials for their assigned protocol(s). IRB members who are not assigned as primary or secondary reviewers are expected to review at least the application, protocol, and consent forms for research studies being considered at the meeting but, of course, may review all submitted materials as follows:

1. IRB application.
2. Informed consent document
3. Request to include vulnerable populations as subjects (e.g., pregnant women, fetuses, children, prisoners, cognitively impaired adults).
4. Recruitment material.
5. Copies of all instruments if the study involves the use of interviews, questionnaires, surveys, or similar instruments.

If applicable:
IRB Meeting Schedule

The IRB is generally scheduled to meet on the second Monday of each month but may be adjusted as necessary to accommodate member schedules, quarter breaks, and other factors that affect member availability.

Presentation and Discussion of Protocols

Protocols undergoing initial and continuing review at the convened meeting are presented individually to the IRB by the Primary and Secondary Reviewers. At the invitation of the IRB, PIs may attend meetings to address specific concerns regarding research protocols, but will be asked to leave the meeting during all deliberations and votes. IRB Administrators will assure members with appropriate scientific expertise, local knowledge, and other expertise specific to the protocols are present at the IRB meeting, along with at least one member who is knowledgeable about or experienced in working with vulnerable subjects, when research involving subjects who are vulnerable to coercion are reviewed. If a member with the appropriate expertise, knowledge, or experience in working with the specific vulnerable population cannot be present, the IRB Administrators will notify the IRB Chair or Director of Integrity to obtain a consultant, if needed, to provide a written report of their evaluation of the protocol.

To be properly presented and discussed, a quorum of the members, which must include a non-scientist, an unaffiliated member, and a prisoner representative (if research including prisoners is discussed) must be present for the entire presentation, discussion, and deliberation. The IRB Administrator (or designee) will determine if a quorum of members is present and inform the Chair when quorum is met. Members not present for a substantial part of the discussion and deliberations should abstain from voting. The presence of a quorum of members is documented in the meeting minutes. For those protocols undergoing initial review, the following are discussed in detail (list is not all-inclusive):

1. The regulatory criteria for approval at 45 CFR 46.111 are met.
2. The setting in which the research occurs (i.e., investigators have adequate time, staff, and facilities to safely conduct and complete the research).
3. The scientific and ethical justification for including vulnerable populations (e.g., children, prisoners, pregnant women, fetuses, and cognitively impaired adults), if applicable.
4. Analysis of the procedures to minimize risk.
5. The procedures to be used to ensure protection of subject privacy and data confidentiality.
6. The scientific qualifications and experience of the investigators and their research
7. The human subjects protection training of the investigators and their research staff.
8. Potential or disclosed investigator conflict of interest.

If applicable:
9. The scientific and ethical justification for excluding classes of persons from the research.
10. Written consultant reports. (If the protocol was reviewed by a consultant, the consultant will not be present for deliberation and the voting on the protocol.)

Criteria for IRB Approval of Research
In order to approve research, the IRB will provide ethical and scientific review of all human subjects research to the extent necessary to determine that all of the requirements of 45 CFR46.111 Criteria for IRB approval of research are satisfied. Visit the [HHS website](http://www.hhs.gov).

To ensure that all regulatory requirements for review have been met, a reviewer checklist may be utilized.

Scientific/Scholarly Review
The IRB relies upon the IRB administrative staff to assure that submissions contain appropriate information to facilitate IRB review. The IRB is ultimately responsible for the scientific/scholarly and ethical review of the research. The IRB may evaluate methods to the extent that the research design impinges upon the consideration of risk and benefit to the participants and may provide advice or make recommendations on methods even in instances where an evaluation of methods does not affect approvability.

Length of Approval Period
The IRB will also determine the interval for the continuing review of the research, appropriate to the degree of risks that will be experienced by subjects. The following conditions are likely to require review more often than annually:

1. There is a high degree of risk to subjects.
2. The stage of research is such that many of the risks are unknown.
3. The proposed procedures have not been used in humans.
4. There have been confirmed instances of serious or continuing noncompliance.
5. An IRB member believes more frequent review is required.
6. Other reasons for which the IRB requests closer monitoring.

Possible IRB Protocol Determinations
Either the IRB at a convened meeting or a designated reviewer (for expedited protocols)
will render one of the following determinations for each protocol:

1. **Approved**: Approved by the IRB as written with no explicit conditions.

2. **Minor Stipulations**: Approved with requirements for minor changes or pending letters of intent from schools or other research sites. These will be identified to the PI and must be completed and documented prior to beginning the research. For these conditions, the IRB Administrators, in consultation with IRB Chairs designated as reviewers, may approve the research on behalf of the IRB upon reviewing the PI's adequate response(s) to the conditions.

3. **Return to PI**: Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications, or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full committee meeting in order to clarify the points in question. The PI must revise the protocol, consent forms, or other documents as specified by the IRB and re-submit the entire protocol for full review at a convened meeting. The PI may request reconsideration of determination by submitting a written response to the IRB. The IRB will invite the PI to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI. The second decision is final.

4. **Disapproved**: This determination may only be made at a convened IRB meeting. The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. The protocol and/or other documents will need to be completely re-written and re-submitted as a new submission. PIs may request reconsideration of disapproved studies by submitting a written response to the IRB. The IRB will invite the PI to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI. For those protocols reviewed using the expedited review process, the designated reviewer may render decisions of approved, approved with explicit conditions, or deferred to full committee. The designated reviewer may not render a decision of disapproved. A decision of protocol disapproval may only be rendered by the IRB at a convened meeting.

5. **Not Expedited/Not Exempt**: This determination may be made by an Expedited Reviewer if the reviewer determines that the Full Committee is more appropriate or necessary to review due to concerns about the protocol design or insufficient human subjects protections.

### Notifications of Determinations

**Exempt Research**

If the research study is determined to meet the criteria for exempt status, the IRB Administrator or a designated member will send an Exempt Determination letter to the
By agreeing to the PI Attestation outlined in the IRB Application, the investigator assures that all investigators and co-investigators are trained in the ethical principles, relevant Federal Regulations and institutional policies governing human subjects research. The investigator assures that:

1. Human subjects will voluntarily consent to participate in the research when appropriate (e.g., surveys, interviews) and investigators will provide subjects with pertinent information such as risks and benefits of participation, contact information for investigators and the IRB office, etc.
2. Human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed.
3. The IRB will be immediately informed of any information or unanticipated problems that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full Committee Review.
4. The IRB will be immediately informed of any complaints from participants regarding their risks and benefits.
5. Confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

**Expedited Review**
Within five working days after the protocol is reviewed by a designated reviewer, the PI will receive a letter of the IRB determination. An approval letter requires no further action and the PI can begin research. Letters giving approval with stipulations will contain a list of required conditions and PIs will not receive final approval until all conditions have been met. When the PI has responded appropriately and completely in a letter to the IRB office addressing all conditions, then final approval is granted. The PI will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For deferred protocols, the PI will be notified by letter of the reasons the protocol was deferred. In order to have the protocol reviewed again, the PI must respond to all the tabled reasons by adjusting the submission documents or attaching additional supportive documentation.

**Full Committee Review**
Within five working days after each IRB meeting a letter is prepared and sent to the PI of each reviewed protocol notifying them of the IRB determination for the protocol. An approval letter requires no further action and the PI can begin research.

Letters giving approval with conditions will contain a list of required conditions and PIs will not receive final approval until all required stipulations have been met. Along with the determination, the IRB will determine whether the PI’s responses to the stipulations...
will need to be reviewed for appropriateness and completeness at another IRB convened meeting or by the IRB Chair or designated reviewer. Responses to clarifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. When the PI has responded to all conditions appropriately and completely through Cayuse IRB then final approval is granted. The PI will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For deferred protocols, the PI will be notified by letter the reasons the protocol was deferred. The entire protocol, with all supporting documents, must be revised as needed and resubmitted.

The PI of protocols that are disapproved will receive a letter that delineates the reasons for disapproval.

**Final Approval and Expiration Dates**
If a study is approved with no conditions, the final approval is effective the day the study is approved, i.e., the date of the convened IRB meeting for full committee protocols. For federally funded expedited protocols, the final approval is the date of reviewer's approval for expedited protocols.

If a study is approved with explicit conditions, the final approval is effective on the day the protocol was reviewed and conditions were imposed by the IRB at a convened meeting (full committee protocols) or the date that the reviewer approved the expedited protocol. This determination will be documented in the IRB meeting minutes. Or, for expedited protocols, in the monthly IRB report. For those studies requiring continuing review, the expiration date for the approval is based on the date it was approved at a convened meeting or approved by a designated reviewer and will be no longer than 365 days (366 days if during a leap year) from the approval date, but may be sooner if more frequent review is stipulated by the IRB.