

## Initial Review of Human Subjects Research

### Purpose

- 1) This policy sets forth both the criteria and process when reviewing initial research proposals that involve human participants.

### Policy

- 1) Research studies involving human participants must fulfill defined regulatory criteria ([45 CFR 46.111](#); [21 CFR 56.111](#)) before Principal Investigators (PIs) can perform any research activities. The Institutional Review Board (IRB) at Chapman University reviews and approves research studies that propose to enroll human participants. There are three levels of IRB review: exempt, expedited, and full board review. For each level of review, the primary responsibility of the Chapman IRB is to ensure that research participants are protected from experiencing undue risk and from being deprived of their personal rights. Guided by the Belmont Report's ethical framework, three ethical principles underlie the conduct of research: respect for persons, beneficence, and justice.

## Exempt Review

### Purpose

- 1) This policy sets forth both the criteria and process to review research eligible for exempt determinations.

### Policy

- 1) At Chapman, the IRB must determine whether research qualifies as exempt; investigators do not make exempt research determinations. Use the streamlined Exempt submission in Cayuse.
- 2) Even if research qualifies for exemption, the research still must adhere to Chapman's ethical standards, this policy, and research training requirements.
  - a) Even though Chapman's IRB could determine that research qualifies as exempt, the research could have ethical concerns. In this case, Chapman's IRB would review the research through expedited review procedures or at a convened IRB meeting.
- 3) The Chapman IRB utilizes a checklist review method to ensure that human participants will be protected while participating in research. The checklist contains the categories for exempt research and other specific requirements for exempt research.

## Research Categories Eligible for Exempt Determinations

For research to qualify as exempt, the research (as a whole) must satisfy one or more of the following regulatory categories:

- 1) **Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - a) **Commonly accepted educational settings** traditionally imply schools. Educational settings may have a broader meaning, one that accounts for learning environments in which adults, clients, patients, professionals, or teachers commonly receive education.
  - b) **Research participation** must not be a condition of the learning environment or any course curricula. Students and learners should retain the right to refuse to take part in research without sacrificing their standing in educational setting.

### Examples of studies under this Category:

1. A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practices.
  2. A study comparing two curricula that are currently being implemented in a school. Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials (but not about specific students).
  3. A study comparing driver's education curricula offered by area driving schools. The researcher will observe classes and compare group driving test scores at the end of the courses.
- 2) **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
    - a) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; or
    - b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.
    - c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§ 46.111\(a\)\(7\)](#).

### Examples of studies under this Category:

1. A study involving an anonymous survey regarding workplace satisfaction at area firms.
2. An observational study of pedestrians crossing a street; the researcher takes notes of what occurs, recording the sex, race, and type of clothing of pedestrians, but does not interact with participants.

- 3) **Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at the criteria (a),(b), or (c) is met:
- a) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; or
  - b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or
  - c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§ 46.111\(a\)\(7\)](#).

If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the **subject authorizes** the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research. See sample language on the Chapman Informed Consent website. Otherwise, the Chapman IRB reviews all research involving deception either by [expedited review procedures](#) or by the [convened IRB](#).

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Examples of benign behavioral interventions that qualify for exemption include having participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

- (i) If the research involves deceiving the participants about the nature or purposes of the research, this exemption would not be applicable unless the subject authorizes the deception. Authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. The final rule allows this type of research to occur without the requirements of informed consent because the intervention is not likely to result in harm or offense to the subject, and the subject must prospectively agree to the intervention and the data collection.

Examples of studies under this Category:

1. A study that involves asking subjects to play an online game that takes about 90 minutes to complete.
2. A study that involves asking subjects to solve puzzles under various noise conditions. Study procedures take about 30 minutes.
3. Healthy adult subjects are asked to take part in two 2 hour-long assessments of memory, attention, and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software.

- 4) **Category 4:** Secondary research for which consent is not required: Secondary research uses identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
- a) The identifiable private information or identifiable biospecimens are publicly available;
  - b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; or
  - c) Research studies that involve Health Insurance Portability and Accountability Act (HIPAA)-regulated information or data will be reviewed in accordance with HIPAA Privacy Rule for research. *Note that at this time, Chapman University is not a HIPAA Covered Entity.*
  - d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, and conducted in compliance with [45 CFR 46.104\(d\)\(4\)\(iv\)](#).

Examples of studies under this Category:

- 1. A research study of treatment outcomes for a drug that involves only the review of patient charts.
- 2. A graduate student has access to identifiable data from a study previously conducted by her faculty advisor, but she only records de-identified data into her own research records.

- 5) **Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects, and that are designed to study, evaluate, improve, or otherwise examine:
- a) public benefit or service programs;
  - b) procedures for obtaining benefits or services under those programs;
  - c) possible changes in or alternatives to those programs or procedures; or
  - d) possible changes in methods or levels of payment for benefits or services under those programs.
- 6) **Category 6:** Taste and food quality evaluation and consumer acceptance studies,
- a) if wholesome foods without additives are consumed, or
  - b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

Examples of studies under this Category:

- 1. A taste study evaluating the differences in taste of various types of apples grown nationally  
A taste study analyzing the effects of an additive to beef if the additive has been determined to be safe by the FDA
- 2. The taste effects of a low-level environmental contaminant on a food product that has been deemed safe by the FDA and EPA

- 7) **Categories 7 & 8** do not apply to research at Chapman University.

## Regulatory Limitations on Exempt Research Involving Vulnerable Populations

- 1) **Children.** For research involving children, Category 2 only applies to studies involving educational tests and observations of public behavior when investigators **do not** participate in the activities being observed. If investigators engage with children, or if the research involves surveys or interviews, category 2 cannot be utilized. In addition, research with children involving benign interventions (category 3) does not qualify for exemption. All other exempt categories can be utilized for research involving children.
- 2) **Prisoners.** Although the Chapman IRB does not currently review research involving prisoners, research that proposes to enroll prisoners may not qualify for exemption ([45 CFR 46.301\(a\)](#)), except when the research intends to involve a broader enrollment population of which prisoners would only be enrolled incidentally in the research.
- 3) **Other defined vulnerable populations.** The IRB will review whether research activities could qualify for exemption when they intend to enroll individuals who are cognitively impaired or economically or educationally disadvantaged. The IRB will determine eligibility for exempt status with attention to the individuals' vulnerable status.

## Procedures for Exempt Review

- 1) Investigators must complete and submit an initial submission in Cayuse IRB and select exempt review under the "Study Information" section. In addition, investigators should describe the:
  - a) Research purpose
  - b) Research procedures and methodology
  - c) Risks and benefits
  - d) Confidentiality of research data and provide supporting documents as relevant (e.g., consent forms, recruitment materials, surveys).
- 2) The IRB administrator assures that reviewers do not have a conflict of interest.
- 3) The IRB administrator assigns research to the IRB Chair or other designated IRB reviewers with appropriate scientific, scholarly, regulatory, or other expertise, to conduct an in-depth review of the submission.
- 4) IRB Chairs or designated IRB reviewers are authorized to review requests for research to be exempt, including those research activities that require limited IRB review as a condition of exemption.
  - a) IRB Chairs or designated IRB reviewers will evaluate requests for research to be exempt and determine whether it satisfies the categories for exemption, and whether adequate provisions have been made to protect both the privacy of human participants and maintain the confidentiality of the data to be collected.
  - b) IRB Chairs or designated IRB reviewers will document applicable exempt categories on the IRB reviewer checklist.
    - i) Determinations of exempt research are documented and archived in the Cayuse IRB system.
  - c) IRB Chairs or designated IRB reviewers are also authorized to request clarifications or modifications or to refer research to be reviewed by expedited or full board procedures.

- i) During their reviews, IRB Chairs or designated IRB reviewers determine whether additional measures or safeguards should be established to protect the rights and welfare of the research participants.
  - d) Researchers will receive the Chapman IRB determination letter in which the applicable exempt category will be documented.
    - i) Researchers must not begin research or perform research procedures (this includes collecting any data intended for research purposes) until the IRB has issued the determination letter.
  - e) Determinations for exempt research require a three-year administrative check-in with PIs. Cayuse IRB sends an automated email informing PIs either to inform the IRB they wish to continue the research with how it was approved, close their exempt research application in Cayuse IRB, if completed, or make modifications to the application to continue with the exempt research.
- 5) When the Chapman IRB has granted an exempt determination, investigators are required to submit any proposed changes to their research via a modification so the IRB can review the study as modified and ensure that the research still qualifies to be exempt according to the regulatory criteria.

### Limited IRB Review

- 1) Limited IRB review is a type of review that must be conducted in order to deem certain research exempt.
  - a) At Chapman, limited IRB review is conducted, at minimum, through expedited review procedures, that is, either by the IRB Chair or an experienced IRB member designated by the IRB Chair.
  - b) Under limited review, an IRB does not consider all the IRB approval criteria under [45 CFR 46.111](#); rather, IRB review is limited to determining whether certain conditions are met.
  - c) Limited IRB review is required to be conducted, as described in the regulations for the protection of human participants at [45 CFR 46.104](#):
    - i) For research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior when the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. ([45 CFR 46.104\(d\)\(2\)\(iii\)](#)); or
    - ii) For research involving benign behavioral interventions in conjunction with specified data collection methods when information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. ([45 CFR 46.104\(d\)\(3\)\(i\)\(C\)](#)).
  - d) When reviewing such research, the Chapman IRB is required to determine that there are adequate provisions in place to protect the privacy of participants and maintain confidentiality of the data.
    - i) If the IRB finds that adequate provisions are in place, the study can be deemed exempt.
    - ii) Conversely, if the IRB finds that adequate provisions are not in place, the IRB can require changes to the research before the IRB deems the research to be exempt. If the changes are not implemented, or cannot be implemented, then the IRB will refer the research to be reviewed by the convened IRB.



# Expedited Review

## Purpose

- 1) This policy sets forth both the criteria and process for the initial review of research involving human participants reviewed under expedited procedures. In accordance with federal regulations, the Chapman Institutional Review Board (IRB) uses expedited review procedures to conduct initial limited review of certain exempt research (see [Research Categories Eligible for Limited Review](#)), as well as initial review of minimal risk research that satisfies certain criteria (see [Research Categories Eligible for Expedited Review](#)).

## Policy

- 1) The IRB may review research activities through expedited review procedures when those research activities:
  - a) Present no more than *minimal risk* to human participants.
  - b) Describe reasonable and adequate protections so that privacy risks and breaches of confidentiality are no greater than minimal if the identification of the participants or their responses will reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.
  - c) Consist of procedures detailed in one or more of the defined categories in the regulations at [Federal Register \(FR\) Volume 63, No 216](#).
  - d) Involve research for which limited IRB review is a condition of exemption under [45 CFR 46.104\(d\)\(2\)\(iii\)](#); [45 CFR 46.104\(d\)\(3\)\(i\)\(C\)](#)
- 2) Research that **cannot** be reviewed by expedited procedures include:
  - a) Classified research involving human participants.
  - b) Research requiring a device risk determination.
- 3) Initial review of minimal risk research must be consistent with the regulatory criteria to approve research involving human participants ([45 CFR 46.111](#)).
  - a) Conversely, initial review of research requiring limited IRB review as a condition for exemption need only consider whether there are adequate provisions in place to protect the privacy of participants and maintain confidentiality of the data.
- 4) IRB members receive reports at the convened IRB meeting apprising them of each research study that was approved through expedited review procedures ([45 CFR 46.110\(c\)](#)), which includes the:
  - a) IRB submission number
  - b) Research study title
  - c) Name of PI
- 5) The Chapman IRB utilizes a checklist review method to ensure that human participants will be protected while participating in research. The IRB reviewer checklist incorporates the regulatory criteria to review and approve/re-approve research involving human participants. The checklist assures that the regulatory criteria have been fulfilled and where applicable; it also contains other requirements to approve proposed research.

## Research Categories Eligible for Expedited Review

For research to qualify as expedited, the research (as a whole) must satisfy one or more of the following regulatory categories:

- 1) **Category 1:** Clinical studies of drugs and medical devices only when conditions (a) or (b) are met:
  - a) Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    - i) Research involving drugs cannot take place at Chapman University. For more information, please refer to [Chapman's Human Research Protection Program Policy](#), section "Evaluation of Risk by the IRB."
  - b) Research on medical devices for which (i) an investigational device exemption application ([21 CFR 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; **or**
  - b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
- 3) **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.
  - a) Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.



- 4) **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
  - a) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 5) **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- 6) **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7) **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## **Procedures for Expedited Review**

- 1) The IRB administrator conducts an administrative review of new studies utilizing a checklist to assess and verify that the proposed research study qualifies expedited review.
- 2) The IRB administrator assures that reviewers do not have a conflict of interest.
- 3) The IRB administrator assigns research to the IRB Chair or other designated IRB reviewers with appropriate scientific, scholarly, regulatory, or other expertise, to conduct an in-depth review of the submission.
  - a) IRB Chairs or designated IRB reviewers may approve the research or request changes to secure approval of the research.
  - b) Research cannot be disapproved using expedited review procedures; such applications must be referred to the convened IRB for review. Only after the convened IRB has reviewed the proposed research can a study be disapproved by the convened IRB.
- 4) IRB Chairs or designated IRB reviewers will document applicable expedited categories on the IRB reviewer checklist.
- 5) Research that has been approved through expedited review procedures receive an approval date the day the IRB Chair or designated IRB reviewer grants approval.

- 6) Researchers will receive the Chapman IRB approval letter in which the applicable expedited category will be documented.
  - a) When one or more of the expedited categories are applicable to the proposed research, the IRB Chairs or designated IRB reviewers document the applicable categories on the IRB reviewer checklist.
  - b) Researchers must not begin research or perform research procedures (this includes collecting any data intended for research purposes) until the IRB has issued the approval letter.
- 7) Renewal of research is not required in the following circumstances and research will therefore not be given an expiration date when:
  - a) Research is eligible for expedited review and not FDA regulated.
  - b) Research is eligible for expedited review and not deemed to require continuing review.
  - c) Research is reviewed by the IRB via limited IRB review.
  - d) Research eligible for expedited review but deemed to require continuing review, that involves only data analysis, including analysis of identifiable private information or identifiable samples, or research assessing follow-up data from research procedures that participants have already completed.

### **Possible IRB Determinations for Expedited Review**

- 1) The IRB determinations made during initial review of research meeting the criteria for expedited review comprise of the following:
  - a) **Approved:** Approved by the IRB as written without explicit conditions. The research may proceed.
  - b) **Minor Stipulations:** The IRB has determined that research is approved with required minor changes, or stipulations, or pending letters of intent from schools or other research sites.
    - i) Minor changes that are required will be clearly delineated so that the PIs understand the IRB's stipulations and can address them fully.
    - ii) Before any research begins, the PIs must address and complete the IRB's stipulations to obtain full IRB approval.
  - c) **Deferred:** The IRB requires additional substantive clarification(s) regarding the proposed research; the research lacks sufficient information and the IRB cannot establish whether it satisfies the criteria for IRB approval of research ([45 CFR 46.111](#); [21 CFR 56.111](#)). The research may not proceed until the IRB has approved a revised application incorporating all necessary information.

## Full Board Review

### Purpose

- 1) This policy sets forth both the criteria and process when reviewing initial research proposals that involve human participants and require full board review (i.e., reviewed by the convened IRB).

### Policy

- 1) Except when an exempt determination is made or expedited review procedures are applied, the Chapman IRB must review research involving human participants at convened meetings, often referred to as full board reviews or full committee reviews. At the convened meetings, a quorum of the IRB committee must be present.
- 2) The Chapman IRB utilizes a checklist review method to ensure that human participants will be protected while participating in research. The IRB reviewer checklist incorporates the regulatory criteria to review and approve research involving human participants. It assures that the regulatory criteria have been fulfilled and where applicable, it also contains other requirements to approve proposed research.

### Quorum

- 1) Quorum consists of a simple majority of the IRB voting membership, which must include at least one member whose primary concern and expertise are in non-scientific areas.
- 2) The IRB Chair, with support from the IRB administrator, will confirm that quorum has been met before calling the meeting to order. The IRB Chair, with support from the IRB administrator, assumes the responsibility to ensure that convened IRB meetings maintain quorum during review and deliberation.
  - a) IRB members must only vote to make review determinations when a quorum is present; accordingly, the IRB administrator will document the votes in the convened meeting minutes.
  - b) The IRB administrator records both arrivals and departures of all members; the IRB administrator must notify the IRB Chair if quorum is not present.
    - i) If quorum cannot be maintained, the proposed research being reviewed must either be deferred to a subsequent meeting or the meeting must cease.
      - (1) Decisions on research can only be made if the majority of the voting members agree on the decision.
      - (2) IRB members who have disclosed a conflict of interest may not vote as a member of the majority.
        - (a) If IRB members recuse themselves because of a conflict of interest, then they cannot be counted to fulfill quorum requirements.
        - (b) Recused IRB members are not counted among those who vote or abstain from voting.
        - (c) If quorum cannot be present because IRB members recuse themselves, the proposed research being reviewed must either be deferred to a subsequent meeting or the meeting must cease.

## Procedures for Full Board Review

- 1) Chapman's IRB utilizes a primary and secondary reviewer system.
  - a) The IRB administrator(s) evaluates and assigns the application, as closely as possible, to primary reviewers and secondary reviewers whose scientific or scholarly expertise align appropriately to conduct a review of the research.
  - b) Primary and secondary reviewers receive assignments to review research involving human participants (e.g., initial review of research, renewal of research, modifications, incident reports) prior to the convened board meeting.
    - i) **Vulnerable Populations.** When assigning reviews, the IRB administrator(s) identifies participant populations likely to be vulnerable to coercion or undue influence.
      - (1) If identified, Chapman's IRB ensures that at least one IRB member knowledgeable about or experienced in working with the vulnerable participants will be assigned to review the proposed research.
    - ii) IRB members will not be assigned to review proposed research if they have a conflict of interest with the research.
  - c) If the Chapman IRB cannot identify a primary or secondary reviewer who possesses the appropriate scientific or scholarly expertise to review proposed research, then the IRB Chair will solicit expert consultants within the Chapman University faculty or from members of the community who possess the knowledge to perform a thorough review of the proposed research.
    - i) Expert consultants who review research for the IRB must disclose any potential conflicts of interest before they conduct their reviews.
    - ii) Consultants cannot vote and do not count toward quorum for a convened meeting.
- 2) Chapman IRB members are required to have access to and review the following materials prior to a convened meeting:
  - a) Cayuse IRB submission for new studies.
  - b) Informed consent document.
  - c) Parental permission and/or assent form(s).
  - d) Recruitment material.
  - e) Copies of all participant facing materials (e.g., screening/interview scripts, questionnaires, surveys, or similar instruments).
  - f) Other materials as relevant (e.g., debriefing forms, documents translated into languages other than English, letters of permission from external sites).

- 3) In advance of convened meetings, primary reviewers must receive and review the submitted documents sufficiently enough to not only present findings comprehensively but also deliberate productively about the proposed research. Primary reviewers lead the discussions of their assigned reviews at the convened meeting.
  - a) Primary reviewers assume the responsibility for:
    - i) Presenting an overview of the research and their findings.
    - ii) Providing an assessment of the research's scientific and scholarly merits.
    - iii) Discussing the risks and benefits of the research.
    - iv) Reviewing the consent process, where appropriate.
    - v) Recommending specific actions that the IRB should take.
- 4) Secondary reviewers, in advance of the convened meetings, are to review the application and all submitted documents, as well as the informed consent document and process described in the proposed research. During discussions and deliberations, secondary reviewers should share their insights and perspectives from their reviews.
- 5) Both primary and secondary reviewers complete the IRB reviewer checklist that describes their assessment of the research.
  - a) Reviewers determine whether the proposed research meets the regulatory criteria for initial approval ([45 CFR 46.111](#); [21 CFR 56.111](#)).
  - b) When IRB reviewers necessitate them, additional checklists are utilized and required when the IRB must consider and document additional regulatory requirements to grant approval of research (e.g., research involving devices).
  - c) Completed IRB reviewer checklists are archived in the Cayuse IRB system or through electronic shared storage; they become part of Chapman's official electronic record of IRB review of research involving human participants.
- 6) All IRB members should be familiar with the items to be reviewed by the convened board. IRB members should review the checklists completed by the primary and secondary reviewers, as well as any reports by consultants, as applicable.

## **IRB Approval and Expiration Dates**

- 1) Research activities that the IRB has approved without explicit conditions have an effective approval starting on the day they are approved; that is, the date the convened IRB reviewed and approved the proposed research.
- 2) If the IRB has approved research activities with explicit conditions, that research will receive a final approval date that is effective on the day the IRB issued approval with the conditions (e.g., the date of the convened meeting).

- 3) Period of Approval. Research approved by the convened IRB requires renewal of research. The approval period is based on the date the convened IRB approved the research. The approval period will not surpass 365 calendar days (366 calendar days if approval has been granted during a leap year) from the approval date. In certain instances, this review interval may be sooner than annually if the IRB determines more frequent review is necessary as noted below.
  - a) In some instances, shorter renewal intervals (e.g., semiannually, quarterly, or after a determined subject enrollment number) may be stipulated. The IRB meeting minutes will document and justify how the convened IRB has determined the review interval.
    - (1) The list that follows provides examples of instances when the IRB could require shorter continuing review intervals:
      - (a) There is a high degree of risk to participants.
      - (b) The stage of research is such that many of the risks are unknown.
      - (c) The proposed procedures have not been used in human participants.
      - (d) There have been confirmed instances of serious or continuing noncompliance.
      - (e) An IRB member believes more frequent review is required.
      - (f) Other reasons for which the IRB requests closer monitoring.
    - b) PIs will be notified in writing of approval and expiration dates for their research. Researchers are encouraged to review determination letters thoroughly and retrieve all newly approved study documents (e.g., informed consent documents, recruitment materials) from the electronic system.

### **Notification of IRB Determinations**

- 1) After the IRB has reviewed the proposed research, the PI will be notified of the IRB determination.
- 2) For deferred research, the PI will be notified of the reasons the research was deferred. The entire submission, with all required documents, will need to be resubmitted after revision for IRB review
- 3) For research that is disapproved, the PI will receive a letter that delineates the reasons for disapproval. PIs may appeal the determination in writing to the IRB Chair.

### **Possible IRB Determinations for Full Board Review**

- 1) The IRB meeting minutes record the determinations that the convened IRB makes, as well as the votes that support these determinations. Once formal IRB review for research has been documented, investigators receive written notification regarding the IRB determinations. The IRB determinations made during initial review or renewal of research comprise the following:
  - a) **Approved:** Approved by the IRB as written without explicit conditions. The research may proceed.



- b) **Minor Stipulations:** The IRB has determined that research is approved with required minor changes, or stipulations, or pending letters of intent from schools or other research sites.
  - i) Minor changes that are required will be clearly delineated so that the PIs understand the IRB's stipulations and can address them fully.
  - ii) Before any research begins, the PIs must address and complete the IRB's stipulations to obtain full IRB approval.
  - iii) For approvals with stipulations, IRB Chair(s) and designated IRB reviewer(s) may approve the proposed research on behalf of the IRB upon reviewing the PI's adequate response(s) to the conditions.
    - (1) Responses to clarifications that are directly relevant to regulatory criteria for approval of research must be reviewed by the convened IRB.
    - (2) When the PI has responded appropriately and completely to all stipulations, an approval is granted. The PI will be issued an approval letter indicating the study expiration date.
- c) **Deferred:** The IRB requires additional substantive clarification(s) regarding the proposed research; the research lacks sufficient information and the IRB cannot establish whether it satisfies the criteria for IRB approval of research ([45 CFR 46.111](#); [21 CFR 56.111](#)). The research may not proceed until the convened IRB has approved a revised application incorporating all necessary information.
  - i) The IRB will invite PIs to the convened IRB meeting if the IRB has additional questions concerning the proposed research.
- d) **Disapproved:** The convened IRB has determined that the proposed research cannot be conducted at Chapman University.
  - i) A disapproval determination may only be rendered at a fully convened IRB meeting.
    - (1) The research activities proposed present risks that outweigh potential benefits; or the research protocol requires significant revisions because it is deficient in several major areas.
    - (2) The research protocol and/or other supporting documents require complete revision and must be submitted as a new submission.
      - (a) PIs may request that the IRB reconsider disapproved research by submitting a written response to the IRB.
      - (b) The IRB may reconsider its original review determination in light of new information the PI offers about the proposed research.

#### Revision history:

- 05Apr2024 – Examples for exempt categories added to this document
- May 2023 - Minor editorial changes only
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