

Reviewer Checklist for New Studies

Reviewers must use this checklist to guide their review of the proposed research. Reviewers must act anytime they select a response with ▲. Reviewers must comment in Cayuse IRB anytime they select a response with ■. Researchers will not see this checklist so if reviewers have comments for the research team, they should be added to the Cayuse IRB submission itself and the visibility for the comment should be changed to “unrestricted.” Once reviewers have completed this checklist they should upload it to the appropriate [Dropbox folder](#).

Research Identification

IRB Number	Click or tap here to enter text.
Principal Investigator	Click or tap here to enter text.
Research Title	Click or tap here to enter text.

Reviewer Conflicts of Interest

- I, the IRB reviewer, do not have a conflict of interest with this research
- I, the IRB reviewer, have a conflict of interest with this research (▲ *The reviewer must stop reviewing and contact the IRB staff as soon as possible so the review can be reassigned.*)

CAYUSE IRB SECTION 2: PERSONNEL

Researcher Training

- All individuals engaged in human subject research have provided current evidence of completing either the “Social and Behavioral Research” or “Biomedical Research” training from the Collaborative Institutional Training Initiative (CITI) Program
- All individuals engaged in human subject research have not provided current evidence of completing either the “Social and Behavioral Research” or “Biomedical Research” training from the Collaborative Institutional Training Initiative (CITI) Program ■

External Collaborators

- The research does not involve external collaborators
- The research involves external collaborators (▲ *The reviewer must contact the IRB staff as soon as possible so the necessary agreements between institutions can be coordinated; IRB review can proceed while institutional agreements are in progress but IRB approval cannot be granted until all agreements are uploaded to Cayuse IRB.*)

CAYUSE IRB SECTION 3: CONFLICTS OF INTEREST

Researcher Conflicts of Interest

- No members of the research team report a conflict of interest

- At least one member of the research team reports a conflict of interest (**▲** *The reviewer must stop reviewing and contact the IRB staff as soon as possible so the conflict can be managed.*)
 - An appropriate conflict of interest management plan has been developed and is explained in consent documents
 - An appropriate conflict of interest management plan has not been developed and is explained in consent documents (**▲** *The reviewer must stop reviewing and contact the IRB staff as soon as possible so the conflict can be managed.*)

CAYUSE IRB SECTION 4: STUDY INFORMATION

Study Funding

<input type="checkbox"/>	This study is <u>not</u> funded	
<input type="checkbox"/>	The study is federally funded	
	<input type="checkbox"/>	Department of Defense
	<input type="checkbox"/>	Department of Education
	<input type="checkbox"/>	Department of Energy
	<input type="checkbox"/>	Department of Justice or Bureau of Prisons
	<input type="checkbox"/>	Environmental Protection Agency
	<input type="checkbox"/>	Food and Drug Administration
	<input type="checkbox"/>	Department of Health and Human Services
	<input type="checkbox"/>	National Institutes of Health
	<input type="checkbox"/>	The study is privately funded
	Source of funding:	Click or tap here to enter text.
<input type="checkbox"/>	The study is internally funded	
	Source of funding:	Click or tap here to enter text.

Previous IRB Review

- This research has not been previously reviewed by a non-Chapman IRB
- This research has been previously reviewed by a non-Chapman IRB and all relevant documents from the previous review have been provided (e.g., consent form, IRB application, IRB approval letter)
- This research has been previously reviewed by a non-Chapman IRB and all relevant documents from the previous review have not been provided (e.g., consent form, IRB application, IRB approval letter) **■**

Risk Level

- The research is minimal risk
- The research is greater than minimal risk (**▲** *Such research must undergo full review.*)

Type of Review

- Exempt review (**▲** *Use the checklist for exempt studies rather than this one.*)

- Expedited review
- Full review

CAYUSE IRB SECTION 6: EXPEDITED OR FULL REVIEW

Relevant Categories

- The researchers have selected the appropriate review category or categories (including subcategories where relevant)
- The researchers have not selected the appropriate review category or categories (including subcategories where relevant) **❗**

- All of the research falls under one or more expedited review categories
- All of the research does not fall under one or more expedited review categories (**▲** *Such research is not eligible for expedited review and must undergo full review.*)
- Not applicable as the research is undergoing full review and expedited review categories do not need to be selected

CAYUSE IRB SECTION 7: RESEARCH DESCRIPTION

Purpose of the Research	Click or tap here to enter text.
Research Procedures	Click or tap here to enter text.
Measures and Materials	Click or tap here to enter text.
Participant Characteristics	Click or tap here to enter text.

Specific Research Procedures

Clinical trials

- The research does not involve a clinical trial
- The research involves a clinical trial
 - The principal investigator and co-investigators have provided current evidence of completing the “Good Clinical Practices (GCP) - Social and Behavioral Research Best Practices for Clinical Research” training from the Collaborative Institutional Training Initiative (CITI) Program (see Section 2)
 - The principal investigator and co-investigators have not provided current evidence of completing the “Good Clinical Practices (GCP) - Social and Behavioral Research Best Practices for Clinical Research” training from the Collaborative Institutional Training Initiative (CITI) Program (see Section 2) **❗**

- The clinical trial is not supported by federal funding

- The clinical trial is supported by federal funding
 - IRB-approved consent forms will be posted on a publicly available Federal website
 - IRB-approved consent forms will not be posted on a publicly available federal website ¹⁴
- Additional information has been added to the consent form about clinical trials (see the [Informed Consent Process](#) for specific elements)
- Additional information has not been added to the consent form about clinical trials (see the [Informed Consent Process](#) for specific elements) ¹⁴

International research

- The research is not international
- The research is international and the research will undergo review by an IRB or research ethics committee in the country where the research takes place
- The research is international but the research will not undergo review by an IRB or research ethics committee in the country where the research takes place (see the [Guidelines for International Research](#) to determine if this is appropriate) ¹⁴

Audio or video recording

- The research does not involve audio or video recorded procedures
- The research involves audio or video recorded procedures and there is an adequate description of the purpose of the recording and whether recording is optional to participate in
- The research involves audio or video recorded procedures and there is not an adequate description of the purpose of the recording and whether recording is optional to participate in ¹⁴

Deception or incomplete disclosure

- The research does not involve deception or incomplete disclosure
- The research involves deception or incomplete disclosure and there is an adequate rationale, description of debriefing procedures, and explanation as to whether participants can withdraw their data
 - A debriefing form has been attached in Section 10 and an alteration of informed consent has been requested in Section 11
 - A debriefing form has not been attached in Section 10 or an alteration of informed consent has not been requested in Section 11 ¹⁴
- The research involves deception or incomplete disclosure but there is not an adequate rationale, description of debriefing procedures, and/or explanation as to whether participants can withdraw their data ¹⁴

Biospecimen collection

- The research does not involve biospecimen collection (e.g., saliva samples, blood draws)
- The research involves biospecimen collection (e.g., saliva samples, blood draws)

- Adequate storage plans for the biological specimens are described in Section 12
- Adequate storage plans for the biological specimens are not described in Section 12

Devices

- The research does not involve the use of a device (e.g., electromyography [EMG], electroencephalography [EEG], inertial sensor, motion capture systems)
- The research involves the use of a device (e.g., EMG, EEG, inertial sensor, motion capture systems) but does not 1) evaluate the safety or effectiveness of a device or 2) collect data that will be submitted to the FDA
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document
- The research involves the use of a device (e.g., EMG, EEG, inertial sensor, motion capture systems) and 1) evaluates the safety or effectiveness of a device or 2) collects data that will be submitted to the FDA (▲ *FDA investigational device exemption regulations may be relevant. See the guidelines for reviewers about medical devices.*)

Drugs

- The research does not involve the use of drugs (i.e., a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease)
- The research involves the use of drugs (▲ *The reviewer must stop reviewing and contact the IRB staff as soon as possible because in vivo testing of drugs cannot be conducted at Chapman.*)

Ingestible substances

- The research does not involve the use of ingestible substances other than drugs or food
- The research does involve the use of ingestible substances other than drugs or food
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Invasive medical procedures (e.g., severance, penetration, or damaging of human tissue)

- The research does not involve invasive medical procedures
- The research does involve invasive medical procedures
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Withholding medical treatment

- The research does not involve withholding medical treatment
- The research does involve withholding medical treatment
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Applying hot or cold

- The research does not involve applying hot or cold to participants
- The research does involve applying hot or cold to participants
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Electromagnetic radiation

- The research does not involve electromagnetic radiation
- The research does involve electromagnetic radiation
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Other medical experiments

- The research does not involve other medical experiments
- The research does involve other medical experiments
 - Participants are provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document, per the [California Protection of Human Subjects in Medical Experimentation Act](#)
 - Participants are not provided an “[Experimental Subject's Bill of Rights](#)” with the informed consent document

Study Design

- The study design is consistent with and able to address the research questions
- The study design is not consistent with and not able to address the research questions

- The study design and procedures do not have any ethical issues (ethical issues may include but are not limited to the Belmont report principles such as respect for persons [voluntary, fully informed consent], beneficence [obligation to protect participants from harm and secure their well-being], and justice [benefits and burdens of research are fairly distributed])
- The study design and procedures have ethical issues ■■

Vulnerable Participants

- The research does not involve vulnerable participants (e.g., children, pregnant women, prisoners, or cognitively impaired individuals)
- The research involves vulnerable participants (e.g., children, pregnant women, prisoners, or cognitively impaired individuals) and appropriate protections are in place
- The research involves vulnerable participants (e.g., children, pregnant women, prisoners, or cognitively impaired individuals) but the appropriate protections are not in place ■■

Research Involving Pregnant Women, Fetuses, and/or Neonates – [Subpart B](#) Determinations

- The research does not involve pregnant women, fetuses, or neonates
- The research does not meet the conditions of [45 CFR 46.204](#), [45 CFR 46.205](#), [45 CFR 46.206](#), or [45 CFR 46.207](#) ■■
- The research meets the conditions of [45 CFR 46.204](#), [45 CFR 46.205](#), [45 CFR 46.206](#), or [45 CFR 46.207](#) (▲ *The reviewer must state this and the specific category under “Findings” when making a decision in Cayuse IRB.*)

Research Involving Prisoners – [Subpart C](#) Determinations

- The research does not involve prisoners
- The research does involve prisoners (▲ *The reviewer must stop reviewing and contact the IRB staff as soon as possible because research with prisoners cannot be reviewed by Chapman’s IRB.*)

Research Involving Children – [Subpart D](#) Determinations

- The research does not involve children
- The research does not meet the conditions of [Subpart D](#) ■■
- The research meets the conditions of [Subpart D](#) and is permissible under the following category: (▲ *The reviewer must state this and the specific category under “Findings” when making a decision in Cayuse IRB.*)
 - [45 CFR 46.404](#) or [21 CFR 50.51](#) - Research not involving greater than minimal risk
 - [45 CFR 46.405](#) or [21 CFR 50.52](#) - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual
 - [45 CFR 46.406](#) or [21 CFR 50.53](#) - Research involving greater than minimal risk and no prospect of direct benefit to individuals, but likely to yield generalizable knowledge about a disorder or condition
 - The parental permission form includes signature lines for both parents

- The parental permission form does not include signature lines for both parents ❏
- [45 CFR 46.407](#) or [21 CFR 50.54](#) - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

Sample Size

- The sample size is appropriate and justified
- The sample size is not appropriate or justified ❏

CAYUSE IRB SECTION 8: RISKS AND BENEFITS TO PARTICIPANTS

Risks	Click or tap here to enter text.
Benefits	Click or tap here to enter text.

Certificates of Confidentiality

- Participants do not provide identifiable and sensitive information that may be relevant in civil, criminal, administrative, legislative, or other legal proceedings
- Participants do provide identifiable and sensitive information that may be relevant in civil, criminal, administrative, legislative, or other legal proceedings but a certificate of confidentiality will be obtained from the National Institutes of Health (NIH) to protect against legal demands such as subpoenas (this is done automatically for NIH-funded research but researchers without NIH funding can also request a certificate of confidentiality)
 - A certificate of confidentiality is disclosed on the consent form
 - A certificate of confidentiality is not disclosed on the consent form but should be as the research is NIH-funded or a certificate of confidentiality has been received by NIH ❏
- Participants do provide identifiable and sensitive information that could be used in civil, criminal, administrative, legislative, or other legal proceedings but a certificate of confidentiality will not be obtained from the National Institutes of Health (NIH) to protect against legal demands such as subpoenas ❏

Consistency of Risk

- The description of risks in Section 8 is consistent with the risk assessment in Section 3
- The description of risks in Section 8 is not consistent with the risk assessment in Section 3 ❏
- The description of risks in Section 8 is consistent with the risks described on the consent documents
- The description of risks in Section 8 is not consistent with the risks described on the consent documents ❏

Data and Safety Monitoring Plan

- A data and safety monitoring plan is not necessary because the research is minimal risk

- A data and safety monitoring plan is provided and is appropriate for greater than minimal risk research
- A data and safety monitoring plan is not provided or is not appropriate for greater than minimal risk research ■


Risk to Benefit Ratio

- Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may result
- Risks to participants are not reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may result ■

CAYUSE IRB SECTION 10: RESEARCH DOCUMENTS

Consent Documents

- Consent, permission, and/or assent forms meet the [requirements of informed consent](#):
 - Are written in a language that is understandable to the participant, parent, or legally authorized representative
 - Include a statement that the study involves research
 - Include an explanation of the purpose of the study
 - Include the duration of the participation
 - Include a description of procedures to be followed
 - Include a statement that participation is voluntary
 - Include a description of any reasonably foreseeable risks or discomforts to the participants or, if applicable, that there may be risks that are currently unforeseen
 - Include a description of benefits to the participants or, if none, a description of the benefits to society
 - Include a statement describing the extent to which confidentiality of records identifying the participant will be maintained
 - Include an explanation of who to contact on the research team for questions, concerns, or complaints about the research
 - Include an explanation of who to contact that is independent of the research team for questions about research participants' rights, to provide input, or to complain

- Include a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- Include a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
- Include a statement that the IRB and other entities, if applicable, may inspect the research records
- Include a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative (if this might be a possibility) or include a statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
- Not applicable because no identifiable information or biospecimens are collected
- When biospecimens are collected, include a statement that identified or de-identified biospecimens may be used for commercial profit and whether the participant will share in the profit or not
- Not applicable because no biospecimens are collected
- When biospecimens are collected, include a statement that the research will or might include whole genome sequencing
- Not applicable because no biospecimens are collected
- Consent, permission, and/or assent forms do not meet the [requirements for informed consent](#) 
- Consent, permission, and/or assent forms include additional elements of informed consent when relevant:
 - Include key information that provides the most relevant information for a participant's informed consent (required if the consent form is longer than 3 pages)
 - Not applicable
 - Include a statement whether clinically relevant research results, including individual research results, will be disclosed to participants, and, if so, under what conditions
 - Not applicable
 - Include an explanation as to whether any compensation is available if injury occurs
 - Not applicable

- Include an explanation as to whether any medical treatments are available if injury occurs
- Not applicable

- Include an explanation that if compensation for injury is available, what it consists of, or where further information may be obtained
- Not applicable

- Include a disclosure of appropriate alternative treatments or procedures, if any, that are available and might be advantageous to the participant
- Not applicable

- Identify any relevant procedures as experimental
- Not applicable

- Disclose appropriate alternative procedures or courses of treatment, if any
- Not applicable

- Describe the amount and schedule of reimbursement to participants, if any
- Not applicable

- Describe any additional costs to individuals that may result from participation in the research
- Not applicable

- Describe anticipated circumstances under which the researchers may terminate an individual's participation without their consent
- Not applicable

- Describe the safety consequences of a participant's decision to withdraw from the research
- Not applicable

- Include the procedures for terminating an individual's participation
- Not applicable

- Indicate whether the study is regulated by the Food and Drug Administration (FDA) and a statement that notes the possibility that the FDA may inspect the records
- Not applicable

- Indicate whether the study meets the requirements for registration on clinicaltrials.gov and include a statement that the study will be registered and no identifying information will be included
- Not applicable

- Include an explanation of whom to contact in the event of a research-related injury
- Not applicable

- Include the anticipated number of participants to be enrolled
- Not applicable

- Include participant rights under the Genetic Information Nondiscrimination Act (GINA) when genetic analysis is performed
- Not applicable

- Include financial obligations of the sponsor, participant, and institution(s)
- Not applicable

- Consent, permission, and/or assent forms do not include additional elements of informed consent when relevant ¹⁴

Other Measures

- Measures and materials described in Sections 7 and 11 are attached in Section 10
- Measures and materials described in Sections 7 and 11 are not attached in Section 10 ¹⁴

External Sites

- The research is not conducted at a site external to Chapman University
- The research is conducted at a site external to Chapman University that has provided permission to conduct the research
- The research is conducted at a site external to Chapman University that has not provided permission to conduct the research ¹⁴

CAYUSE IRB SECTION 11: RECRUITMENT, COMPENSATION, AND INFORMED CONSENT

Recruitment

- Recruitment of participants will not occur
- The recruitment process and materials (see Section 10) are appropriate for the research
- The recruitment process and materials (see Section 10) are not appropriate for the research ¹⁴

- Recruitment of the researchers' own patients, students, staff, or employees will not occur
- Recruitment of the researchers' own patients, students, staff, or employees will occur and an appropriate justification and precautions have been described

Recruitment of the researchers' own patients, students, staff, or employees will occur but an appropriate justification and precautions have not been described

Compensation

Compensation is not provided to participants

Compensation is provided to participants

The compensation is appropriate for the nature of the research

The compensation is not appropriate for the nature of the research

Compensation is appropriately prorated (e.g., the manner in which compensation is disbursed will not unduly influence participants to remain in the study when they would otherwise leave)

Compensation is not appropriately prorated (e.g., the manner in which compensation is disbursed will influence participants to remain in the study when they would otherwise leave)

Consent Process

The researchers will obtain informed consent from participants

The researchers will not obtain informed consent from participants (see criteria for Waiver of Documentation of Informed Consent below)

The consent process provides sufficient opportunity for individuals to consider their participation

The consent process does not provide sufficient opportunity for individuals to consider their participation

The circumstances of consent minimize the possibility of undue influence and coercion

The circumstances of consent do not minimize the possibility of undue influence and coercion

The consent process is free of exculpatory statements through which the participant or the legally authorized representative releases or appears to release the researchers, the sponsor, the University, or its agents from liability for negligence

The consent process is not free of exculpatory statements

Waiver of Documentation of Informed Consent (i.e., signature)

A waiver of documentation of informed consent is not relevant to the research

A waiver of documentation of informed consent is not requested but should be

A waiver of documentation of informed consent is requested and at least one of the following apply under [45 CFR 46.117\(c\)\(1\)](#): (**▲** *The reviewer must state this and the specific category under "Findings" when making a decision in Cayuse IRB.*)

- The only record linking the participant to the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality
- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context
- The participants are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, and there is an alternative mechanism for documenting that informed consent was obtained

Waiver or Alteration of Informed Consent

- A waiver or alteration of elements of informed consent is not relevant to the research
- A waiver or alteration of elements of informed consent is not requested but should be (e.g., in the case of deception)
- A waiver or alteration of elements of informed consent is requested and all of the requirements under [45 CFR 46.116\(f\)\(3\)](#) are met: (*The reviewer must state this under “Findings” when making a decision in Cayuse IRB.*)
 - The research involves no more than minimal risk to the participants
 - The research could not practicably be carried out without the requested waiver or alteration
 - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
 - The waiver or alteration will not adversely affect the rights and welfare of participants
 - Whenever appropriate, participants or legally authorized representatives will be provided with additional pertinent information after participation

Parent Permission

- Parent permission is not relevant to the research
- Parent permission will not be obtained but should be obtained
- Parent permission will be obtained or meets at least one of the following criteria for a waiver: (*The reviewer must state this and the specific category under “Findings” when making a decision in Cayuse IRB.*)
 - Parental permission is not a reasonable requirement to protect the children (e.g., in cases of neglect or abuse; see [45 CFR 46.408\(c\)](#))
 - All of the requirements in [45 CFR 46.116\(f\)\(3\)](#) are met:
 - The research involves no more than minimal risk to the participants
 - The research could not practicably be carried out without the requested waiver or alteration

- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- The waiver or alteration will not adversely affect the rights and welfare of the participants
- Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation

Child Assent

- Child assent is not relevant to the research
- Child assent will not be obtained but should be obtained ■■
- Child assent will be obtained or meets at least one of the following criteria for a waiver: (▲ *The reviewer must state this and the specific category under “Findings” when making a decision in Cayuse IRB.*)
 - Children are not capable of providing assent due to their age (e.g., those younger than 7 years old), maturity, or psychological state (see [45 CFR 46.408\(a\)](#))
 - The research will directly benefit the children (see [45 CFR 46.408\(a\)](#))
 - All of the requirements in [45 CFR 46.116\(f\)\(3\)](#) are met:
 - The research involves no more than minimal risk to the participants
 - The research could not practicably be carried out without the requested waiver or alteration
 - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
 - The waiver or alteration will not adversely affect the rights and welfare of the participants
 - Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation

Consent for Non-English Speaking Participants

- The consent documents have been provided in language(s) appropriate for the participants under investigation
- The consent documents have not been provided in language(s) appropriate for the participants under investigation ■■

CAYUSE IRB SECTION 12: CONFIDENTIALITY OF RESEARCH DATA

- Adequate privacy and confidentiality procedures are in place
- Adequate privacy and confidentiality procedures are not in place ■■

OVERALL REVIEWER RECOMMENDATIONS

Expedited Category (if not full review research)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	9
Clinical studies of drugs and medical devices	Collection of blood samples	Collection of biological specimens	Collection of data through noninvasive procedures employed in clinical practice	Research involving materials collected for nonresearch purposes	Collection of data from voice, video, digital, or image recordings	Research on individual or group characteristics or behavior	Continuing review of research where the IRB has documented that the research involves no greater than minimal risk

(▲ *The reviewer must indicate the relevant category or categories when making a decision in Cayuse IRB.*)

Continuing Review for Expedited Studies (full review research automatically undergoes continuing review on an annual basis)

- Continuing review is not recommended
- Continuing review is recommended (▲ *The reviewer must indicate this when making a decision in Cayuse IRB.*)

Provide a rationale if continuing review is recommended:

Criteria for IRB Approval

- The research meets all criteria under [45 CFR 46.111](#) or [21 CFR 56.111](#)
 - Risks to participants are minimized
 - Procedures are consistent with sound research design and do not unnecessarily expose the participants to risk
 - When possible, the research utilizes procedures already being performed on the participants for diagnostic or treatment purposes
 - Risks to participants are reasonable in relation to anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result
 - Selection of participants is equitable
 - Informed consent will be sought from prospective participants or their legally authorized representative as required
 - Informed consent will be appropriately documented
 - When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants
 - When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data
 - The management of participant information is adequate
- The research does not meet all criteria under [45 CFR 46.111](#) or [21 CFR 56.111](#) ■

Reviewer Decision

- Approved (used when the research meets the criteria for approval under [45 CFR 46.111](#) or [21 CFR 56.111](#) as submitted)
- Minor stipulations (used when the research will meet the criteria for approval under [45 CFR 46.111](#) or [21 CFR 56.111](#) but very minor things need to be addressed such as making IRB-specified changes to the Cayuse IRB application or informed consent documents, confirming

assumptions or understandings on the part of the IRB regarding how the research will be conducted, or submitting additional documents)

Deferred (used when the IRB reviewer is unable to make the determinations required for approval under [45 CFR 46.111](#) or [21 CFR 56.111](#) due to a lack of information about one or more criteria)

Disapproved (used when the convened IRB has determined that the research does not meet the criteria for approval under [45 CFR 46.111](#) or [21 CFR 56.111](#); the principal investigator is notified of the IRB decision and the reasons for it; the principal investigator may respond)

Other

Notes	Click or tap here to enter text.
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Click or tap here to enter text. _____

Date _____

Reviewer Name

Date