CLAFLIN UNIVERSITY
INSTITUTIONAL REVIEW BOARD (IRB) SUPPLEMENTAL MATERIALS

Application Review Type Categories:

EXEMPT

"Exempt" research is human subjects' studies are exempt from federal regulations governing human subject protections, that present no greater than minimal risk to the subject(s) and fit into one or more exempt categories mentioned below:

Federal Exemption Categories 1-6 (per 45 CFR 46.104(d)):

1. Educational Practices: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or assessment of educators who provide instruction such as:

(i) Research on regular and special education instructional strategies; or
(ii) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior: Research involving these procedures is exempt if:

(i) The information obtained is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; or
(ii) Any disclosure of the subject's responses outside of the research could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; or
(iii) Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if Committee for the Protection of Human Subjects (CPHS) conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

3. Benign behavioral interventions: In conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subjects prospectively agrees and at least one of the following criteria is met:

(i) The information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to subjects; or
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if CPHS conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

4. Secondary Research for which Consent is not Required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) These sources are publicly available; or

(ii) The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, and the investigator does not contact or reidentify subjects; or

(iv) The information is collected by or on behalf of the federal government using government generated or collected information obtained for non-research activities.

5. Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency, or otherwise Subject to the Approval of Department or Agency Heads: This research is exempt if it is designed to study, evaluate, improve, or otherwise examine:

(i) Public benefit or service programs; or

(ii) Procedures for obtaining benefits or services under those programs; or (iii)

(iii) Possible changes in methods or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

6. **Taste and Food Quality Evaluation and Consumer Acceptance Studies:** This research is exempt, if:

(i) Wholesome foods without additives are consumed; or

(ii) A food is consumed that contains a food ingredient at or below the level and for a use 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 (FSIS) of the U.S. Department of Agriculture (USDA); or

(iii) A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

When a study is reviewed via the EXEMPT review process, it means that only the IRB chair needs to review the initial and revised study without it being brought before the IRB committee.

Continuing review is not required for EXEMPT approved applications. But when changes to research are proposed, the changes must undergo IRB review by the IRB chair and be approved before implementation.

IRB exemption codes: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html

EXPEDITED REVIEW

Expedited review covers research that involves only minimal risk procedures and falls into one of the expedited categories defined by the federal regulations. For example:

- The study of individual or group behavior in which the behavior is not manipulated, and the subjects are not exposed to any stressful situation.
- The drawing of small amounts of blood.
- Moderate exercise by healthy volunteers.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure:

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is 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).

b. Research on medical devices for which:

(i) An investigational device exemption application (21 CFR Part 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. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, 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 subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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. **Prospective collection of biological specimens for research purposes by noninvasive means:**
   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. **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.
   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 (the strength of sensory function);
   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. **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. ***NOTE: Some research in this category may be exempt from the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.***

6. **Collection of data from voice, video, digital, or image recordings made for research purposes:** Expedited Review does not apply if identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

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. ***NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.***

8. **Continuing review of research previously approved by the convened IRB as follows:**
   a. Where:
   (i) The research is permanently closed to the enrollment of new subjects;
   (ii) All subjects have completed all research-related interventions;
   (iii) The research remains active only for long-term follow-up of subjects; or

   b. Where no subjects have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.

9. **Continuing review of research:** Not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

***Please refer to https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html, for more information.**

****When a study is reviewed via the EXPEDITED review process, it means that only the IRB chair, or one or more experienced members of the IRB committee needs to review the study without it being brought before the IRB committee.***

****Continuing review is not required for EXPEDITED approved applications. But when changes to research are proposed, the changes must undergo IRB review by the IRB chair and same experienced IRB committee member(s) that reviewed the initial application and be approved before implementation.***

FULL REVIEW

Studies that involve more than minimal risk require a full review by the IRB committee members. The research requires approval from a majority of the IRB committee members. The committee discusses the study and determines whether the Criteria of Approval of Human Subject Research are met, and decides to approve, approve with stipulations, defer, or disapprove the study.

Once a study is reviewed by the IRB, the IRB chair will communicate any changes requested by the committee and will work with you to resolve any issues.

Examples of Research That Require Full Board Review:

- Clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery.
- Complex research design requiring the expertise of multiple board members and a specialist (non-voting consultant) in the field to evaluate.
- Deception.
- IRB Chair, IRB committee members determine risks are greater than minimal.
- Vulnerable populations, particularly prisoners, children under the age of 18, and pregnant women.
- Individuals with impaired decision-making capacity.
- Economically or educationally disadvantaged people.
- Procedures that might cause physical harm.
- Procedures that might cause significant psychological/emotional distress.
- Collection of information about highly sensitive topics.
- Collection of information about illegal behavior.
- Collection of information that could seriously harm the participant legally, socially, financially etc. if other people could identify them.

After the meeting, the IRB chair will send a letter indicating one of the following:

- **Approval:** This letter indicates nothing else is needed and you may proceed using the protocol or other documents submitted.
- **Modifications Required to Secure Approval:** This letter will include minor modifications required before the application can be approved. Once the modifications are made and submitted, the IRB chair will review the submission and send the approval letter.
- **Deferral:** This letter indicates that there are outstanding clarifications required involving the study design or risk. Once the submission is updated with the requested changes from the IRB committee members, the submission will need to be returned to the IRB committee for review.

FULL review is required for any research involving human subjects that do not qualify for EXEMPT or EXPEDITED review. FULL review studies may be granted approval for a maximum of one year. The IRB will determine the approval period of the study depending on the complexity of the study, study conducted in compliance with federal, regional, and local guidelines, and number of enrolled subjects. An IRB committee can shorten an approval period (number of months) when they agree that a more frequent review could improve subjects' protection. All amendments or revisions that are approved during a study's approval period will not impact the expiration date of completing the study.

NOT RESEARCH

Focus groups, surveys or interviews with faculty or students intended only to evaluate and improve program(s) or service(s) provided by the institution or to assess its needs and does not result in publication or submitting the results to granting agency for funding.

When a study is reviewed via the for NOT RESEARCH review process, it means that only the IRB chair needs to review the study without it being brought before the IRB committee.

Continuing review is not required for NOT RESEARCH approved by IRB chair. But when changes to research are proposed, the changes must undergo IRB review by the chair and be approved before implementation.

CONFLICT OF INTEREST

PURPOSE: To prevent any conflict of interest (COI) from influencing the review process either by competing with an IRB member's or consultant's obligation to protect human subjects or by compromising the credibility of the review process.

The regulations protecting human research subjects are based on the ethical principles described in the Belmont Report. Transparency and full disclosure are indicators of the Principle of Respect for Persons. This principle maintains that individuals should be treated as autonomous agents and demands that subjects enter the research voluntarily and with adequate information.

DEFINITIONS: Conflict of interest (COI) is a situation in which financial or other personal or professional circumstances may compromise, or have the appearance of compromising, an IRB member's professional judgment or objectivity in reviewing or evaluating a research study.

Claflin IRB according to federal guidelines require to assure that there are no conflicts of interest in research projects that could affect human subject participation. If this study involves or presents a potential COI, additional information will need to be provided to the IRB. Examples of potential COI include, but not limited to:

Financial COI:

1. A researcher or family member participating in research on a technology owned by a business in which the faculty member holds a financial interest.
2. A researcher or family member has a financial or other business interest in an entity which is supplying funding, materials, products, or equipment for the current research project.
3. A researcher or family member serves on the Board of Directors of a business which is supplying funding, materials, products, or equipment for the current research project.
4. A researcher receives consulting income from an entity that is funding the current research project.

Nonfinancial COI:

1. A researcher participating in research on a technology, process or product developed by that researcher.
2. Participation in the research, whether the IRB member or member of his/her immediate family, or anyone with whom they have a close relationship is listed as the investigator on the study, or as a member of the research team.

3. Supervision of a project (IRB member is an academic sponsor of the Principal Investigator, or a situation in which any investigator must report to or is under the professional supervision of the IRB member).
4. Other nonfinancial interests that may be COIs, such as if the IRB member has an interest that he/she believes conflicts with their ability to review a project objectively; or the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or the IRB member is considered a personal or professional adversary of the investigators.

PROCEDURES:

Full Review by the Convened IRB

1. IRB member(s) should alert the other IRB members and the chair about any COI that may be previously unknown. The IRB chair will give an opportunity to the IRB member with COI to recuse. If the member with COI is reluctant to recuse themselves, the decision will be made by the IRB through a confidential vote prior to the meeting.
2. Every agenda includes a printed/electronic reminder that any member with a COI must leave the room during the deliberation and voting on the study.
3. The agenda also indicates the names of any IRB members known to have a COI associated with a particular study.
4. The member may provide information requested by the committee.
5. The IRB chair will record the recusal of the member(s) from the IRB deliberation and vote in the meeting minutes. The minutes will indicate that a COI was the reason for the recusal.
6. The recused IRB member will not be counted as part of the quorum for that agenda item. If a quorum is not present because of this absence, then the IRB cannot take further action or vote on the protocol. The protocol will have to be rescheduled for a meeting at which there will be a quorum.

Expedited Review

1. If the IRB chair or designee reviewing an expedited study discloses a COI previously unknown to the member assigning the review, the study will be rerouted to a member who does not have a COI.

Other

1. The same procedures apply to review of unanticipated problems and other instances of noncompliance.

REGULATIONS

45 CFR 46.107(d):
https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.108

21CFR 56.107(d):
https://www.ecfr.gov/

Financial Conflict of Interest: HHS (U.S. Department of Health and Human Services) Guidance
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html

CHILDREN

If the study ***includes*** children, this inclusion must meet one of the following criteria for risk/benefits assessment according to the federal regulations (45CFR46, subpart D): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html

Criteria for Risk/Benefits Assessment According to the Federal Regulations:

- (404) Minimal Risk.
- (405) Greater than minimal risk but holds prospect of direct benefit to subjects.
- (406) Greater than minimal risk, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.