

Policy Number: 12

Title: IRB Review of Human Subjects Research - Exempt

Date of Last Revision: 10/12/07, 08/21/10, 11/09/10, 01/24/11, 06/05/13, 05/01/16, 06/01/16, 10/19/17, 02/28/18, 04/02/18, 08/19/19, 09/09/19, 01/21/20, 05/28/20

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the Federal regulations and complies with UC Irvine's ethical standards.

I. Exempt Eligibility

A. Research activities involving human subjects may be exempt from the requirement that they receive IRB full or expedited review as per the Office for Human Research Protections and the Food and Drug Administration.

B. Exempt confirmation may be made by various mechanisms at UCI, as follows:

- 1. Undergraduate Research Opportunities Program (UROP):** All undergraduate exempt research is submitted for exempt review and confirmation through UROP. When research is considered for UROP submission, the following exceptions apply;
 - a) The subjects can be identified directly or indirectly (access to key linking individual with information) when asking them to disclose sensitive information (e.g., illegal behavior, or sensitive themes such as sexual experiences, physical abuse, alcohol or drug use, undesirable work behavior, or other information that may be embarrassing or psychologically painful) that could place subjects at risk for criminal or civil liability, or might be damaging to subjects' financial standing, employability or reputation.
 - b) The research involves interaction with prisoners: Individuals confined in a correctional or detention facility, including involuntary assignment to community-based alternatives to incarceration (drug treatment facilities, etc.).
 - c) The research involves adult participants who may not be legally/mentally/cognitively competent to consent.
 - d) The research involves individuals under the age of 18.
 - e) Deception or incomplete disclosure is involved.
 - f) The research involves a prospective collection of biological specimens for research purposes by noninvasive means (e.g., saliva).
 - g) The research involves a prospective collection of data through non-invasive procedures routinely employed in clinical practice – including the use of FDA approved / cleared medical devices (e.g., use of ultrasound, blood pressure cuff, fMRI, EKG, etc.).
 - h) The research involves access to or the use of protected health information (PHI).

2. **Exempt Self-Determination Tool:** Lead Researchers (and Faculty Sponsors as applicable) use the Exempt Self-Determination Tool to confirm exemption categories 1-3. When using the Exempt Self-Determination Tool, the following exceptions apply;
 - a) Exempt Categories 4-6
 - b) Inclusion of the following target populations:
 - (1) Children (under the age of 18)
 - (2) Prisoners
 - (3) Adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
 - (4) American Indian/Alaska Native tribes
 - c) Access to or the collection of:
 - (1) PHI that arises in the course of providing health care (i.e. medical record and/or medical encounter)
 - (2) Student education records
 - d) Collecting participant identifiers **and** participants disclose sensitive information that could place subjects at risk for criminal or civil liability, or might be damaging to subjects' financial standing, employability or reputation
 - e) Non UCI personnel involved in research by intervening or interacting with the participants and / or by having access to participant identifiable private information for research purposes
 - f) International Research
 - g) A study team member that has a disclosable financial conflict of interest
3. **IRB Confirmation of Exemption:** Lead Researchers (and Faculty Sponsors as applicable) may receive exempt confirmation by the IRB through designated Human Research Protections (HRP) Staff Reviewers or an IRB Chair using the following mechanism;
 - a) An IRB Application for Exemption
 - (1) Investigators must submit a completed IRB application to conduct Exempt human subjects research that otherwise does not qualify for UROP review or completion of the Exempt Self-Determination Tool. IRB Applications for Exempt Research are accepted on a rolling basis.
 - (2) Exempt confirmation may be granted for no more than three (3) years. A Continuing Protocol Application (CPA) may be submitted to continue the research.

C. **2018 Common Rule Exempt Categories:** For research that falls under the 2018 Common Rule (i.e., new studies approved on or after January 21, 2019 or for continuing studies approved before January 21, 2019 receiving a new or renewal of a federal award (See Policy # 18)), research may be granted exempt status if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.104(d):

1. **45 CFR 46.104(d)(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.

2. **45 CFR 46.104(d)(2):** Research that includes only **interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures, or observation¹ of public behavior** (including visual or auditory recording) **if at least one of the following criteria are met:**
- i. The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;
 - ii. Any **disclosure** of the human subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR**
 - iii. The information obtained is recorded by the investigator in such a manner that the **identity of human subjects can readily be ascertained**, directly or through identifiers linked to the subjects, **and an IRB conducts a limited review to make the determination required by 45 CFR 46.111(a)(7)**

Note: For Category 2iii, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

3. **45 CFR 46.104(d)(3i):** Research involving **benign behavioral interventions** in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) **or audiovisual recording if the subject prospectively agrees to the intervention and information collection and 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 subjects cannot readily be ascertained directly** or through identifiers linked to the subjects;
 - B. Any **disclosure** of the subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' 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 subject, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**

Note: For Category 3iC, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of

¹ Children may be included if procedures include educational tests or observation of public behavior only and the researcher does not participate in the activities being observed.

criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

- ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects 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.
- iii. If the research involves deceiving the subjects 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 he or she will be unaware of or misled regarding the nature or purposes of the research.

4. **45 CFR 46.104(d)(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. The identifiable private information or identifiable biospecimens are **publicly available**;

Note: Category 4i applies to secondary research use of archives in a public library, for example, or to government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive. It would also apply if a commercial entity made identifiable biospecimens publicly available to anyone on request or for a fee.

- ii. Information, which may include information about the biospecimens, is recorded by the investigator in such a manner that the **identity of human subjects cannot readily be ascertained** directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii. The research involves only information collection and analysis involving the investigator's use of **identifiable** health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **OR**

Note: Category 4iii is allowable when a UCI healthcare workforce member uses identifiable health information for research purposes and the information obtained for research will not be disclosed outside of the covered entity (i.e., not outside of UCI Health). **IMPORTANT!** Disclosure beyond UCI Health for

research purposes does not meet category 4iii and the project should be submitted as Expedited Category 5.

- iv. The research is **conducted by, or on behalf of, a Federal department or agency** using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. **45 CFR 46.104(d)(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 public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
6. **45 CFR 46.104(d)(6): Taste and food quality evaluation and consumer acceptance studies:**
- i. If wholesome foods without additives are consumed; **OR**
 - ii. 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.
7. **45 CFR 46.104(d)(7): Storage or maintenance for secondary research for which broad consent is required:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

Note: UCI will not adopt Category 7. UCI's interpretation of Broad consent is that it is a system-wide program that allows institutions to track via a central system biospecimens and data for which individuals provide their broad consent, or decline, as well as the terms of the broad consent to determine which future research uses remain within scope. This interpretation aligns with the Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP) interpretation. Consequently, UCI is taking the same position as all UC's, Children's Hospital Orange County, Harvard, and Johns Hopkins and is not implementing Category 7, because UCI currently lacks a system-wide program for collecting broad consent.

8. **45 CFR 46.104(d)(8): Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:**
- i. **Broad consent** for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens **was obtained** in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
 - ii. **Documentation of informed consent or waiver of documentation of consent was obtained** in accordance with 45 CFR 46.117;
 - iii. **An IRB conducts a limited IRB review** and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; **and**
 - iv. The investigator **does not include returning individual research results** to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual results.

Note: UCI will consider Category 8 on a case-by-case basis. Researchers interested in Category 8 should contact HRP Staff for more information OR consider Expedited Review under Category 5.

D. **Pre - 2018 Common Rule Exempt Categories:** For research that does not fall under the 2018 Common Rule (i.e., continuing studies approved before January 21, 2019 that are not receiving a new or renewal of a federal award (See Policy # 18)), research may be granted exempt status if all research activities involve procedures listed in one or more of the specific categories under **45 CFR 46.101(b)**:

1. **45 CFR 46.101(b)(1)²:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, 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. **45 CFR 46.101(b)(2)³:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - ii. Any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. **45 CFR 46.101(b)(3):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if:
 - i. The human subjects are elected or appointed public officials or candidates for public office; or
 - ii. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

2

The study procedures should not:

- Entail a significant deviation in time or effort from those educational practices already existent in the study site; or
- Involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
- Note: The school or other institution grants written approval for the research to be conducted.

3

If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Audio/video recordings and photographs may be permissible in this category.

4. **45 CFR 46.101(b)(4)**: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - a. To qualify for this exemption, data, documents, records, or specimens must have been collected before submission of the IRB application.
 - b. Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source. Investigators are required to provide a data abstraction sheet to the IRB.

5. **45 CFR 46.101(b)(5)**: Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining (i) "public benefit or service programs:"

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
 - The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
 - There must be no statutory requirements that the project be reviewed by an IRB; or
 - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- ii. Procedures for obtaining benefits or services under those programs;
 - iii. Possible changes in or alternatives to those programs or procedures; or
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs.

Note: This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

6. **45 CFR 46.101(b)(6) and 21 CFR 56.104(d)**: 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- II. **2018 Common Rule Exempt Categories:** Exceptions to exempt research:
- A. These categories do not apply to research involving prisoners unless they are incidentally included.
 - B. Exempt categories 1-4 do not apply to FDA regulated research.
 - C. None of these exemption categories apply to research involving derivation and use of human embryonic stem cells or human embryonic germ cells, including somatic cell nuclear transplantation.
 - D. Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.
 - E. Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, OHRP at 45 CFR 46 does not address emergency use of test articles. Emergency use constitutes emergency medical care, the patient is not considered to be a research subject; therefore prior IRB review and approval is not required. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.
- III. **Pre - 2018 Common Rule Exempt Categories:** Exceptions to exempt research:
- A. These categories do not apply to research involving prisoners.
 - B. Exempt categories 1-4 do not apply to FDA regulated research.
 - C. None of these exemption categories apply to research involving derivation and use of human embryonic stem cells or human embryonic germ cells, including somatic cell nuclear transplantation.
 - D. Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.
 - E. Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, OHRP at 45 CFR 46 does not address emergency use of test articles. Emergency use constitutes emergency medical care, the patient is not considered to be a research subject; therefore prior IRB review and approval is not required. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.
- IV. All research conducted under exempt review is subject to all applicable UCI institutional and IRB policies and procedures.
- V. Exempt research activities are subject to the same subject protections and ethical standards as outlined in The Belmont Report.
- VI. Single IRB review requirements **do not apply** to exempt research.
- VII. The full Committee is advised of research proposals/activities that have been registered under the exempt review procedure. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing exempt review procedures, a report

documenting registration of exempt research for the previous month is provided to the IRB Committee as a standing item on the IRB Committee meeting agenda.

- VIII. Modifications to Exempt protocols initially confirmed by the IRB are reviewed and approved by a designated HRP Staff Reviewer or an IRB Chair. If the modification affects the status of the protocol review level, the designated HRP Staff Reviewer or IRB Chair will determine the appropriate review level (i.e. Expedited or full Committee review).

References:

OHRP 45 CFR 46

45 CFR 46.104(d)

45 CFR 46.101(b)

45 CFR 46.101(i)(footnote 1)

45 CFR 46.102(i)

45 CFR 46.201(b)

45 CFR 46.401(b)

21 CFR 56.104(c) and (d)

OHRP, *Exemption for Research and Demonstration Projects on Public Benefit and Service Programs*.

<http://archive.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm>

OHRP, *Exempt Research and Research That May Undergo Expedited Review*, May 5, 1995.

<http://www.hhs.gov/ohrp/policy/hSDc95-02.html>

OHRP Compliance Activities: Common Findings and Guidance -7/10/2002

[NOT-OD-16-094](#)

45 CFR 46.114

Procedure Number: 12.A

Title: Procedure for IRB Review of Human Subjects Research – Exempt

Procedure:

This procedure provides guidance in accordance with regulations to review and approve human subjects research in an exempt category.

I. Lead Researcher (LR) Responsibilities

- A. Where exempt research is reviewed by UROP, the Lead Researcher (and Faculty Sponsor as applicable) complete documentation as specified on the UROP website: <https://www.urop.uci.edu/grants.html>.
- B. Where exempt self-determination is allowed, the Lead Researcher (and Faculty Sponsor as applicable) complete the Exempt Self Determination Tool. The Exempt Self Determination Tool is also located on the IRB website: <http://www.research.uci.edu/ora/forms/>.
- C. For exempt research that requires UCI IRB review, the IRB Application is completed in its entirety and electronically submitted to the HRP staff for processing. The IRB Application and instructions on what to submit are located on the IRB website: <http://www.research.uci.edu/ora/forms/>.
- D. The IRB website also includes information on the above processed and on who to contact with questions
- E. When research requires UCI IRB review, the Investigator replies to all requests for revisions and/or clarifications requested by the HRP Staff Reviewer or IRB reviewer, when applicable.
- F. The Investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate participant protections (e.g., confidentiality).

II. Reviewer Responsibilities

- A. The Reviewer reviews the "Application for IRB Review" and validates or declines the researcher's claim for review under the exempt category.
- B. The Reviewer reviews the proposed research, consents, and applicable documents to determine if the research meets the ethical standards of the Belmont Report. The Reviewer documents the exempt determination on the "Reviewer's Checklist."
- C. When the research involves interaction with subjects, a determination is made by the Reviewer whether some type of consent process is appropriate. The Reviewer documents the consent process on the "Reviewer's Checklist." The Reviewer utilizes the checklist to ensure that the consent document provided to subjects contains such information as:
 - 1. a statement that the activity involves research;
 - 2. a description of the procedures;
 - 3. a statement that participation is voluntary;
 - 4. a statement that there are adequate provisions to protect the privacy and confidentiality of the subjects; and
 - 5. the name and contact information for the researcher.

- D. If the Reviewer disagrees with the proposed level of risk, the appropriate level of review is determined (i.e., Expedited). An IRB Chair will be consulted if the appropriate level of review is full Committee.
- E. If the Reviewer approves the request, the Reviewer signs the "Reviewer's Checklist" and a letter of Exempt Registration is generated.
- F. When revisions are requested prior to initial registration, the modified documents are re-reviewed and, if acceptable, exempt registration is granted.
- G. If proposed changes to an exempt study are submitted for review and approval, the Reviewer will review and approve.
- H. If needed, the IRB Chair or designated IRB Committee member is available to assist the Reviewer in determining if the study meets exemption criteria. If the Reviewer has a conflict of interest, another experienced Reviewer will conduct the review.
- I. HRP Staff Reviewers are delegated the authority to register IRB applications and approve modifications related to research activities deemed exempt from the federal regulations regarding the protection of human subjects under 45 CFR 46.101 (b). Exempt studies are accepted on a rolling basis and are administratively reviewed weekly by an HRP Staff Reviewer.
- J. Exempt Research receives a three year registration with the UCI IRB. An abbreviated version of the CPA may be submitted to continue the research. The abbreviated CPA prompts the LR to confirm currently registered information about the research, as well as the status of enrollment. Finally, the LR can upload any relevant documents that the study team may want reviewed as part of the Exempt CPA.
- K. Should the LR (and Faculty Sponsor if applicable) request, HRP Staff or an IRB Chair may confirm exemption for UCI faculty or staff who have completed (in its entirety) the Exempt Self-Determination Tool. A signed copy of the Tool will be returned to the LR (and Faculty Sponsor if applicable), confirming exemption or requiring submission of an IRB Application for Exemption, Expedited or Full Committee or submission to UROP.
- L. Delegation is provided in the HRP Staff Reviewer Delegation of Authority document maintained on the HRP WIKI page – and signed by the IRB Chairs for A, B and C, Vice-Chair for Team D, as well as the Executive Director of Research Protections.
 - 1. An HRP Staff Reviewer is defined as follows:
 - a) **HRP STAFF REVIEWER:**
 - (1) **Tier 1:** Administrator or above, CIP or CCRP certified and appointed as IRB members or alternate members may review and approve transactions related to exempt and expedited level protocols. Exceptions are noted as applicable.
 - (2) **Tier 2:** Analysts or above, CIP or CCRP certified may review and approve transactions related to exempt and expedited level protocols. Those without current CIP or CCRP have been designated by an IRB Chair or the Executive Director of Research Protections to have the appropriate experience to review and approve transactions related to exempt and expedited protocols. Exceptions are noted as applicable.
 - 2. An HRP Staff Reviewer (both tiers) may review and approve exempt protocols **except under the following conditions:**
 - i. 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings when research involves:
 - 1. pregnant women (*where they are the focus of the research*)

2. children
3. individuals with cognitive or medical impairments
4. students (e.g., undergraduates, medical students)
- ii. 45 CFR 46.101(b)(2 & 3): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior when the research involve:
 1. pregnant women (where they are the focus of the research)
 2. children
 3. individuals with cognitive or medical impairments
 4. research involving deception/incomplete disclosure
- iii. Exempt applications that involve a disclosure of financial interest
3. HRP Staff Reviewers (both tiers) may review and approve modifications related to exempt protocols in accordance with HRP Policy # 17.

III. **Human Research Protections (HRP) Team Responsibilities**

- A. The HRP team assures that the submission is complete. Documentation submitted for IRB review includes:
 1. IRB Application
 2. Protocol Narrative
 3. Investigator's Assurance document
 4. Disclosure of Investigators' Financial Interest form
 5. Proposed Data Collection instruments, or citations, if standardized, if applicable
 6. Proposed Consent document, if applicable
 7. Assent form, if applicable
 8. Recruitment advertisements, if applicable
- B. The Analyst or Administrator communicates (via e-mail) the Reviewer's findings to the LR, Faculty Sponsor (FS) and Administrative Contact (AC), when applicable and provides assistance with IRB submission requirements.
- C. The HRP team will also review the proposed research to determine if it meets the ethical standards of the Belmont Report.
- D. The Analyst or Administrator prepares the letter of Exempt Registration.
- E. The HPS database entries are completed.
- F. Registered documents are processed in HPS and FileNet (effective April 1, 2019).