

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 7

Exempt Research
Policy and Procedure

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I. Policy

- A. Research that meets the categories set forth by the federal regulations [45 CFR 46.104(d); 21 CFR 56.104(d); 38 CFR 16.101(b)] may qualify for exemption.
- B. Responsibility for determining what research is exempt:
 1. Exempt research is exempt from IRB review; therefore, requests for exemption may be reviewed by an IRB Chair, experienced IRB member, a designated member of the IRB or qualified OIRB staff member with expertise in applying human subject research exempt determinations.
 2. Exemption determinations may not be made by researchers.
 3. Research is exempt from the human research protection regulation (45 CFR 46) when the research meets the criteria listed in C.1 and C.2 below. Limited IRB review, as noted in 5.b)(3), 5.c)(3), 5.g), and 5.h) below, is completed by a single IRB member via the expedited review mechanism in which the IRB member determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of subject data. For research under exempt categories g) and h) below, the IRB will adopt a process for exemptions when the institution's process for regulatory compliance can be confirmed.
 4. To be determined exempt, the research must (all of the following must be true):
 - a) Present no more than [minimal risk](#), and
 - b) For research funded by HHS or DoD, it must not involve [prisoners](#) as participants unless the research is aimed at involving a broader subject population that only incidentally includes prisoners.
 - c) Not be subject to FDA regulations ("[FDA regulated research](#)") – category 1 – 5 only, and
 - d) For research funded by HHS, DoD or ED, it must not involve [children](#) under:
 - (1) Category 2(b) unless the research involves observations of public behavior and the investigators do not participate in the activities being observed.
 - (2) Category 3
 - (3) Category 4 if identifiable information will be recorded.
 5. To be determined exempt, the research must also fall within one or more of the categories below:

- a) Research conducted in established or commonly accepted educational settings, involving normal education practices, where the research is not likely to have an adverse impact on students learning required educational content or the assessment of educators who provide instruction, such as:
- (1) Research on regular or special educational instructional strategies, or
 - (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- b) Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator, unless:
- (1) Information obtained is not identifiable; and
 - (2) 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, insurability or reputation, or
 - (3) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (4) A [limited IRB](#) review is conducted if the identifiable data will be recorded.
- c) Research involving benign behavioral interventions in conjunction with the collection of information, if all of the following conditions are met:
- (1) Information obtained is not identifiable; and
 - (2) 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, insurability or reputation, or
 - (3) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (4) A limited IRB review is conducted if the identifiable data will be recorded.
 - (5) If deception is being used in the research, subjects have provided authorized [deception](#).
- d) Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met::
- (1) are publicly available, or
 - (2) includes information that is to be recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the subject will not re-identify the subjects, or

- (3) 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, or
 - (4) is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected
- e) Research and demonstration projects which are supported by or conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, improve or otherwise examine:
- (1) The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit or services programs;
 - (2) Procedures for obtaining benefits or services under those programs;
 - (3) Possible changes in or alternatives to those programs or procedures; or
 - (4) Possible changes in methods or levels of payment for benefits or services under those programs.
 - (5) Projects for which there is no statutory requirement for IRB review;
 - (6) Projects that do not involve significant physical invasions or intrusions upon the privacy interests of subjects;
 - (7) Authorization or concurrence by funding agencies that exemption from IRB review is acceptable.
- f) Taste and food quality evaluation and consumer acceptance studies:
- (1) If wholesome foods without additives are consumed; or
 - (2) 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- g) Storage or maintenance for secondary use of identifiable private information or identifiable biospecimens for which broad consent is required:
- (1) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained; and
 - (2) Broad consent is appropriately documented or waived (where appropriate); and
 - (3) An IRB conducts a limited IRB review; and

- (4) If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.
 - h) Research involving the use of identifiable private information or identifiable biospecimens for which broad consent is required:
 - (1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained
 - (2) Documentation of informed consent or waiver of documentation of consent was obtained
 - (3) The investigator does not include returning individual research results to subjects as part of the study plan. However, it is permissible under this exemption to return individual research results when required by law regardless of whether or not such return is described in the study plan.
 - (4) An IRB conducts a limited IRB review.
 - C. For research involving the STVHCS, activities involving the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally:
 1. The activity is research;
 2. Participation is voluntary;
 3. Permission to participate can be withdrawn;
 4. Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and
 5. Contact information for the STVHCS investigator.
 - D. Ethical Principles Relevant to Exempt Research. The principles of respect of persons, beneficence and justice are applied to all research conducted at the HSC including human research that has been determined to be exempt.
- II. Procedure
- A. Submission and Screening
 1. The PI makes a preliminary determination to submit a study for exempt review based on an assessment of the protocol establishing that it falls into one or more of the categories specified in the federal regulations.
 2. The PI submits a completed Exemption Application to the OIRB. Instructions for preparing the application are available on the IRB website. The investigator may call the OIRB with questions.
 3. Upon receipt of the application, the study is in-processed and reviewed for completeness and accuracy per the [Receiving, Routing and Administrative Review of Submission Policy and Procedure.](#)

4. The OIRB staff will route the application to an experienced member of the OIRB staff or a designated member of the IRB.
5. If it is clear to the OIRB staff that the application does not meet the criteria for exempt review, the OIRB staff contacts the PI and recommends resubmitting either a non-research, non-human research, expedited or full review application. An IRB Expedited Reviewer is generally consulted.

B. IRB Exempt Review

1. The designated reviewer receives the exempt application materials.
2. The reviewer is responsible for reviewing the application to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The reviewer may request additional information from the PI to aid in providing clarifications where necessary. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects. The reviewer uses the Expedited Approval/Administrative Review Documentation Form to note the results of the review.
3. Criteria used to determine that participants are protected in Exempt Research
 - a) Criteria 1: All of the proposed research procedures fit one or more of the exemption categories specified in the federal regulations (listed above)
 - b) Criteria 2: The research does not include any of the following:
 - (1) Prisoners for research funded by HHS or DoD unless the research is aimed at involving a broader subject population that only incidentally includes prisoners;
 - (2) Survey or interview techniques which include children as subjects for research funded by HHS, DoD or ED (this applies to exemption category #2 only);
 - (3) The observation of children where the investigator participates in the activities being observed for research funded by HHS, DoD or ED (this applies to exemption category #2 only);
 - (4) Recording of identifiable information for children (this applies to exemption category #4)
 - (5) [FDA regulated research](#) (this applies to exemption categories #1-5).
 - c) Criteria 3: The research involves no more than [minimal risk](#) to participants.
 - d) Criteria 4: Selection of participants is [equitable](#) (as applicable).
 - e) Criteria 5: If there is recording of non-sensitive, [identifiable](#) information, there are adequate provisions to maintain the [confidentiality](#) of the data.
 - f) Criteria 6: If there are [interactions](#) with participants, there will be a consent process that will disclose the following information (as applicable):
 - (1) That the activity involves [research](#).

- (2) A description of the procedures.
 - (3) Risks and benefits.
 - (4) That participation is voluntary.
 - (5) How information will be protected to maintain confidentiality.
 - (6) Name and contact information for the investigator.
- g) Criteria 7: There are adequate provisions to maintain the [privacy](#) interest of participants.
- h) Criteria 8: With regard to disapproval of exempt research where limited IRB review is required, the IRB follows the [Initial Review of Research Policy and Procedure](#).
4. The reviewer contacts the PI for any revisions needed to qualify the study for exempt status.
 5. The PI is responsible for responding to the designated reviewers issues in a timely manner. Once received, the reviewer determines whether the revisions are sufficient for determination of exempt status.
 6. The reviewer makes the final determination and notes the appropriate category(ies) on the Expedited Approval/Administrative Review Documentation form
- C. Review Outcome(s)
1. The designated reviewer makes one of the following decisions:
 - a) Determination that the research does not qualify for exempt status.
 - (1) The rationale for the determination and recommendations for submission of non-research, non-human research, expedited or full review application will be communicated to the PI where applicable;
 - (2) If the reviewer determines the research does not qualify for exempt status, the PI may request that the proposal be reviewed by the convened IRB who may determine the exemption applies. Alternately, the PI may submit the research proposal as an expedited study if the study meets the criteria for an expedited review. If the study does not meet the criteria for an expedited review, the PI submits a full board review application and requests that the OIRB schedule a full board review.
 - b) Exempt determination and ready for implementation (general comments or suggestions may be included but not required for approval). If ready for implementation, the OIRB staff notifies the PI of the decision per the [Reporting Policy and Procedure](#).
 2. Appeals - If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The PI may send the request to the reviewer and/or the IRB Director or Chair for final resolution. If the investigator is still dissatisfied with IRB decision, he/she may send the study to the full IRB for review.

3. IRB records for all exempt determinations include the citation of the specific category justifying the exempt status.
4. When a research study using non-identifiable information has been determined to be exempt, continuing reviews are not required and an expiration date of 3 years is set. Any IRB related activity (e.g. administrative changes, noncompliance, unanticipated problems, etc.) will result in an extension of the expiration date for another three years. Thirty days prior to the expiration date, an email notification will be sent to the PI to contact the OIRB to extend this determination if needed. After three years of inactivity with the IRB, the protocol will be inactivated. No letter will be sent.
5. When a research study using identifiable information has been determined to be exempt (including exempt research conducted under limited IRB review), continuing reviews are not required however, follow-up and an institutional expiration date will be set (see the OCR [Institutional Review policy](#)).
6. The IRB or the Institutional Official retains the authority to suspend or terminate the IRB's determination of research approved where limited IRB review was required.

D. Changes in ongoing Exempt research

1. Any changes to the research activities must be reviewed by a designated reviewer (see [II.A.4. above](#)) prior to implementing (except where necessary to eliminate apparent immediate hazards to the subject).
2. The PI must submit the proposed changes, and any revised documents to the OIRB by email.
3. The designated reviewer will determine whether the change alters the exemption determination.
4. If the changes do not affect the exempt determination and are acceptable, the reviewer documents the determination in the IRB file and updates the expiration date. The PI is then notified.
5. If the changes do affect the exempt determination such that the study will no longer be eligible for exempt status, the reviewer contacts the PI and develops a plan to either withdraw the change or submit the study as a new human research protocol under the appropriate review process (expedited or full review).

III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))