19.0 PROCEDURES for THE EXEMPT REVIEW PROCESS

19.1 OBJECTIVE

To describe the policies and procedures for the exempt review process.

19.2 GENERAL DESCRIPTION

Research procedures that meet the categories set forth by the federal regulations [45 CFR 46.101(b); 21 CFR 56.104(d); 38 CFR 16.102(b)] may qualify for certification of exemption. The Institutional Review Board (IRB) must review and approve all exemptions claimed for research conducted at the Howard University (HU) or by employees or agents of HU facilities. Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one of the eight categories of exempt research.

19.3 Exempt Determinations and Limited IRB Review

Determinations regarding whether research subject to the revised Common Rule qualifies for exempt status will be made by the ORRC and when necessary by the Chair or designated member of the IRB. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair or a Chair-designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities. [§__.109(a)]

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB (i.e., within X business days). [§__.108(a)(3)(iii)]

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter. [§__.109(f)(ii), §__.115(a)(3)]

19.4 Limitations on Exemptions

Children: *Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained, and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children. [§__.104(b)(3)]*

Prisoners: *Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. [§__.104(b)(2)]*

19.5 Exempt Categories [§__.104(d)]

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also FDA-regulated.

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. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(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 the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

3. 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:

(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 the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

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.

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. 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;

(ii) Information, which may include information about biospecimens, 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, 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 ['HIPAA'], 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

(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. 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 website 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. 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.

Note: Exempt categories 7 & 8 always require limited IRB review and are only available when broad consent will be (or has been) obtained.

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 §__.111(a)(8):

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);

(ii) Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with §__.117 (See Sections 8.6 and 8.7); and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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 §__.116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117 (See Sections 8.6 and 8.7);

(iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" and makes the determination that the research to be conducted is within the scope of the broad consent referenced in 8.i above; ***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 research results.

The IRB must review research in categories that are exempt from the federal human research requirements to determine whether an exemption is appropriate.

19.6 RESPONSIBILITY

Execution of SOPP: IRB Members, Office of Regulatory Research Compliance (ORRC) Staff, and Principal Investigator (PI)/Study Personnel

19.7 PROCEDURES

19.7.1 Assigning Reviewers

- Each year, after finalizing the list of IRB members, ORRC staff selects experienced members from the Medical and Non-Medical IRB to serve as either a primary or a secondary expedited reviewer. ORRC staff forwards the list to the IRB Chair for approval. Upon approval by the Chair, it is disseminated to staff and IRB members.

- The IRB member who serves on Nonmedical IRB may review Nonmedical IRB exempt studies that require approval from the IRB Committees.

- Each reviewer (whether primary or secondary) is responsible for notifying the ORRC staff if he/she is not able or available to conduct the review during the period assigned. The reviewer is also responsible for notifying ORRC staff if he/she has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOPP. ORRC staff document who served as exemption reviewer on the assigned line at the top of the applicable reviewer form (i.e., IRB Exemption Review Worksheet).

19.7.2 Submission and Screening

- The PI makes a preliminary determination that a protocol is eligible 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. The IRB makes the final determination regarding whether a protocol is eligible for exemption.

- The PI submits a completed Exemption Certification Form to the ORRC. Instructions for preparing the application are available in the IRB Survival Handbook and on the ORRC website. The investigator may call the ORRC with questions.

- Upon receipt of the application, designated ORRC staff screens the application including the informed consent process and documentation for completeness and accuracy. The designated ORRC staff reviews the PI's exempt category selection for appropriateness. The designated ORRC staff completes and sends to the exempt reviewer an "Exemption Review Worksheet" which offers recommendations for the appropriate exempt category(s) and justification for the chosen category(s). If it is clear to the designated ORRC staff the application does not meet the criteria for exempt review, the designated ORRC staff contacts the PI and recommends that he/she consider resubmitting either an expedited or full review application.

- In addition, ORRC RCO screens for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights to Privacy Act (FERPA) concerns. If the PI includes a HIPAA form or checks “HIPAA” in the application or if there is a HIPAA or FERPA concern, ORRC staff forward the application to the ORRC Research Privacy Staff for review. The RPS reviews the application and submits suggestions in writing, and ORRC staff forward them to the exemption reviewer, who then makes the final determination.

- Based on the screening, ORRC staff contacts the PI for any additional information needed for a thorough review.

- ORRC staff enters the application into the ORRC protocol database tracking system. The ORRC staff assigns a number to the application and, for reporting purposes, places it on an agenda.

- After screening the application, ORRC staff retains the original application in the ORRC and forward a copy of the application to a primary reviewer (or to a secondary reviewer in the absence of the primary reviewer or in the event of a conflict of interest).

19.7.3 IRB Exempt Review

- The reviewer for exempt protocols receives the following:
    - Completed exemption application
    - “Issues to be Addressed When Conducting Exempt Review” (guidance to reviewers)
    - Data collection instruments (if applicable)
    - Grant/contract proposal (if applicable)
    - Consent form or requests for waiver of informed consent or a waiver of documentation of informed consent
    - Any applicable HIPAA forms
    - IRB Exemption Review Worksheet
    - Any additional information ORRC staff may have requested from the PI (usually via email) or ORRC recommendations to reviewer

- The reviewer is responsible for reviewing the application upon receipt to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects.

- During review, the reviewer ensures that the research does not include any of the following:

- Prisoners;
- Survey or interview techniques which include children as subjects (this applies to exemption category #2 only);
- The observation of children where the investigator participates in the activities being observed (this applies to exemption category #2 only);
- FDA-regulated research (this applies to exemption categories #1-5).

- The reviewer contacts the PI for any clarification needed and documents the issues discussed with the PI on the IRB Exemption Review Worksheet.

- If the reviewer is unable to respond within approximately 7 days, ORRC staff sends up to two reminders. If the reviewer is still unable to respond, ORRC staff forward the protocol to another reviewer.

19.7.4 Review Outcome(s)

- The reviewer makes one of the following recommendations by completing the IRB Exemption Review Worksheet and returning it to the ORRC as soon as the review is completed but, if possible, no later than 7 days from receipt:
  - Additional information needed to determine exempt status;
  - Required revisions needed to qualify study for exemption;
  - Disapproved of exempt status with rationale for disapproval and recommendations for submission of expedited or full review application;
  - Approved (general comments or suggestions may be included but not required for approval).

- ORRC staff forwards the reviewer's recommendation in writing to the PI in accord with ORRC Customer Service Standards.

- The PI is responsible for submitting any requested revisions to the ORRC. The ORRC forwards the revisions to the reviewer for review and approval if appropriate. The reviewer determines whether the revisions are sufficient for approval of exempt status, and, if so, ORRC staff send an approval notification to the PI.

- If the reviewer determines the revisions are inappropriate or insufficient, he/she may request that the PI make further revisions. This review and revision process continues until the research is either approved or disapproved as exempt.

- If the IRB disapproves the exemption request, 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 review application and requests that the ORRC schedule a full review.

- IRB records for all exempt determinations include the citation of the specific category justifying the exemption.

- When the IRB has certified a research study as exempt, the IRB does not require CRs. The exemption approval is in effect for a six-year period. Approximately three months prior to the end of the six-year period, the Investigator must submit a new exemption application if the project is to continue.

- 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 Chair or Vice 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.

19.8 REFERENCES

45 CFR 46.101(b)
45 CFR 46.102(i) 21
CFR 56.104(d)

20.0 INITIAL FULL REVIEW by THE INSTITUTIONAL REVIEW BOARD (IRB)