1.0 Purpose:

1.1 Policies differentiate between research involving human participants that is exempt and research involving human participants that is not exempt.

1.2 A determination of exemption should consider the criteria for exemption of all applicable laws, regulations, codes, and guidance.

1.3 The Organization should provide written decisions and maintain records of exemption determinations.

1.4 The person making a decision about exemptions should have the authority to represent the Organization, and have no direct involvement in the activity being examined.

1.5 The person making a decision should be familiar with laws, regulations, codes, and guidance governing the research, organizational policies, and the nature of the research to make sound judgments.

1.6 Policies describe the communication of exemption determinations to researchers.

2.0 Definitions:

3.0 References:

3.1 45 CFR 46.104

3.2 45 CFR 46.301(a)

3.3 45 CFR 46.401(b)

3.4 21 CFR 56.104(c)–(d)

4.0 Procedure:

4.1 Submission

4.1.1 Initial review

4.1.1.1 Applications for new research proposals are submitted electronically. They should include the Research Application form, protocol, budget, and Information Sheet for participants if applicable.

4.1.2 Continuing review/Termination

4.1.2.1. Reports submitted for projects requesting continuation should include a copy of the report form, including a summary of activity within the report period, and any abstracts or publications that have resulted from the study.

4.1.2.2. Reports for projects to be terminated should include a final report and copies of any abstracts or publications that have not been submitted previously. Projects should not be terminated until all activities requiring use of identifiable specimens or data are completed, with no possibility of needing further access to these materials.

4.1.3 Proposed modifications to previously approved research

4.1.3.1. The HRPP should be notified of any modifications to the study so that a determination may be made as to whether they will change the exempt status.

4.2. Review Process

4.2.1. All submissions are reviewed by HRPP staff, who determine the completeness and appropriateness of the submitted items. If anything is missing or is found to require revision, HRPP staff will contact the research staff to request the needed materials. Simultaneously for initial submissions, one of the Research Institute Senior Scientists will review the protocol for scientific merit, and may contact the investigator for revisions/clarifications. When feasible, these reviews will be coordinated.

4.2.2. Grants & Contracts staff review the budget and contract when applicable. If internal funding is requested, the study will be scheduled for review by the Scientific Review Committee.

4.2.3. If the project is being funded by external funds, HRPP review may be simultaneous with the Grants review, but final approval will not be granted until all requirements of both are met.

4.2.4. HRPP staff ensure that Financial Disclosures for investigators are done if required. Final approval for a study to proceed will not be given until this requirement is met.

4.2.5. Determination of Extent of IRB Oversight

4.2.5.1. HRPP staff will be responsible for review of the documentation needed to make a determination of whether IRB oversight of the research activity is required. Investigators do not have the authority to make a definitive independent determination that research involving human subjects is exempt from IRB oversight.

4.2.5.2. Criteria for making determinations:

4.2.5.2.1. The following ethical criteria for approval apply to exempt activities as well as to those activities requiring IRB oversight:

4.2.5.2.1.1. The research involves no more than minimal risk to participants.

4.2.5.2.1.2. Selection of any subjects is equitable.

4.2.5.2.1.3. If there is recording of identifiable data, there are adequate provisions to protect the privacy of any participants and the confidentiality of their data.

4.2.5.2.2. In addition, research activities involving human subjects (including children except where noted, pregnant women, fetuses, and neonates) that are exempt from IRB review are

activities in which the only involvement of the participants will be in one or more of the following categories:

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.
   a) This includes most research on regular and special education instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
   b) The research does not involve prisoners.
   c) The research is not FDA regulated.

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 45 CFR 46.111(a)(7).

   The first two criteria of this category (i and ii) may not be applied to research with minors when involving surveys and/or interviews. They may only be applied to research with minors when involving educational tests or the observation of public behavior and the investigators do not participate in those activities. The third criteria of this exemption (iii) may not be applied to research with minors.

The research is not FDA regulated.

3) (i) 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 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

(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 subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 6.111(a)(7).

(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. HHC defines brief duration for an intervention (not including data collection, unless intertwined) as lasting no longer than a few minutes to a few hours on a single day. 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.

Research involving minors is not eligible for this category of exemption.

The research does not involve prisoners.

The research is not FDA regulated.

4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for a non-related primary or initial activity, 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, 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);

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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.

This category may not be applied to research involving primary collection from subjects; collection must be performed for a non-related purpose. Collection can be either prospective or retrospective.)

The research does not involve prisoners.

The research is not FDA regulated.

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.

The research does not involve prisoners.

The research is not FDA regulated.

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

   The research does not involve prisoners.

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 45 CFR 46.111(a)(8).

   Research category 7 is not an option at HHC at this time.

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) 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 research results.

Research category 8 is not an option at HHC at this time.

HHC will not implement exemptions involving broad consent located at 45 CFR 46.104(d)(7) and 45 CFR 46.104(d)(8) at this time.

4.2.5.3. Any voting member of the fully convened IRB shall have the authority to make formal exempt determinations. On a regular basis, however, the HRPP Director, Vice Chair, and Designated Reviewers will conduct the primary review of request for exemption.

4.2.6. **Limited Review**

4.2.6.1. Four of the exempt categories in the revised Common Rule now include limited IRB review, and may be reviewed through a limited IRB review procedure as applicable via IRB expedited review procedures. HHC IRB is currently implementing two (2) of these exempt categories [45 CFR 46.104(d)(2)(iii) and 45 CFR 46.104(d)(3)(i)].

4.2.6.2. Limited IRB review must be performed by an experienced IRB member. Specific findings must be made to approve research through a limited IRB review procedure. The IRB member performing limited IRB review shall document their findings for approval or otherwise refer the research for expedited or convened IRB review as appropriate.

4.2.6.3. Reviewers ensure that the criteria for approval as required by 45 CFR 46.111(a)(7) are met – when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

4.2.6.4. Research approved through the limited IRB review procedure is not subject to ongoing continuing review requirements unless otherwise determined by the IRB.

4.2.6.5. Modifications to research reviewed through limited IRB review may be reviewed through Expedited procedure. In reviewing modifications to the research through limited IRB review, the IRB member will make and document findings if the IRB approval criteria for limited IRB review are still satisfied.

4.3. Post-Review Process

4.3.1. Approval letters will be signed by the HRPP Director or Designated Reviewer, and sent by HRPP staff to the investigator electronically. The approval letter will

indicate at least that the study is approved, the date of approval, type of review and category or categories justifying the exemption, and will include notifications regarding the progress report due date, and any future modifications.

4.3.2. As exempt studies involve no more than minimal risk, the IRB does not require continuation or annual administrative reviews. The exemption approval is in effect for a three-year period. Approximately three months prior to the end of the three-year period, the HRPP Office notifies the PI that the exemption will expire and that he/she must submit a continuing review application if the project is to continue. ..

5.0 Documentation:

5.1 The HHC HRPP office will maintain records related to exempt studies for a minimum of 3 years after completion of the study.

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	SMH	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	7/22/15	Specified individuals with the authority to make exempt determinations
03	CLB	3/15/20	Revisions to address new categories under the Revised Common Rule

Elements II.2.A, II.2.B., II.2.C.