| Policies & Procedures Function & Operations | DETERMINATION OF EXEMPTION | Effective Date: 1/4/2017<br>Last reviewed: 1/4/2017<br>Last updated: 1/4/2017 |
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## 1. POLICY

There are six federal categories of research activities involving human subjects that may be exempt from the requirements of the Policy for the Protection of Human Subjects (45 CFR 46). A seventh category of exempt research activities has been defined by Brown University (Brown) using flexibility permitted by Brown's Federalwide Assurance (FWA).

Investigators do not have the authority to determine that their own research qualifies for exempt status. This determination must be made by the Human Research Protection Program (HRPP) staff, upon review of an application for exempt status submitted by the investigator. Research may not begin until the investigator has received notification that the research qualifies for exempt status. To be eligible for exempt status, all of the proposed research activities of a study must fit in one or more of the six federal exemption categories listed in section 1.2 of this policy and/or qualify for Brown's exempt category seven (7) as described in section 1.3.

Although studies that qualify for exempt status do not fall under the same federal requirements for research involving human subjects as non-exempt studies, investigators still have a responsibility to protect the rights and welfare of participants. They are expected to adhere to Brown policies and conduct their research in accordance with the ethical principles of Justice, Beneficence, and Respect for Persons as described in the Belmont Report.

Exempt determinations do not have expiration dates. In order to maintain accurate records of on-going research, the HRPP will contact the investigator periodically to confirm that the research continues unchanged. The investigator is expected to notify the HRPP office when an exempt research project has been completed and before changes are made to procedures.

### 1.1 Research That Is Not Exempt

The federal exemption categories 1 through 6 [45 CFR 46.101(b)] listed in section 1.2 do NOT apply to the following:

- Research that involves greater than minimal risk.
- Survey or interview of children (Category 2).
- Observation of the public behavior of children when investigators interact with the children (Category 2).
- Research involving prisoners.
- Research regulated by the Food and Drug Administration (FDA). With the exception of Category 6, FDA-regulated research does not qualify for exempt status. Research will not qualify for exempt status under Category 6 if there have been food and color additives incorporated into the food product and these additives are used in research with the intent to apply to the FDA for marketing of the additive.

## 1.2 Federal Exempt Categories 1-6

1. *Educational Practices*. 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. *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, or reputation.
3. *Educational Tests, Survey Procedures, Interview Procedures, or Observation of Public Behavior*. Research involving these procedures that is NOT exempt under Category 2 is exempt under this category if:
   i. subjects are elected or appointed public officials or candidates for public office; or
   ii. federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. *Existing Data.* Research involving collection or study of existing data, documents, records, or specimens if:
   i. these sources are publicly available; or
   ii. the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. *Research and Demonstration Projects Conducted by or Subject to the Approval of Department or Agency Heads.* This research is exempt if it is designed to study, evaluate, or otherwise examine:
   i. public benefit or service programs;
   ii. procedures for obtaining benefits or services under those programs;
   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;
   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 US 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.

**1.3 Brown Exempt Category 7:** Research that involves no greater than minimal risk to subjects, but does not conform to a specific exempt category under 45 CFR 46.101(b), and does not fall within the exclusions listed under 1.1 or under 1.3.1.

**1.3.1** Such research is NOT exempt if it involves any of the following:

1. **Federally funded research, or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts** (for a current list of these agencies click here.
2. Prisoners as subjects.
3. Children/minors as subjects.
4. Federal personnel or the Department of Veterans Affairs.
5. Procedures, devices, or drugs subject to FDA oversight.
6. Biomedical procedures.
7. Clinical interventions.
8. Sponsor or other contractual restrictions.
9. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
10. Identifiable, private existing data.
11. The information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing in any other way.

**1.3.2** Category 7 minimal risk (46.102[i]) exempt research activities that will not induce distress beyond that of daily life may include (but are not limited to) non-physically invasive interventions or performance of tasks such as:

- Reading/writing/drawing tasks.
- Physical activities such as walking, sitting, or manipulating an object.
- Computer tasks and/or Internet searches.
- Talking and/or listening to words, then making selections, or "think-aloud" exercises.
- Viewing media.
- Role-playing.
- Completing a specific physical or mental action ("imagining").
- Passive monitoring of space (environment) with sensors.
- Playing a game.
- Height/weight measurements.

**1.3.3** If the research is determined to qualify for Category 7 Exempt status and later becomes federally funded, supported, or regulated, or changes such that it includes any of the exclusion factors in 1.1 or 1.3.1 above, the researcher must immediately cease research activities until IRB approval is obtained. ***This will require submission of a new application***.

### 1.4 Action Taken If Proposed Research Does Not Meet Criteria for Exemption

If the HRPP determines that the proposed research does not meet the criteria for exempt status, the investigator will be notified in writing and asked to submit the appropriate application materials for non-exempt review.

### 1.5 Modifications to an Exempt Protocol

All proposed changes to a project previously deemed exempt from IRB review must be submitted to the HRPP for review and determination of continued eligibility for exemption prior to implementation. In some circumstances, proposed changes to the protocol may disqualify the project from exempt status, in which case either expedited or full committee review would be required, as appropriate.

## 2. SCOPE

This policy applies to investigator claims for exemption from 45 CFR 46 requirements and for Category 7 Exemption claims under Brown's FWA.

## 3. RESPONSIBILITIES

HRPP staff:

- Responsible for reviewing and making a determination regarding research applications that claim exemption from 45 CFR 46 under federal categories 1-6 or Brown's Category 7 Exempt Research.
- Responsible for providing consultation in the review of claims of exemption. The HRPP Associate Director or her/his designee has final authority to determine a finding of exempt status.

Principal Investigator:

- Responsible for notifying the HRPP prior to making any changes to an exempt protocol and upon completion of an exempt study.

## 4. PROCESS

1. The investigator submits to the HRPP a Form #2: *Application for Exemption* and any additional required information/documentation (e.g., copy of survey instrument, grant proposal, etc.).
2. The HRPP reviews the application to determine if the investigator has submitted all of the necessary documentation and supporting materials for exempt review and ensures that all required elements are complete and in proper format. The HRPP evaluates the exemption request for (1) level of risk; (2) category of activity; and (3) other relevant considerations.
3. If the submission does not meet the federal definitions for research involving human subjects, the staff member provides the investigator with a letter confirming this determination.
4. If the research qualifies as exempt, the staff member provides the investigator with a letter confirming exempt status.
5. If the research does not qualify for exemption, the staff member contacts the investigator to request a non-exempt application for expedited or full committee review.
6. Because exempt determinations do not have expiration dates, HRPP staff will contact the investigator periodically to confirm that the exempt research is continuing and unchanged. The Investigator is expected to notify the HRPP when the exempt research has been completed.

## 5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101

21 CFR 56.104

21 CFR 56.105