# HRP-503 Application For Exempt Determination

|  |
| --- |
| * This application is intended for the submission of studies that fall into any of the categories listed in the HRP-312 Exempt Determination worksheet. If your study does not fit any category in the HRP-312 Exempt Determination Worksheet, please close out this document and use either the full HRP-503 application form or the HRP-503 for chart/ specimen review (if it applies). Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable. If the question is not applicable to the study, mark the section “N/A”. Do not delete any sections.   NOTE: No prisoners can be involved in exempt research. Typically, no interactions with minors can occur in exempt research either.   * This application is intended for the submission of studies that fall into any of the categories listed in the HRP-312 Exempt Determination worksheet. If your study does not fit any category in the HRP-312 Exempt Determination Worksheet, please close out this document and use either the full HRP-503 application form or the HRP-503 for chart/ specimen review (if it applies). Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable. If the question is not applicable to the study, mark the section “N/A”. Do not delete any sections. * If there is a formal protocol for this study, please upload it. It is permissible to refer to the protocol to answer questions below where possible. * Be sure to complete any supplement questions from one or another ancillary office that you receive during the RUTH application process. Please make certain that any protocols, this 503 application and responses to ancillary offices do not contradict each other and the information is incorporated in all documents where appropriate. Be sure to save the Ancillary office responses you provided within REDCap and upload them to RUTH. * Keep an electronic copy of this version of the document. You will need to modify this copy when making changes. |

1. Introduction

*State the problem or question being addressed (e.g., describe the population, disease, current standard of care, if one exists, and limitations of knowledge or available therapy), and the rationale for conducting the study. Include necessary and relevant background information citing literature and previous research efforts as needed.*

1. Study Design and Scientific Rationale
   1. Overall Design

*A description of the study design should include:*

* *A description of the type/design of the study to be conducted and why it was chosen*
* *Specification of the method for selecting study cases or participants*
* *Specification of the number of study groups and time frame for the study*
* *Indication if this will be a single site or multi-site* study.
* *Name and brief description of study procedure(s)*
* *If appropriate, description of control group(s) used; attention-control or other comparison conditions. Provide a rationale for the selection of control group(s) and discuss limitations associated with it. Selection of control groups should be based on how best to address the research question. In some cases, subjects can serve as their own controls..*
  1. **Exempt Category**

*Indicate which of the below categories your study falls into. There may be multiple categories that apply to your study.*

[ ] 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 §46.111(a)(7).

[ ] 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: (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 §46.111(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. 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. 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, 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 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. 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.

1. Study Population
   1. Inclusion Criteria

*Inclusion criteriaare characteristics that define the population under study, e.g., those criteria that every potential participant must satisfy, to qualify for study entry. Provide a statement that individuals must meet all of the inclusion criteria in order to be eligible to participate in the study and then list each criterion.*

Some criteria to consider for inclusion are: provision of appropriate consent and assent, willingness and ability to participate in study procedures, age range, health status, specific clinical or psychological diagnosis, and symptoms, background.

* 1. **Exclusion Criteria**

Exclusion criteria are characteristics that make an individual ineligible for study participation. Provide a statement that all individuals meeting any of the exclusion criteria at baseline will be excluded from study participation and then list each criterion. If specific populations are excluded (e.g., elderly or pediatric populations, women or minorities), provide a clear and compelling rationale and justification, to establish that inclusion is inappropriate for the purpose of the research. Limited English proficiency should not be an exclusion criterion.

*Include a statement regarding equitable selection or justification for excluding a specific population.*

* 1. **Recruitment and Retention**

*Identify general strategies for participant recruitment and retention or data collection. Consider inclusion of the information below:*

* + - Anticipated enrollment sample size by gender, race and ethnicity, and age
    - How will participants will be identified and contacted
    - Planned recruitment strategies (e.g. university student research pool, patient advocacy groups, online recruitment services, community advisors, national newspaper, local flyers). Include rationale for why the strategy will be appropriate for reaching the targeted study population.
    - When applicable, consider and include strategies adapted to the cultural context of the study or population
    - Describe how you will screen for eligibility and if you will require a waiver of HIPAA authorization. If you are using an outside firm to screen or data mine for subjects please provide details here.
    - For multi-site studies (whether Mount Sinai is the IRB of record for all sites or only for the Sinai site), description and number of recruitment sites (e.g., inpatient hospital setting, student health service, community center), and anticipated number of participants to be recruited from each site
    - If the study requires multiple survey or interview completion, describe procedures that will be used to enhance participant retention (e.g., multiple methods for contacting participants, reminders, incentives)
  1. **Compensation/ Incentives**

Specify if participants will be compensated or provided any incentives (e.g. vouchers, gift cards,) for study participation. Describe the type of incentive, amount, and timing of such compensation in relation to study activities (include financial and non-financial incentives).

Describe steps to minimize coercion or undue influence, i.e., whether appropriate level of incentive is used so not to be viewed as coercive

Describe who will receive incentives (if not the participant). For example, if participants are minors, state whether the minor or the parent/guardian will receive the incentive.

1. Setting of the Human Research

*For research conducted outside MSSM and its affiliates (to be listed in the RUTH smart form) under the supervision of the Sinai investigator, please indicate the following:*

* + - Site(s) name(s) and location.
    - Site-specific regulations, laws or customs affecting research.
    - Local scientific and ethical review structure.

1. Resources Available to Conduct the Human Research

*The aim here is to assess if the research is likely to be successful and thus justify the efforts and risks taken by the subjects).*

Explain the feasibility of meeting goals for this project.

For research involving considerable data extraction or mining, describe who will be providing those services.

For research conducted outside MSSM and its research affiliates, describe the facilities used for conducting the research.

.

1. Data/Specimen Source(s)

Describe each source of study data.

Describe the methods that will be used to identify records/cases/specimens (e.g. Mount Sinai Data Warehouse, EPIC, etc.).

1. Number of Records/Cases/Specimens for Acquisition and Review

*Specify local number of records/cases/specimens for retrieval and review*

Indicate the total number of records/cases/specimens to be reviewed locally.

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

1. Study Timelines

*Mention the time range (mm/dd/yy – mm/dd/yy) for record/cases/specimen review already collected or to be collected.*

The estimated date for the investigator to complete this study (complete primary analyses).

1. Data/Specimen Storage, Transmission and Confidentiality

Describe the data and specimens to be sent out or received. If storage will occur at Sinai and elsewhere (e.g. the sponsor) be sure to answer these questions for both sets of samples as, at the very least, governance of future uses will differ.

As applicable, describe:

* + - How will data/specimen be collected?
    - How will data/specimen be transmitted?
    - How will data/specimen be stored? Provide data standards where known
    - How long will data/specimen be stored?
    - What are the SOPs, if any that govern data sharing?

1. Research Information Sheet

*Specify if you will interact with subjects either physically or through surveys, interviews, etc.*

*Complete the exempt research information sheet (*[*https://icahn.mssm.edu/research/pphs/researcher/forms*](https://icahn.mssm.edu/research/pphs/researcher/forms)*) and attach it to your application in RUTH.*