The purpose of HRP-503B is to provide a template to create a protocol for IRB review for the purpose of making an IRB determination that any given activity qualifies for an exempt status.**When to Use This Form:**

* For studies that fit into one of the exempt categories listed in Section 1 of the form.
  + All procedures conducted as part of the overall study must fit into one or more of the exempt categories. This includes procedures occurring at other institutions.

**When Not to Use This Form:**

* For studies involving prisoners unless the research is aimed at involving a broader subject population that only incidentally involves prisoners
* For studies that present greater than minimal risk to participants.
* For FDA-regulated research.
* For studies that involve banking either locally or at another institution. Banking is the storage of data or specimens for future research, including, but not limited to research by other investigators if the future research involves a new study (or studies) with its own aims. Studies contributing to dbGaP or other federal repositories do not qualify for exempt review.
* For studies where the investigator has agreed to conduct the study per International Center for Harmonization of Good Clinical Practice (ICH-GCP).
  + This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
  + Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.

**Instructions:**

* Review the “Choosing a Protocol Template” Reference Guide found on the IRB Resources website to ensure that a different template wouldn’t be more appropriate for your study.
* Fill in the header information.
* Do not modify the footers of the template. Template version information in the footer is for IRB use only.
* Hover over the superscript numbers within the template to view helpful information and requirements related to completing specific sections of the template.
* Complete each section in the template. If the section does not apply, type N/A.
* Attach all data collection forms, survey/instruments, and/or interview questions (as applicable) to the appropriate sections within your Click submission. Unless otherwise requested, recruitment materials do not need to be reviewed by the IRB for exempt studies.
* If you will use a consent form it must be submitted for IRB review. “Consent form” in this context means any consent materials, including information sheets, e-mails, etc. If the study involves protected health information (PHI), a consent form containing the required HIPAA language (see the confidentiality section of **HRP-502E- new regs - Exempt Consent Form Template**) or standalone HIPAA Authorization Form (**HRP-502J - Standalone HIPAA for Reliances**) must be used, unless an alteration or waiver of HIPAA Authorization is being requested. Use of the Seattle Children’s Exempt Consent Form Template is not required.
* If this research involves the HRP-508A - Department of Defense Protocol Supplement will also need to be completed. A list of Department of Defense components can be found in the supplement.
* Remove the Instruction pages (keep to reference later as necessary) before uploading your protocol to Click IRB.

**PROJECT TITLE:**

Equity in COVID-19 Vaccine Accessibility and Distribution

**PRINCIPAL INVESTIGATOR:**

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*Pediatrics Residency*

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Contents

[1. Exempt Category 5](#_Toc76560149)

[2. Study Objectives 8](#_Toc76560150)

[3. Study Background 8](#_Toc76560151)

[4. Study Population 8](#_Toc76560152)

[5. Procedures Involved 8](#_Toc76560153)

[6. Risks to Subjects 9](#_Toc76560154)

[7. Confidentiality and Privacy 9](#_Toc76560155)

[8. Subject Recruitment 10](#_Toc76560156)

[9. Consent 10](#_Toc76560157)

[10. HIPAA Authorization and RCW Criteria 11](#_Toc76560158)

# Exempt Category

**Select the exempt category the proposed project fits under. More than one category could be selected.**

**Exempt Categories:[[1]](#endnote-1)**

**45 CFR 46.104(d)(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.

**45 CFR 46.104(d)(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:

(1) The information obtained is recorded by the investigator in such a manner that identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(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, educational advancement, or reputation; OR

(3) 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 the IRB is able to determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

* *Options (1) and (2) may not be applied to research involving minors, if survey or interview procedures will be used.*
* *Options (1) and (2) may not be applied to research involving minors and observation of public behavior except when the investigators do not participate in the activities being observed.*
* *Option (3) may not be applied to research involving minors.*

**45 CFR 46.104(d)(3):** Research involving benign behavioral interventions[[2]](#endnote-2) 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:

(1) 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;

(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, educational advancement, or reputation; **OR**

(3) 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 the IRB is able to determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

* *This category may not be applied to research involving minors*
* *If the research involves deceiving the subjects regarding the nature or purposes of the research, this category may not be applied 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.*

**45 CFR 46.104(d)(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:

(1) The identifiable private information or identifiable biospecimens are publicly available;

(2) 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;

(3) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA for the purposes of ‘‘health care operations’’ or ‘‘research’’ as those terms are defined or for ‘‘public health activities and purposes’’

* *To qualify for this sub-category, the research must involve identifiable health information[[3]](#endnote-3) that**will remain within a HIPAA covered entity, such as Seattle Children’s.[[4]](#endnote-4)*

(4) 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.*

*Option (4) is* ***rare*** *at Seattle Children’s.*

**45 CFR 46.104(d)(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.[[5]](#endnote-5)

*Use of this category is* ***rare*** *at Seattle Children’s.*

**45 CFR 46.104(d)(6):**  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 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.

*Use of this category is* ***rare*** *at Seattle Children’s.*

# Study Objectives

* 1. Study’s purpose, specific aims, or objectives:

The aim of this study will be to

* 1. Hypothesis to be tested, if any:

✍*Click here to enter text.*

# Study Background[[6]](#endnote-6)

* 1. Scientific or scholarly background:

✍*Click here to enter text.*

* 1. Gaps in current knowledge:

✍*Click here to enter text.*

# Study Population

* 1. Describe what group(s) of people will be subjects[[7]](#endnote-7) in the study:

✍*Click here to enter text.*

* 1. Inclusion criteria for each subject population:

✍*Click here to enter text.*

* 1. Exclusion criteria for each subject population:

✍*Click here to enter text.*

* + 1. Justification if subjects who use a language other than English or subjects with a parent/legally authorized representative (LAR) who uses a language other than English, will be excluded from the research:**[[8]](#endnote-8)**

✍*Click here to enter text.*

* 1. Number of study subjects to be enrolled at Seattle Children’s:

✍*Click here to enter text.*

* 1. Minors: Indicate specifically whether you will enroll individuals who are not yet adults (infants, children, teenagers):[[9]](#endnote-9)

Yes, we **will** enroll individuals who are not yet adults.

No, we **will not** enroll individuals who are not yet adults.

# Procedures Involved

* 1. Study design:

✍*Click here to enter text.*

* 1. Research procedures:[[10]](#endnote-10)

✍*Click here to enter text.*

* 1. Process to ensure study information is available throughout the research to individuals who use a language other than English:[[11]](#endnote-11)

✍*Click here to enter text.*

* 1. Source of data, biospecimens and/or subjects:[[12]](#endnote-12)

✍*Click here to enter text.*

* 1. If your study involves secondary research use of data and/or biospecimens, provide a comprehensive list of all the variables, information, and/or biospecimens that will be used. If applicable, distinguish the information/variables that will be used, but not recorded (e.g. written down, typed in, etc.):[[13]](#endnote-13)

✍*Click here to enter text.*

# Risks to Subjects

* 1. Reasonably foreseeable risks for each subject population, related to their inclusion in the research:[[14]](#endnote-14)

✍*Click here to enter text.*

# Confidentiality and Privacy

* 1. Procedures to secure research records[[15]](#endnote-15), data, and/or biospecimens during storage, use, and transmission:  
     ✍*Click here to enter text.*
  2. Steps that will be taken throughout the research to protect the privacy interests:[[16]](#endnote-16)

✍*Click here to enter text.*

* 1. Location where data and/or biospecimens will be stored:[[17]](#endnote-17)

✍*Click here to enter text.*

* 1. Individuals with access to data and/or biospecimens:[[18]](#endnote-18)

✍*Click here to enter text.*

* 1. Manner in which data and/or biospecimens will be stored (identifiable, coded, de-identified):

✍*Click here to enter text.*

* 1. Process for the transmission of data and/or biospecimens outside Seattle Children’s:

✍*Click here to enter text.*

* + 1. Comprehensive list of data and/or biospecimens that will be transmitted:

✍*Click here to enter text.*

* + 1. Individual(s) who will transmit data:[[19]](#endnote-19)

✍*Click here to enter text.*

# Subject Recruitment

* 1. Recruitment methods:[[20]](#endnote-20)

✍*Click here to enter text.*

* 1. Steps that will be taken to protect the privacy interests during recruitment:[[21]](#endnote-21)

✍*Click here to enter text.*

* 1. Subject compensation:[[22]](#endnote-22)

✍*Click here to enter text.*

# Consent[[23]](#endnote-23)

* 1. Describe the consent process[[24]](#endnote-24) or reasoning for not having a consent process[[25]](#endnote-25):

✍*Click here to enter text.*

* + 1. If using an electronic consent, the alternative way of obtaining consent for individuals who are not able to receive/access/use the electronic consent system being used or explanation as to why an alternative process is unnecessary:[[26]](#endnote-26)

✍*Click here to enter text.*

* + 1. Steps that will be taken to protect privacy during the consent process:**[[27]](#endnote-27)**

✍*Click here to enter text.*

* 1. Plan for documenting consent:[[28]](#endnote-28)

✍*Click here to enter text.*

* + 1. If using electronic consent, plan to manage consent documentation over the life of the study in a way that maintains integrity and accessibility:[[29]](#endnote-29)

✍*Click here to enter text.*

# HIPAA Authorization and RCW Criteria[[30]](#endnote-30)

* 1. HIPAA Authorization: Check all boxes that apply.

The study does not involve the receipt, creation, use and/or disclosure of protected health information.

HIPAA authorization will be obtained via a signed consent form or authorization form[[31]](#endnote-31).

The study will access PHI without prior authorization from subjects (including for recruitment purposes). *Complete Section 10.2. to request a waiver of authorization.*

Subjects will review an information sheet with the appropriate HIPAA language but provide their authorization verbally only[[32]](#endnote-32). *Complete Section 10.2. to request an alteration of authorization for the written signature.*

A limited data set will be used and/or disclosed. *Complete Section 10.2. so that an RCW determination can be made.*

* 1. HIPAA Waiver/Alteration and RCW Criteria:[[33]](#endnote-33)
     1. Explain why the use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:
        1. An adequate plan to protect the identifiers from improper use and disclosure:

✍*Click here to enter text.*

* + - 1. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

✍*Click here to enter text.*

* + - 1. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

✍*Click here to enter text.*

* + 1. Explain why the research could not practicably be conducted without the waiver of authorization:

✍*Click here to enter text.*

* + 1. Explain why the research could not practicably be conducted without access to and use of the PHI:

✍*Click here to enter text.*

1. A comprehensive list of approval criteria for exempt research can be found in HRP-312 – Worksheet – Exemption Determination (found under the “Worksheets” tab of the Click Library). [↑](#endnote-ref-1)
2. 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. Examples may include having subjects play an online game or solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. [↑](#endnote-ref-2)
3. Health information is any information, including demographic or genetic information, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. [↑](#endnote-ref-3)
4. For example, studies where identifiable health information will remain stored on an Seattle Children’s server would qualify, but a study in which identifiable health information will be stored in the University of Washington (UW) REDCap platform will not qualify because the UW REDCap is not housed within a HIPAA covered entity. [↑](#endnote-ref-4)
5. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. [↑](#endnote-ref-5)
6. Include rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. [↑](#endnote-ref-6)
7. A subject refers to any living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. See HRP-001 – SOP – Definitions for other relevant definitions (available under the “Standard Operating Procedures” tab of the Click Library [↑](#endnote-ref-7)
8. For the study to be approved, there must be equitable selection of subjects. If subjects will be excluded based on language, the IRB will look for a sufficient justification for the exclusion. In most circumstances, the cost of translation and/or interpreter services will not be considered sufficient justification for the exclusion of participants who use a language other than English. [↑](#endnote-ref-8)
9. Some exempt categories do not allow for the inclusion of minors as subjects. If minors will be enrolled in the study, confirm that you have chosen a category in Section 1 that allows for the enrollment of minors. [↑](#endnote-ref-9)
10. Include enough information for the IRB to determine whether the study fits into the category for which you are applying. Include, the location where the research will be conducted. If your study involves deception, that should be stated in this section. [↑](#endnote-ref-10)
11. Applicable to information conveyed in writing and verbally. For example, your plan could include translating all study documents and having a study team member or interpreter available who can speak the language to answer questions. [↑](#endnote-ref-11)
12. For example, medical records, residency program, pathology, etc. [↑](#endnote-ref-12)
13. Respond N/A if the study does not involve secondary research using data and/or biospecimens. Attach a separate data collection sheet, if preferred. [↑](#endnote-ref-13)
14. As appropriate, your response should speak to whether disclosure of human subjects’ responses outside the research would place subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. Describe the probability, magnitude, duration, and reversibility of the risks. [↑](#endnote-ref-14)
15. Including the signed consent/assent/permission forms and any information/documentation collected during the consent process. [↑](#endnote-ref-15)
16. Privacy refers to persons and their interests in controlling the access of others to themselves. For example, based on privacy interests, people want to control the time and place where they give information, the nature of the information they give and who receives and can use the information. [↑](#endnote-ref-16)
17. If data will be stored in a database, electronic platform, cloud storage, etc. identify the specific database, platform, program, etc. being used and the hosting institution. For example, UW RedCap. If you are applying for category 45 CFR 46.104(d)(4)(3) and identifiable health information will be stored outside Seattle Children’s, indicate whether the institution/organization where identifiable health information will be stored is a HIPAA covered entity. [↑](#endnote-ref-17)
18. Rather than list names of study team members, identify individuals by role or affiliation (e.g., study team members from UW and SCH will have access or all study team members will have access. If applicable, distinguish between those who have access to identifiable versus anonymous data. [↑](#endnote-ref-18)
19. List individuals by role and not name. [↑](#endnote-ref-19)
20. Describe when and how potential subjects will be approached. [↑](#endnote-ref-20)
21. For example, potential participants will be approached in a private setting, so others will not overhear the conversation or letters sent to potential participants will not contain information considered to be sensitive. [↑](#endnote-ref-21)
22. Describe the amount, method (e.g. gifts, check, gift cards) and timing of any payments to subjects. [↑](#endnote-ref-22)
23. The term “Consent” in this section also refers to assent and permission for minor participation, so if you will enroll minors your responses must also address assent and permission, as applicable. [↑](#endnote-ref-23)
24. If the research involves an interaction with participants, the study team must generally disclose the following during the consent process: (1) the activities involve research (2) the procedures to be performed (3) that participation is voluntary (4) the name and contact information for the investigator.

    Include the following in the response:

    Speak to the suitability of the intended consent process for the intended audience, taking into consideration the subject’s and/or parent/LAR’s age, language, comprehension level, and familiarity with technology tools (if applicable).

    If using an electronic process to send consent information or obtain documentation of consent (e.g., e-signature), identify the process to be used to send the consent information (e.g., e-mail).

    If using an electronic process (e.g., e-mail), describe the procedures that ensure the electronic process allows subjects/parents/LARs to ask questions they may have before signing (e.g., by in-person discussions, telephone calls, videoconferencing). If conducting a consent conference, describe the method to be used for the conference (e.g., telephone call, video conference), specifying any programs (e.g., Zoom) to be used. If applicable, indicate that the consent discussion will be audio or video recorded and whether recording will occur within any programs being used (e.g., Zoom).

    If using an electronic process, describe how the subject and/or parent/LAR will navigate the consent materials, including whether the subject/parent/LAR will have the ability to move backwards and forwards within the electronic system and to stop and continue at a later time. Also indicate how long it will take.

    The availability of study personnel to assist subjects and/or their parent/LAR in using the electronic process, if applicable.

    If you choose to use a form as part of the consent process, it must be submitted to the IRB for review. A template exempt consent form, “HRP-502E-Exempt Consent Form Template”, is available in the Click library. [↑](#endnote-ref-24)
25. For example, “There is no consent process because we will not interact with participants.” [↑](#endnote-ref-25)
26. Some study teams are currently considering creative solutions for such individuals; these potential solutions include snail mail, drive through paperwork for consent, and loaner device/hotspots for e-consenting. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion. [↑](#endnote-ref-26)
27. For example, the consent discussion will take place in a private room. [↑](#endnote-ref-27)
28. For exempt studies, a signature is generally only required if the study involves PHI. Address the following in the response, as applicable:

    Identify the means of documenting consent (e.g., in writing, verbally, etc.). If obtaining an electronic signature, identify the specific software/application to be used.

    Include a description of how the consent form will be delivered, including any programs (e.g. REDCap) to be used.

    Include a list of any information about the individual that will be collected during the consent process.

    If the research is conducted outside of Washington State, provide confirmation that the electronic documentation of consent is legally effective in that jurisdiction. Note, the study team’s location while conducting the study dictates the jurisdiction. [↑](#endnote-ref-28)
29. For example, consent forms will be downloaded as soon as they are full executed and saved electronically in a location accessible to the study team. [↑](#endnote-ref-29)
30. HIPAA rules apply if in the course of conducting the study, researchers may obtain, create, use, and/or disclose individually identifiable health information. [↑](#endnote-ref-30)
31. The form to be used to obtain HIPAA Authorization must be reviewed by the IRB. [↑](#endnote-ref-31)
32. The form to be used to obtain HIPAA Authorization must be reviewed by the IRB. [↑](#endnote-ref-32)
33. Provide justifications/explanations for each procedure for which a waiver/alteration is being requested. [↑](#endnote-ref-33)