**Request for Determination of Exempt Status, Categories 1-6**

Complete this form if you believe that your activity may meet the criteria for a determination of exempt status. The determination of exempt status must be made by an independent person knowledgeable in the interpretation of Human Subjects Research regulation and guidance. At NJH, this responsibility is delegated by policy to HRPP Staff who also have the authority to require modifications to exempt research in order to ensure protections of human subjects.

A determination of exempt status does not in any way absolve the investigator from his or her responsibilities in protecting the rights and welfare of the subjects participating in the research. Exempt research is subject to the policies and oversight of the Human Research Protection Program. All principles of the Belmont Report and NJH policies on the protection of patient(s) privacy and confidentiality also apply.

**For research that does not require limited IRB review, once a research study has been certified as "exempt," there is no need to report back to the IRB other than to report the study closure, request an extension of the exemption beyond the approval period, or if ANY changes or modifications are made to the study.**

**Additional requirements for exempt category 2 & 3 research that require limited IRB review:**

Under the New Common Rule, some exempt categories include a provision for limited IRB review. For **exempt categories 2 & 3**, the requirement for limited IRB review is triggered when:

1. *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
2. *Any disclosure of the human subjects’ responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation*

Limited IRB review requires that the IRB determines that the criteria for IRB approval at 45 CFR 46.111(a)(7) is satisfied: *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

**In addition to this form, include the following with your submission:**

1. The protocol
2. Any subject materials such as recruitment materials, information sheets, consents, scripts, and questionnaires or surveys

**I. Basic Information**

1. Protocol Title:
2. Do any of the research staff have a Conflict of Interest?

If Yes, Is a COI management plan in place? [ ]  Yes [ ]  No - Documentation of COI review and any conflict management plans must be included with your submission.

1. Funding Support:

**Note:** *Please consult with the HRPP Office if the research is supported by the Department of Justice/National Institute of Justice because DOJ is not currently a signatory to the Common Rule and may need to be considered under different standards.*

[ ]  NA, this project is unfunded

[ ]  Grant. Describe:

[ ]  Contract. Sponsor:

[ ]  Other. Describe:

1. Principal Investigator:

Name:

Address:

Email Address:

Phone Number:

1. Study Personnel *(study personnel include all individuals who interact, intervene with human subjects, or identifiable human data or biospecimens)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NAME | DEGREES/ LICENSURE | STUDY ROLE(e.g., Coordinator) | EMAIL ADDRESS | PHONE NUMBER |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**II. Basic Criteria for Eligibility for Exemption**

1. Does the proposed subject population include prisoners?

[ ]  No. Go on to the next question.

[ ]  Yes.

1. If yes, is the research aimed at involving a broader subject population that only incidentally includes prisoners?

[ ]  Yes. Describe:

[ ]  No. The research is not eligible for exemption. Apply to the NJH IRB for either expedited or convened board review.

1. Is the research subject to FDA regulations (i.e., clinical investigation of drugs, devices, biologics, and other FDA-regulated products)?

[ ]  Yes. Category 6 (certain taste & food quality studies) is the only allowable category that is exempt from the requirements of FDA regulations for IRB review. If your research does not fit the criteria for Category 6 you must apply to the IRB for either expedited or convened board review.

[ ]  No. Go on to the next question.

**III. Exempt Categories**

In order to be exempt, the only involvement of human subjects must be in one or more of the following categories.

1. Indicate all of the categories which you believe are applicable to this research:

[ ]  **Category 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.

* 1. Describe the educational settings where the research will be conducted.

* 1. Describe the educational practices involved in the research and, if applicable, any deviations from standardly accepted practices.

* 1. Describe how the normal educational practices are:
		1. Not likely to adversely impact students’ opportunity to learn required educational content.

* + 1. Not likely to adversely impact the assessment of educators who provide instruction.

[ ]  **Category 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:

[ ]  Criteria 1: Information is recorded in a non-identifiable manner (i.e., cannot

be linked back to subjects)

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; OR

Describe:

[ ]  Criteria 2: Information is not sensitive (i.e., low risk of harm if disclosed)

Note: *The information can be recorded in an identifiable manner*

**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

Describe:

[ ]  Criteria 3\*: Identifiable information (that might be sensitive) with limited IRB

review of privacy and confidentiality

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.

\*Note: The IRB must conduct a **limited IRB review** to make the following determination: *There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

 Describe:

1. Describe research interactions involving the following (as applicable):

[ ]  Educational tests

[ ]  Survey procedures

[ ]  Interview procedures

[ ]  Observation of public behavior

Note: *Exempt Category 2 is limited to the above research interactions and cannot involve any research intervention. For research involving an intervention, see Exempt Category 3.*

1. Children (choose one)

[ ]  Will not be included in Category 2 research; OR

[ ]  When Criteria 1 or 2 is met, children will only be included in Category

2 research involving the following:

[ ]  Educational tests

[ ]  The observation of public behavior when the investigator(s) do not participate in the activities being observed. Describe:

Note: ***Criteria 3*** *does NOT apply to research involving children.*

[ ]  **Category 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:

[ ]  Criteria 1: Information is recorded in a non-identifiable manner (i.e., cannot

be linked back to subjects)

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; OR

Describe:

[ ]  Criteria 2: Information is not sensitive (i.e., low risk of harm if disclosed)

Note: *The information can be recorded in an identifiable manner*

**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

Describe:

[ ]  Criteria 3\*: Identifiable information (that might be sensitive) with limited IRB

review of privacy and confidentiality

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.

\*Note: The IRB must conduct a **limited IRB review** to make the following determination: *There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

Describe:

* 1. **Benign behavioral intervention confirmation**
		1. ALL of the following must be true (yes)

|  |  |  |
| --- | --- | --- |
| **The behavioral interventions are:** | **Yes** | **No** |
| Brief in durationDescribe the duration of the interventions:  | ☐ | ☐ |
| Not expected to cause physical or emotional harm* Harmless
* Painless
* Not physically invasive
 | ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| Not likely to have a significant adverse lasting impact on the subjects (i.e., not expected to cause persistent or long-lasting discomfort or negative effects); and | ☐ | ☐ |
| The investigator has no reason to think the subjects will find the interventions offensive or embarrassing (considering the population, context, topic and other characteristics of the research) | ☐ | ☐ |

* + 1. Provided all above criteria are met, examples of 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. Describe the benign behavioral interventions involved in this research:
	1. Describe the information that will be collected from adult subjects.

* 1. Identify how the information will be collected.

[ ]  Verbal responses

[ ]  Written responses (including data entry)

[ ]  Audiovisual recording

* 1. Adult subjects must prospectively agree to the research. The procedures for obtaining prospective agreement from subjects to participate in the intervention and the data collection must be described below in Section IV.4.
	2. Does this research involve deceiving the subjects regarding the nature or purposes of the research?

[ ]  No

[ ]  Yes.

* + 1. If yes, will subjects be informed that they will be unaware of or misled regarding the **nature or purposes** of the research and be asked to prospectively agree to the deception? *For example, including the possibility of deception as an opt-in when seeking consent from students to participate in a research pool.*

[ ]  Yes. Describe:

Note: *When using deception in Exempt Category 3, all research procedures must be prospectively disclosed. For example, a subject may not be videotaped without prospectively agreeing to being videotaped.*

[ ]  No. The research is not eligible for exemption Category 3.

[ ]  **Category 4:** Secondary research for which consent is not required: **Secondary** **research** uses of (existing or prospectively collected) identifiable private information or identifiable biospecimens, if **at least one** of the following criteria is met:

[ ]  The identifiable private information or identifiable biospecimens are publicly available; OR

 Describe:

[ ]  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; OR

 Describe:

[ ]  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](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=fbe09e6471954ba39d6ad71f838af9a9&ty=HTML&h=L&mc=true&r=PART&n=pt45.1.164#se45.1.164_1501) or for “public health activities and purposes” as described under [45 CFR 164.512(b)](https://www.ecfr.gov/cgi-bin/text-idx?SID=b73b1b370f7aa1468cf29a783bf93ba1&mc=true&node=se45.1.164_1512&rgn=div8) Note: *This does not include biospecimens*; OR

 Describe:

[ ]  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](https://obamawhitehouse.archives.gov/omb/memoranda_m03-22/#b), [44 U.S.C. 3501](https://www.law.cornell.edu/uscode/text/44/3501) 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](https://www.law.cornell.edu/uscode/text/5/552a), and, if applicable, the information used in the research was collected subject to the [Paperwork Reduction Act of 1995](https://www.gpo.gov/fdsys/pkg/PLAW-104publ13/html/PLAW-104publ13.htm), 44 U.S.C. 3501 et seq.

 Describe:

[ ]  **Category 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.

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.**

* 1. Are **ALL** the above described requirements for this exemption satisfied?

[ ]  Yes. The published list that names this research or demonstration project is attached or can be found on the following website:

[ ]  No. The research is not eligible for exemption Category 5.

[ ]  **Category 6:** Taste and food quality evaluation and consumer acceptance studies, if:

[ ]  Wholesome foods without additives are consumed; or

[ ]  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:** If the research is FDA-regulated, this [exemption](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.104) only applies to the requirement for IRB review at [21 CFR 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56).  The regulations at [21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50), including informed consent, still apply.  However, if the research is minimal risk, the requirement for informed consent may be able to be [waived](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf).

1. Are there any research activities that are not encompassed within one of the above categories?

[ ]  Yes. Describe:

[ ]  No

**IV. Protection of Human Subjects**

1. How do you plan to identify subjects for recruitment or records/biospecimens for inclusion in the study?

1. Describe any inclusion and exclusion criteria or reference where this information can be located in the protocol.

1. Answer the following questions to describe plans for maintaining the confidentiality of the information/biospecimens gathered in the research
	1. Describe the provisions that will be taken to protect the confidentiality of subjects’ information/biospecimens and research data (e.g., storage of research data in a locked file cabinet, separate storage of key to code that allows re-linking of data, encrypted files, etc.).

* 1. Are there any other security controls (not already mentioned above) that are in place to protect the integrity of the information/biospecimens?

[ ]  Yes. Describe:

[ ]  No

* 1. If identifiers will be removed or replaced, is there a possibility that such information/biospecimens could be re-identified?

[ ]  Yes. Describe:

[ ]  No

[ ]  NA – there is no plan to remove or separate identifiers from research data.

* 1. How will the information/biospecimens be used?

* 1. Will the information/biospecimens will be shared or transferred to a third party or otherwise disclosed or released?

[ ]  Yes. Describe:

[ ]  No

* 1. What is the likely retention period or life of the information/biospecimens?

* 1. Is there a potential risk of harm to individuals should the information/biospecimens be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the study?

[ ]  Yes. Describe:

[ ]  No

1. If the research involves interaction with or observation of subjects, please answer the following. If not applicable to your study, write N/A.
	1. Describe how subjects will be recruited to participate in the research. Include any materials that will be used to recruit subjects in your submission package.

* 1. Describe the provisions to protect the privacy interests of subjects. Include a description of (1) the settings where subjects will be interviewed, surveyed, tested or observed for the purposes of the research; (2) the settings where research procedures will take place, (3) any provisions being taken to maximize privacy:

* 1. Although the regulations do not **ALWAYS** require consent for exempt research, researchers have an ethical obligation under the Belmont Report to ensure that subjects are properly informed and voluntarily agree to participate in research whenever possible (e.g., the research involves interactions with subjects in person or through surveys or interviews). A formal consent form is not required, but consent scripts, survey cover letters, or information sheets for exempt studies should include all of the following elements:
* A statement that the activities involve research
* A description of the procedures to be performed
* *For Category 3 research that involves subject deception:* A statement that subjects will be unaware of or misled regarding the nature or purposes of the research
* A statement that participation is voluntary
* The investigator's name and contact information

Will potential subjects be asked to provide informed consent? [ ]  Yes [ ]  No

If yes, describe the consent process and include with the submission any materials that will be used to explain the research and/or document consent.

* 1. Describe any measures that will be taken to ensure that subjects don’t feel obligated or pressured to participate in the research.

1. Will Protected Health Information (PHI) *(See Appendix 1)* be accessed, used, or disclosed for the purposes of the research?

[ ]  Yes [ ]  No

*If yes, please answer the following:*

* 1. Provide a comprehensive description of the PHI needed for the study or provide a data sheet as an attachment.

* 1. Describe the sources of the PHI, including whether PHI is being obtained from any non-NJH sources

* 1. If the sources of the PHI include any external (non-NJH) entities, explain the steps you are taking to ensure compliance with the entities’ HIPAA and data use requirements.

* 1. Will you be disclosing NJH PHI to any external parties such as a collaborator, sponsor, or other organization?

[ ]  Yes [ ]  No

If yes, is the data to be disclosed:

[ ]  Stripped of all elements considered to be identifiers under HIPAA (See Appendix 1)

[ ]  A Limited Data Set. Please complete a Data Use Agreement (See Appendix 2).

[ ]  Identifiable (contains PHI and is not restricted to a Limited Data Set).

* 1. Will you obtain written HIPAA authorization from subjects for use of their data or are you requesting a waiver of HIPAA authorization? Note: The requirement to obtain authorization, or a waiver of authorization, does not apply if your only use or exposure to PHI will be a Limited Data Set (See Appendix 2).

[ ]  NA. Limited Data Set

If there is more than one subject group (e.g., prospective subjects and historical control), indicate all that apply.

[ ]  Written authorization. *Include a copy of the authorization form with your submission.*

[ ]  All Subjects [ ]  Some Subjects. Explain:

[ ]  Waiver of Authorization.

[ ]  All Subjects [ ]  Some Subjects. Explain:

If you are requesting a waiver for some or all subjects, please provide responses to the following so that the IRB can determine whether or not the project qualifies for a waiver.

* + 1. Describe your plan to protect PHI from improper use and disclosure

* + 1. Describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). ***Note****: In many cases, identifiers will need to be retained after the research is completed (e.g., for publication or data verification purposes or because of contractual requirements or grant terms).*

* + 1. Describe why the research could not practicably be conducted without the waiver

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

**V. Principal Investigator Certification**

I will conduct the study identified above in the manner described in this application, the protocol, and any additional materials included in this, or subsequent, submissions. I will submit any proposed changes to the research to the National Jewish Health Human Research Protection Program Office prior to implementation, to evaluate whether the research remains exempt.

If a waiver of authorization is being requested, my signature below also certifies that:

(1) The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule

(2) The PHI that will be accessed, used, or disclosed for the purposes of the research is the minimum necessary to achieve the objectives of the research

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature Date

**Appendix 1: Protected Health Information**

*Protected health information means, generally,* health information that is individually identifiable (i.e., patient-specific) and that is created, maintained, used or disclosed by or for by a covered entity. More specifically, the term refers to information that:

1. identifies or could reasonably be used to identify the individual; and
2. relates to:
3. an individual’s physical or mental health or condition;
4. the provision of health care to an individual, or
5. Payment for health care provided to an individual.

Health Information that includes or is combined with any of the following elements is considered identifiable under HIPAA.

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
	1. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
	2. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

**Appendix 2: Limited Data Sets**

*Limited Data Set*refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual’s Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

*Data Use Agreement*refers to an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

Direct Identifiers that **must be excluded** for PHI to be considered a Limited Data Set:

1. Names.
2. Postal address information, other than town or city, state, and ZIP Code.
3. Telephone numbers.
4. Fax numbers.
5. Electronic mail addresses.
6. Social security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers.
11. Vehicle identifiers and serial numbers, including license plate numbers.
12. Device identifiers and serial numbers.
13. Web universal resource locators (URLs).
14. Internet protocol (IP) address numbers.
15. Biometric identifiers, including fingerprints and voiceprints.
16. Full-face photographic images and any comparable images.

A Limited Data Set **may include**: city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers.