Revised 8/11

RESEARCH EXEMPTION REQUEST (Category 4)
Purdue University
Institutional Review Board

Ref. # _____

Exemption under Title 45 CFR §46.101

(b)(4) exempts research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

PLEASE BE AWARE that you cannot begin the project until you have received notification that the exemption has been granted.

1. Check one of the following:

☐ This submission replaces a previous exemption, IRB Ref#

☐ This is a new study

2. Project Title:

3. Anticipated Funding Source:

4. Principal Investigator [See *Policy on Eligibility to serve as a Principal Investigator for Research Involving Human Subjects*]:

Name, Title, Department, Building, Phone, Fax, E-mail address

5. Co-Investigators and key personnel [See *Education Policy for Conducting Human Subjects Research*]:

Name, Title, Department, Building, Phone, Fax, E-mail address

6. Consultants [See *Education Policy for Conducting Human Subjects Research*]:

Name, Title, Department, Building, Phone, Fax, E-mail address

7. Anticipated Duration of Study: Please indicate when this project will end.

Project END Date:	

Conflict of Interest

8. Do the investigators have a significant financial interest in this study?

☐ YES If yes, proceed to question 9.

☐ NO If no, skip to question 10.

9. Have you filed a Conflict of Interest Disclosure Statement (Form C-1)?

☐ YES If yes, proceed to question 10 below.
☐ NO If no, refer to Conflict of Interest: Policies and Management.

10. Do the investigators have any other known conflict of interest in this study?

☐ YES If yes, please attach an explanation identifying the conflict.
☐ NO

Use of Protected Health Information (PHI) – HIPAA Requirements

11. As part of this project, will you

a. Collect protected health information (PHI)* from subjects in the course of providing treatment or experimental care; or
b. Have access to PHI* in the subjects' records?

Please read the definition of PHI below before answering.

> *PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:
>
> 1. identifies or could be used to identify an individual;
> 2. is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
> 3. 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 healthcare to an individual.
>
> The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information:
>
> 1. student records maintained by an educational institution; and
> 2. employment records maintained by an employer related to employment status.

If your project uses these kinds of records, it is not subject to HIPAA. However existing IRB rules and procedures still apply.

Health-related information is considered PHI if (any of the following are true):

1. the researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);
2. the records were created by any of the entities in statement 1 above and the researcher obtains the records from an intermediate source which is not a school record or an employer record related solely to employment status; OR
3. the researcher obtains it directly from the study subject in the course of providing treatment to the subject.

Health-related information is NOT considered PHI if the researcher obtains it from:

1. student records maintained by a school;
2. employee records maintained by an employer related to employment status; OR
3. the research subject directly, if the research does NOT involve treatment.

☐ **YES**. Answer question 12 to determine if you will access a limited data set.
☐ **NO**. Skip to question 13.

12. Limited Data Set

A limited data set must have all the identifiers listed below removed from the data. It is the responsibility of the researcher and the party releasing the PHI to have in place and maintain a copy of a data use agreement that meets HIPAA requirements.

The following identifiers for the individual and the individual's relatives, employer or household members must be removed to create a limited data set:

1. Names
2. Postal address information other than town/city, state and zip code
3. Telephone number
4. Fax number
5. Email address
6. Social security number
7. Medical record number
8. Health plan number
9. Account numbers
10. Certificate or license numbers
11. Vehicle identification/serial numbers, including license plate numbers
12. Device identification/serial numbers
13. Universal resource locators (URLs)
14. Internet protocol address (IPs)
15. Biometric identifiers
16. Full face photographs or comparable images

☐ **YES**. I will access a limited data set and will enter into a data use agreement with the party that releases the PHI. A copy of the data use agreement signed by both parties must be submitted to the IRB with the Research Exemption Request.
☐ **NO**. If you will access PHI and the data will not qualify for a limited data set, the research is **NOT** exempt. Please submit an IRB application for the project along with a HIPAA authorization or request for waiver/alteration of HIPAA authorization.

Summary of Activities

(use lay language, do not cut and paste from or refer to grant or abstract)

13. Briefly state your research question.

14. Describe the source of the specimens (e.g., pathological or diagnostic specimens which are considered waste and destined to be destroyed) or records (e.g., medical, educational, employment or existing data set).

To qualify for exemption in this category, you must plan to use an existing data set or specimens (or collecting waste tissue after it has been released to pathology) without access to identifiers. Specimens received as extra during a clinical procedure require a regular IRB application and written informed consent from the subject.

15. Are the data you are using publicly available?

☐ **YES.** Continue to question 17.
☐ **NO.** Continue to question 16.

16. Do you already have permissible access to the records or specimens (i.e., through a job, internship etc.)?

☐ **YES.** Describe how you have permissible access to the records.

☐ **NO.** Continue to question 17.

17. Will the records you receive be stripped of all identifiers that would make it possible for you to identify a subject?

☐ **YES.** Continue to question 18.
☐ **NO.** This research does not qualify for exemption Category 4 status. Please complete the regular IRB Application, requesting expedited review if appropriate.

18. Confirm that the data/specimens you will review already exist.

☐ **YES.** The dataset already exists and/or specimens already exist or, in the case of waste tissue, will be received by the researcher only after its release to pathology.
☐ **NO.** The dataset does not exist and/or the specimens do not already exist. If the data and/or specimens (other than waste tissue) do not already exist, then the research does not qualify for exemption Category 4 status. Please complete a regular IRB Application, requesting expedited review if appropriate.

19. Confirm that you will record the information in such a way that if it will not allow identifiable information to be to be linked with data.

☐ **I will not have access to, or create, a link.**
☐ **I will have access to a link.**
If you have access to or create a link, you do not qualify for exemption Category 4. Please complete a regular IRB Application, requesting expedited review if appropriate.

As principal investigator of this study, I assure that the information supplied in this form and attachments are complete and correct. I have read the *Researcher Responsibilities* and will conduct this research in accordance with these requirements.

Principal Investigator Signature: _____ Date: _____

Submit this signed form and attachments to the Human Research Protection Program office either via hardcopy or electronically. Forms received without signatures will be returned. A signed form and attachments can be submitted electronically as an email attachment to irb@purdue.edu. If a signed form is submitted electronically, a paper copy need not be submitted.

U.S Mail Address:
Human Research Protection Program
Purdue University
YONG, Rm. 1032
155 Grant Street,
West Lafayette, IN 47906-2114

Campus Address:
Human Research Protection Program
YONG 10th Floor, Rm. 1032

Need help? Contact HRPP office at 765-494-5942.
Office Hours: M-F 8-11 am 1-5 pm