**Instructions:**

Use this form for research projects involving the use of existing, *de-identified* datasets/specimens. This type of research meets the regulatory definition of research with human participants, and falls under the umbrella of exemption category 4.

In order to have a research project recognized as exempt, investigators will need to submit this request for exemption form, along with other study-related materials. The IRB Administrator will evaluate the exemption request and provide formal notification to investigators if their projects meet the criteria for exemption.

Please note that for each change that is proposed or occurs during the execution of the research activity, the investigator needs to consult with the IRB office to determine if the change affects the eligibility of the research activity to continue to be reviewed/approved as exempt research.

**Exemption under Title 45 CFR §46.101**

          (b)(4) exempt 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 INCLUDE THE FOLLOWING DOCUMENTS WITH THIS REQUEST:**

* [**Principal Investigator Agreement**](https://www.saintlukeshealthsystem.org/institutional-review-board)
* **Data Collection Form/List of specific data points to be included in this study**
* **Any applicable unexecuted agreements (i.e., data use agreements)**

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Project Title:**   |  | | --- | |  |   **2. Anticipated Funding Source:**   |  | | --- | |  |   **3. Principal Investigator:**   |  | | --- | |  | | Name, Title, Department, Building, Phone, E-mail address |   **4. Co-Investigators and key personnel:**   |  | | --- | |  | | Name, Title, Department, Building, Phone, E-mail address |   **6.  Anticipated Duration of Study:**Please indicate when this project will end.   |  |  | | --- | --- | | Project END Date: |  | |

**Conflict of Interest**

**7. Do any of the investigators have a significant financial interest in this study?**

YES.

NO.

**8.** **Have you filed a Conflict of Interest Disclosure Statement?**

YES. If yes, proceed to question 9 below.

NO. If no, please complete the [Conflict of Interest Disclosure Form](https://www.saintlukeshealthsystem.org/institutional-review-board) and return it, hardcopy, to the CORA office on the 3rd floor of the main hospital.

**9. Do any of 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**

**10. As part of this project, will you**

1. Collect protected health information (PHI)\* from subjects in the course of providing treatment or experimental care; OR
2. Have access to PHI\* in the subjects’ records?

Please read the definition of PHI below before answering.

\***Protected Health Information** 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 11 to determine if you will access a limited data set.

**NO** Skip to question 12.

**11. Will you obtain access to a limited data set?**

|  |  |
| --- | --- |
|  | **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 should 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**

***Please use lay language, do not cut and paste from, or refer to a grant or abstract.***

**12. Briefly state your research question.**

**13. 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).**

**14. Please list all data points (i.e., elements, variables, fields, information, etc.) that will be received/used for this study.**

**Please note: *Only the data listed below will be considered for exempt for use in this study. Post-hoc decisions to use other data require a new exempt request or a protocol submitted for expedited or full review.***

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 signed informed consent from the subject.

**14. Are the data you are using publicly available?**

**YES.** Continue to question 17.

**NO.** Continue to question 15.

**15. 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 16.

**16. 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 17.

**NO.** This research does not qualify for exemption Category 4 status. Please contact the IRB at [irb@saint-lukes.org](mailto:irb@saint-lukes.org) or visit the [Saint Luke’s IRB webpage](https://www.saintlukeshealthsystem.org/institutional-review-board) to locate the forms for retrospective research, if appropriate.

**17. 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 contact the IRB at [irb@saint-lukes.org](mailto:irb@saint-lukes.org) or visit the [Saint Luke’s IRB webpage](https://www.saintlukeshealthsystem.org/institutional-review-board) to locate the forms for retrospective research, if appropriate.

**18. Confirm that you will record the information in such a way that it will not allow identifiable information to be linked back to the 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 contact the IRB at [irb@saint-lukes.org](mailto:irb@saint-lukes.org) or visit the [Saint Luke’s IRB webpage](https://www.saintlukeshealthsystem.org/institutional-review-board) to locate the forms for retrospective research, 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 [Principal Investigator Agreement](https://www.saintlukeshealthsystem.org/institutional-review-board) and will conduct this research in accordance with these requirements.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Submit this signed form and attachments, hardcopy, to the CORA office on the 3rd floor of the main hospital, or via interoffice mail, attn: IRB office. Incomplete forms, or those submitted without signatures will be returned.