JEFFERSON—Office of Human Research

RECORD / CHART REVIEW / COMPUTER DATABASE

RESEARCH STUDY

Version Date – FOR OHR USE: 11/1/18

This form must be completed for any record/chart review and/or computer database research. Please submit this form to the Office of Human Research using the IRB Portal. **Form must be typewritten.**

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator:

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Division:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What type of record/chart review/database will be reviewed for research? Please check as appropriate:

[ ] Medical Record/Chart Review [ ] Films/X-rays

[ ] Computer/Database [ ] Hospital administrative/billing records

[ ] Quality Improvement Records [ ] Other types of record (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. a. Individuals who will be responsible for querying medical records/charts and/or database. (This must be a Jefferson Faculty member or employee). Use additional space if necessary.

|  |  |
| --- | --- |
| Name | Precise role with study/project |
|  |  |
|  |  |

1. Please list the names of all individuals who will be given access to the data.

|  |  |
| --- | --- |
| Name | Precise role with study/project |
|  |  |
|  |  |

1. Purpose of the study (describe succinctly).
2. How many subject or database records will be reviewed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Will data be sent outside of Jefferson? [ ] Yes [ ] No

If no, please note that subsequent release of data outside of Jefferson requires approval by the IRB. Investigators will need to update their request.

1. If yes, where will data be sent?
2. Why is it necessary to send data outside of Jefferson?

1. How will data be sent? (Describe actual methods and include plans for coding and/or encryption.)
2. Time period of the data to be collected: *mm/dd/yyyy* to *mm/dd/yyyy*.

 *(This refers to the data itself, not the time period over which you are collecting it.)*

* 1. If database(s) are to be queried, please specify:

 [ ] Department of Radiology [ ] Departmental Databases/registries

 [ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If record(s)/chart(s) to be queried, please specify.

[ ] Hospital Records [ ] Departmental records

[ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Data to be used for:

[ ] Publication [ ] Oral presentation

[ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Please check all categories of data that will be obtained during the record/database review?

[ ] Demographics [ ] Drug/Device utilized

 (age, sex, BMI, etc.)

 [ ] Diagnosis [ ] Length of Stay

 [ ] Lab values [ ] Radiology testing

 [ ] Clinic Notes [ ] Procedures/Treatment

 [ ] Billing/Charges [ ] Provider of record who saw patient and signed discharge note

 [ ] Location of service [ ] Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (OR, ED, inpatient, outpatient) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

HIPAA (Health Insurance Portability & Accountability Act) Privacy Rule Protections:

1. The following information is considered identifiable under the Privacy Rule regulations. Please check off whether any of the following will be obtained.

[ ] Patient/Subject Name

[ ] Address street location

[ ] Address town or city\*

[ ] Address state\*

[ ] Address zip code\*

 [ ] Elements of Dates (except year) related to an individual. For example, date of birth,

admission or discharge dates, date of death\*

[ ] Telephone number

[ ] Fax Number

[ ] Electronic mail (email) address

[ ] Social security number

[ ] Medical record numbers

[ ] Health plan beneficiary numbers

[ ] Account numbers

[ ] Certificate/license numbers

[ ] Vehicle identification numbers and serial numbers including license plates

[ ] Medical device identifiers and serial numbers

[ ] Web URLs

[ ] Internet protocol (IP) address

[ ] Biometric identifiers (finger and voice prints)

[ ] Full face photographic images

[ ] Any unique identifying number, characteristic code

[ ] Link to identifier (code)

If any of these elements are checked off, the data cannot be considered de-identified and authorization from the subject or a waiver of authorization (OHR-3) from the IRB is required.

\*Use of these items alone falls under provisions of a “limited data set”, which requires the signing of a data use agreement (OHR-6) by Principal Investigator. Please complete and attach, if applicable.

1. If links to identifiers are used, please describe the coding mechanism.