# Research Involving Secondary Use of

# Data, Documents, Records or Specimens

* If your proposed project involves any activities other than the secondary use of data, documents, records or specimens do not use this form.
* Secondary research refers to the research use of information or biospecimens that were collected for another purpose such as clinical care, education records, or a different research project.
1. Protocol Title: Click here to enter text.
2. Protocol Version Date: Click here to enter text.
3. Principal Investigator: Click here to enter text.
4. Funding:

 Will this project be sponsored or funded:

Yes [ ]  No [ ]

If yes, indicate the sponsor and upload a copy of the contract or grant:

 Click here to enter text.

1. Background

Provide the scientific or scholarly background, rationale, and significance of the research based on existing literature and how will it add to existing knowledge.

Click here to enter text.

1. Objectives

State the hypotheses to be tested.

Describe the purpose and primary objectives of this project.

Click here to enter text.

1. Inclusion and Exclusion Criteria for Selection of Subject Data or Specimens

Inclusion Criteria:

 Click here to enter text.

 Exclusion Criteria:

 Click here to enter text.

Age Range: Click here to enter text.

Provide the age range of all subjects that meet the inclusion criteria.

**Existing:** Do all the data, documents, records or specimens already exist at the time this study is submitted for initial IRB review?

Yes [ ]  No [ ]

**Date Range:**

Provide the date range of the data, documents, records or specimens to be analyzed or collected:

From: **Month*/*Day/Year to Month/Day/Year**

1. Number of Records or Specimens to be requested:

Enter the number of charts/records/specimens to be reviewed or analyzed: Click here to enter text.

Provide a rationale (e.g. statistical justification) for the number requested: Click here to enter text.

1. Accessing Data, Documents, Records or Specimens

List the source(s) of all the information, data or specimens, for this project. Include all medical record or imaging systems, lab results, billing records, student records, log-books, repositories, registries, specimen, databanks or other sources. Provide links to any applicable websites.

Click here to enter text.

\*Authorization of Access

Investigators are required to comply with internal or external regulations, policies or agreements for accessing data, documents, records or specimens for research purposes. Before your project is approved by the IRB you must submit the appropriate authorization or if necessary, the Privacy Officer or Registrar’s approval or any data use agreement to access the information described in this protocol. Provide information as necessary regarding your access: Click here to enter text.

1. Check any identifiable information you will be accessing, recording or disclosing:

|  |  |  |  |
| --- | --- | --- | --- |
| **Identifiers** | **Accessing** | **Recording** | **Disclosing** |
| 1 | Names or Initials. |[ ] [ ] [ ]
| 2 | Street address |[ ] [ ] [ ]
|  | Town or City |[ ] [ ] [ ]
|  | Parish or County |[ ] [ ] [ ]
|  | Complete Zip Code |[ ] [ ] [ ]
| 3 | All elements of dates (except year) 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). |[ ] [ ] [ ]
| 4 | Telephone numbers. |[ ] [ ] [ ]
| 5 | Facsimile numbers. |[ ] [ ] [ ]
| 6 | Electronic mail (email) 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 | Other unique identifying number, student ID number or code | ☐ | ☐ |[ ]

1. Data Fields

List all other data fields that will be collected from records or other sources or attach a data dictionary (Excel file) to the IRB application.

Click here to enter text.

1. Protection of Data, Documents, Records or Specimens

Indicate how the data, documents, records or specimens that you obtain and/or the study information you record will be adequately protected from improper use and disclosure.

[ ]  All electronic data and recorded information will be on an authorized system computer requiring a password for access.

[ ]  Private personal computers, laptops and portable devices will not be used to store or access the data

[ ]  All electronic data and recorded information will be encrypted.

[ ]  All paper records will be stored in a locked room/file-cabinet with access limited to the study team.

[ ]  All specimens will be stored in a secured/locked lab or freezer with access limited to the study team.

[ ]  I will obtain a Certificate of Confidentiality; explain: Click here to enter text.

[ ]  Other - Describe Click here to enter text.

[ ]  \*By checking this box the principal investigator is acknowledging that study records will be maintained in accordance with Texas A&M Rules and SAPs. HIPAA authorizations signed and dated by subjects must be maintained for at least six years after completion of the research.)

1. Explain how data or specimens will be transported or transmitted:

Click here to enter text.

1. Destruction of Personal Identifiers

Indicate the earliest opportunity you will use to destroy all personal identifiers obtained and recorded:

[ ]  Upon data entry and validation

[ ]  At completion of data analysis

[ ]  At completion of specimen processing

[ ]  If there are no plans to destroy the identifiers please provide justification below;

Please explain: Click here to enter text.

Will there be a link, code or any other process that will allow you to connect your

study data back to the identity of the subject? Yes [ ]  No [ ]

If yes, identify the person(s) that will maintain the link or code: Click here to enter text.

1. Data or Specimen Banking for Future Use

*Data or specimen banking for future use is not to be confused with holding data or specimens for analysis at a later time for this project.*

If congruent with any applicable consent, authorization or agreement, will identifiable data or identifiable specimens be banked for future use in another research project?

 [ ]  Yes [ ]  No

If yes, describe where the data or specimens will be stored, how any personal identifiers will be maintained and the procedures to release data, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. (A separate repository protocol may be required).

Click here to enter text.

16) Other Procedures Involved

Describe any additional procedures and methods involved in your study as applicable.Click here to enter text.

17) Study Timelines

Provide the estimated date for the investigators to complete this study:

Click here to enter text.

18) Risks to Subjects

Research involving data, documents, records or specimen pose the risk of loss of confidentiality. Are there any other risks besides breach of confidentiality?

 Yes [ ]  No [ ]

 If ‘Yes’ please describe: Click here to enter text.

19) Potential Benefits

Describe the potential benefits to subjects, science and/or society that may accrue as a result of this research: Click here to enter text.

20) Vulnerable Populations

 This research will include information on the following populations: Check all that apply:

[ ]  Children [ ]  Students

[ ]  Pregnant Women [ ]  Employees

[ ]  Neonates [ ]  Cognitively Impaired

[ ]  \*Prisoners

21) Sharing Study Results

[ ]  Results will not be shared with subjects

[ ]  Results will be shared with subjects as described:

 Click here to enter text.

[ ]  Results of this study will be published.

[ ]  Results of this study will be presented at the following:

Click here to enter text.

[ ]  Results of this study will be shared with the following drug or device companies or other industry related sponsors. Click here to enter text.

22) Locations and Sites

List all sites or locations where this research will be conducted. Indicate if there will be any external (non-TAMU) collaborators.

Click here to enter text.

Will someone other than the Principal Investigator listed on this protocol be responsible for the research listed at the sites above?

Yes [ ]  No [ ]

 If ‘Yes’ please provide details: Click here to enter text.

23) Resources Available

Describe your facilities or setting: Click here to enter text.

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Click here to enter text.

24) Consent Requirements

Waiver of Informed Consent Process:

Waiver of consent is frequently requested for retrospective reviews and analyses that are conducted for research purposes.

**Do you want to request a Waiver of Consent?**

[ ]  Yes [ ]  No If yes, please complete the section below:

The research involves only minimal risk because:

Click here to enter text.

Waiving consent does not adversely affect the participants’ rights because:

Click here to enter text.

Explain why this research cannot be conducted without this waiver because (in other words, why can you not obtain consent from the individual before you start accessing their records):

Click here to enter text.

25) HIPAA Authorization for Research

**Do you want to request a waiver of authorization?**[ ] Yes [ ]  No

If ‘Yes’, upload a copy of the Waiver of Authorization signed by the principal investigator.