Human Research Protection Program Protocol for Previously Collected Data

When to use this form: A Human Research Protection Program (HRPP) Protocol for Previously Collected Data can sometimes be used in place of a full IRB (Institutional Review Board) application when researchers plan to utilize existing data that has already been collected. This process is commonly known as “exempt” or “expedited” review, and it depends on the specific circumstances. Here are some scenarios when using a HRPP protocol may be applicable:

1. Exempt Research: If the research involving previously collected data meets specific criteria outlined by UT Permian Basin or the relevant regulatory authorities (e.g., the Common Rule), it may qualify for exemption from a full IRB review. Exempt categories often include research involving the analysis of anonymous or de-identified data.
2. Minimal Risk: If the research process poses minimal risk to participants, the HRPP may expedite the review process or exempt it from full review. Minimal risk generally means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.
3. Secondary Data Analysis: When researchers are using data that has been previously collected for a different study or purpose, and data are anonymous or de-identified, it may not require the same level of scrutiny as primary data collection. However, this still depends on UT Permian Basin policies and ethics regulations.
4. No Identifiable Information: If the previously collected data contains no identifiable information about the participants, such as names, addresses, or any other directly identifiable data, UT Permian Basin may allow the submission of an HRPP to streamline the review process.
5. Aggregate Data: If the research solely involves the analysis of aggregate data where individuals cannot be discerned, it may qualify for an expedited or exempt review.
6. Program Evaluation: In some cases, research conducted as part of a program evaluation or quality improvement initiative may be subject to different review processes or exemptions.

|  |
| --- |
| STUDY TEAM INFORMATION |
| Project Title |  |
| Investigator Name |  |
| Faculty Supervisor (Students Only) |  |

For faster processing, ensure all study staff have completed the required human research training available on the IRB website.

This protocol should only be used for retrospective analysis of existing data. The IRB may ask you to complete the full IRB protocol if your project includes procedures outside of retrospective analysis.

Contact irb\_chair@utpb.edu with questions.

|  |
| --- |
| PROJECT INFORMATION |

* 1. Expected project time period:

From: Click or tap to enter a date.

To: Click or tap to enter a date.

* 1. Explain how many data records or specimens you expect to analyze.

Click or tap here to enter text.

1.3 Do you currently have funding or expect to obtain funding in the future?

[ ]  Yes

[ ]  No

* 1. If you currently have funding, please identify the type of funding (e.g., Federal, University, State, Contractual, Private Sponsor, or Other).

Choose an item.

Select your award’s current status.

Choose an item.

* 1. Study Purpose: Describe the purpose of the research. Explain what is intended to be discovered; include goals, aims, and objectives and/or state the hypothesis to be tested.

Click or tap here to enter text.

* 1. Provide a brief scientific or scholarly background for the research activities, address gaps in current knowledge that may be filled by this research project.

Click or tap here to enter text.

|  |
| --- |
| 2. RISK & BENEFITS |

2.1 Does this study involve any of the following?

[ ]  Genetic information

[ ]  Biological specimens

[ ]  Information pertaining to illegal activity

[ ]  Information pertaining to substance abuse

[ ]  Information relating to sexual attitudes, orientation, or practice

[ ]  Private identifiable information

[ ]  Personal or sensitive information

[ ]  Information pertaining to disability status

[ ]  Private records (academic, medical, etc.)

[ ]  Information that if released could damage an individual’s financial standing, employability, reputation, or cause social stigmatization or discrimination

[ ]  Information that if released could cause stigmatization or discrimination within a specific community

[ ]  Other

[ ]  None of these

2.2 Describe the nature and degree of the risk or harm checked above. Describe if the number of samples/records you are receiving affects the degree of risk.

Click or tap here to enter text.

2.3 What steps will be taken to minimize the risks or harm and protect the subjects’ welfare (when risk is greater than minimal)?

Click or tap here to enter text.

2.4 Describe the anticipated benefits of the research for the individual, society, or science.

Click or tap here to enter text.

|  |
| --- |
| 3. DATA INFORMATION  |

3.1 Data Storage and Transfer Information

a. Summarize the original procedures for collection of the data/specimens, including the original investigators/owners of data, and the original intent for collection of the data/specimens.

b. Describe where the data/specimens are currently being stored and, if specimens, whether they are currently held in a tissue/specimen bank (or other facility).

c. Explain who will give the UT Permian Basin investigators access to the data/specimens for this project.

Click or tap here to enter text.

3.2 What type of data will you be analyzing? (Check all that apply)

[ ]  De-identified data (no direct/indirect identifiers)

[ ]  Identifiable data

[ ]  PHI (Protected Health Information)

[ ]  Academic Records

3.2a If the data are de-identified, will you have access to a key or code that could link data to identifiable private information (e.g., a person’s name, email)?

[ ]  Yes – the PI or study team will have access to a master key

[ ]  No – the PI and study team will not have access to a master key

[ ]  Unsure – I do not know if I will have access to a master key

3.3 Check the types of the identifiers present in the data set you are analyzing: (Check all that apply)

[ ] Names

[ ] Geographic subdivisions

[ ] Birth dates, date of death, admission/discharge dates

[ ] Age (without birth dates)

[ ] Student/employee IDs

[ ] Ethnicity/Race

[ ] Telephone or fax numbers

[ ] Electronic mail address

[ ] Social security numbers

[ ] Social media or Website Usernames

[ ] Medical or mental health records

[ ] Account numbers

[ ] Certificate or license numbers

[ ] Vehicle Identifiers and serial numbers

[ ] Device identifiers or serial numbers

[ ] Web Universal Resource Locators (URLs)

[ ] Internet Protocol (IP) address numbers

[ ] Biometric identifiers

[ ] Other unique identifiers

3.4 Explain what type of data will be included in your analysis. Explain why it is necessary to obtain or store identifiers. Describe the size of the data set or the number of specimens that will be analyzed.

Click or tap here to enter text.

3.5a. Explain how the data was originally collected. Explain if the data was originally approved for research or non-research purposes, and if the project was approved by an IRB.

Click or tap here to enter text.

3.5b. Will participants be contacted or compensated for the use of their data?

Choose an item.

3.6 Informed Consent Information

a. Explain how you will obtain consent from participants for use of this data, or why you do not plan to obtain consent.

b. Describe the process of obtaining consent. Include names of individuals on the research team who will obtain consent, where/when the process will take place and how you will ensure the subjects’ understanding.

c. For educational records or Protected Health Information (PHI), explain how you will satisfy the requirements for an authorization to use this data for research purposes under HIPAA and FERPA regulations

Click or tap here to enter text.

|  |
| --- |
| 4. DATA SECURITY |

4.1. Data Security Plan

a. Outline your data security plan, including protocol for personnel handling data, physical security safeguards, and electronic security safeguards.

b. Describe the steps that will be taken to secure data during storage, use, and transmission.

c. Provide details such as where and how the data will be stored, for how long it will be kept, how it will be disposed/destroyed. Explain if the data will be returned to the original owner.

Click or tap here to enter text.

4.2. Artificial Intelligence (AI) Tools

If you intend to use AI, you must notify participants that you intend to use AI and the capacity/context of its use.

a. a. Do you intend to use an artificial intelligence (AI) tool(s)?

b. How will you use AI (to collect data from humans through interaction or intervention, to obtain, analyze, or otherwise access identifiable data about human research participants, or as an extension or representative of the investigator by answering questions for potential, current, or past human research participants)?

c. Since investigators do not fully know the scope of the AI tools ability to use or re-access previously collected data, investigators who use AI must inform potential participants that their data may be used and/or re-accessed by an AI without their knowledge or consent in the informed consent document(s). Your signature below acknowledges your agreement to notify potential participants of the use and context of AI in your study and include a statement that their data may be used and/or re-accessed by an AI without their knowledge or consent.

Principal Investigator signature:

Date:

Additional Project Staff Signatures & Dates