How to Submit Data/Chart Reviews

- Choose this review type if you are looking at records, data, or specimens.

- You can examine Protected Health Information (PHI) and identifiers with this review type.

- Reminder that HIPAA Identifiers include:
  - All elements of dates (except year) for dates directly related to an individual
  - All geographic subdivisions smaller than a State

Additional information can be found on the HIPAA Identifiers page on the IRB website.

Exempt vs. Expedited Data/Chart Reviews

This review type branches down two paths: Exempt Review or Expedited Review. As you answer submission questions in myIRB, the program will present the appropriate path.

- **Exempt Data/Chart Review**
  - **Most record reviews will follow this path.** You can access data, keep a link to the data, and work retrospectively and prospectively. You can include tissue samples that have no links to identifiers or are publicly available. HIPAA regulations apply when keeping a link. If you keep a link, IRB will evaluate your de-identification plan and the practicability of your request for a HIPAA Waiver of Authorization.

- **Expedited Data/Chart Review**
  - If you are working with **identifiable tissue that is not publicly available**, your record review will be approved under an expedited category.

For technical instructions on creating a chart review in myIRB, view the Chart Review Submission Guide.

Study Title and Staff Smartform

Study Title and Staff

All items marked with an orange asterisk ( ) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

1.0 * IRB Committee:

- (●) IRB-01
- ( ) IRB-02

Clear

Visit http://irb.ufl.edu/ for information on which committee to choose for review of your project.

* **1.1** Is this a multi-institutional research project where the UF IRB will be the single IRB of record for other participating sites OR are you ceding review to another IRB of record? (IAAs are required between UF and other institutions)

( ) **Yes** (●) **No** Clear

2.0 * Project Title:

TVA Monster Study

3.0 Short Title:

The "Short Title" is a simplified, short title for advertising on UFHealth.org or CTSI website.

4.0 Provide a summary description or abstract for this study:

max 500 char

Summary Description Here

Study Title and Staff Smartform (Continued)

Guidance related to image on prior page:

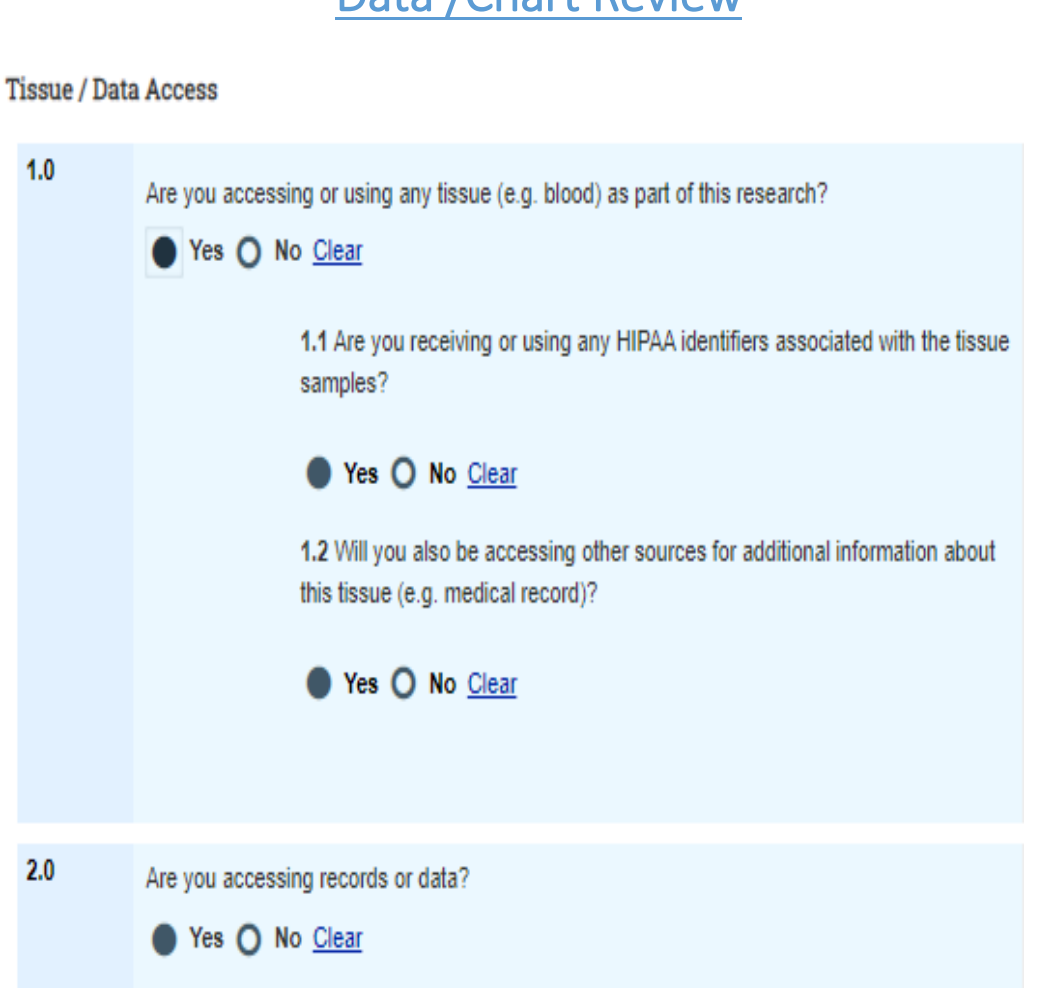
- **Item 4.0**: Provide a summary description for the study

- The Principal Investigator (PI), PI-Proxy, and Faculty Mentor **must** have the study staff role of "Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations".

- No study staff should have the role of "Obtaining Informed Consent" or writing orders in EPIC.

- Only select "Accesses or obtains, for research purposes, and PHI from a paper or EMR" when the actual medical record is being accessed. Do not select this item when data are obtained from other sources such as a data trust or an Integrated Data Repository (IDR).

Data /Chart Review


Tissue / Data Access

1.0

Are you accessing or using any tissue (e.g. blood) as part of this research?

● Yes ○ No Clear

1.1 Are you receiving or using any HIPAA identifiers associated with the tissue samples?

● Yes ○ No Clear

1.2 Will you also be accessing other sources for additional information about this tissue (e.g. medical record)?

● Yes ○ No Clear

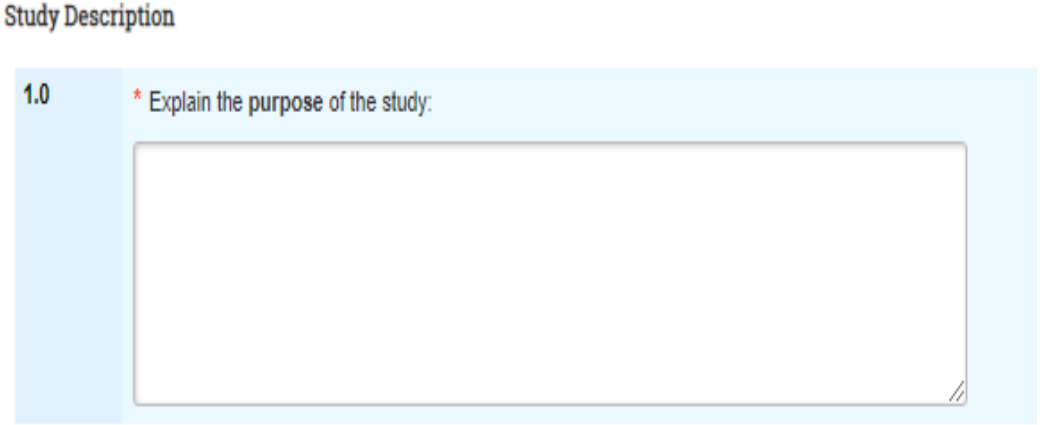
2.0

Are you accessing records or data?

● Yes ○ No Clear

- By virtue of the requested review type, at least one of the items on this smart form must be answered “yes”. Otherwise, this is not a Data/Chart review submission.

Study Description Item 1.0



- **Please include all applicable details of how your study is being conducted. This smart form is in lieu of a study protocol.** Failure to include detailed information on this answer will result in the submission being returned for correction ***and will delay IRB approval***.

- Item 1.0 must describe the study purpose. The purpose should not state that the study is a Quality Improvement (QI) or Quality Assurance (QA) project. Please a clear explanation and specific details. If you believe your project is QI or QA, please consult the IRB's Quality vs. Research Guidelines for guidance.

Study Description Item 2.0

2.0 Describe the **steps involved** in conducting this study.

If applicable, provide details for each of the following:

- the inclusion/exclusion criteria,
- How you will obtain the list of records/tissue you intend to review
- How data will coded in the analysis phase of the research
- and a data analysis plan

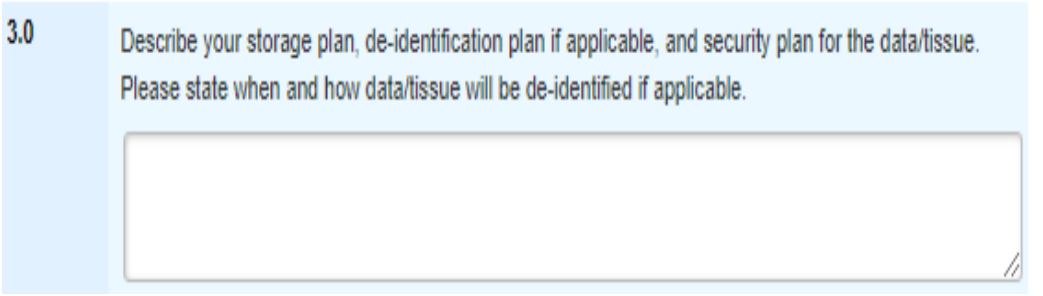
Additional instructions on smart form:

Please include all applicable details of how your study is being conducted. This question is in lieu of a study protocol.
*Failure to include **detailed** information will result in the submission being returned for correction.*
This will delay approval.
Contact the IRB office if you require assistance.

Study Description Item 2.0 (Continued)

- **Inclusion/exclusion criteria**: What kind of data/records/specimens will you review or analyze?
- How will you obtain the list of records you intend to review or analyze?
  - If you are only receiving a data set, what is the source of the data?
- What is the date range for the review/analysis? If you plan to use prospective data or specimens, you must justify **why** obtaining authorization is not practicable or state **how** authorization will be obtained.
- What is your data analysis plan? How will these data be coded during this phase of your project?
- You do NOT need to list all the variables you intend to use here. Please include those variables on the Data Collection smart form.
- If this is a multicenter project, describe that process, including what data are maintained at UF and what will be sent to external sites.
  - Will the data be de-identified, or will you receive a Limited Data Set?

Study Description Item 3.0



- Please clearly state **where** you will store and secure data. Locations for data storage/security **must be** a UF IT approved server/system.
- You must clearly state **when** and **how** you will de-identify data.
- Any data key codes **must be** destroyed to be de-identified. Separating key codes is insufficient.
- If you will keep identifiers separate, the data collection smartform must also reflect this.
- Remember that dates **are** identifiers! If you include date variables, please clarify if you are stripping or converting to ages or time periods.
- Zip codes must be reduced to the first three numbers **or** grouped in areas more than 20,000 people.

Study Description Item 4.0

4.0

* By what authority does the Principal Investigator and Co-Investigator(s) have access to the data/tissue? If accessing medical records please state who is part of the covered entity.

Covered Entity is defined as:

1. UF Health Science Center + Shands, or
2. NF/SG VHS

Contact the IRB office if you have questions.

Additional clarification on smart form:

Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers, including researchers, who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

N.B.: UF Privacy requires the potential for a clinical relationship to exist between the study team and the subject population in order to access Electronic Medical Records (EMR). If none exists, either add a person to the study team who has the potential for a clinical relationship, or devise a way to obtain data without accessing medical records (e.g., UF Health Integrated Data Repository).

Exempt/Multiple Sources Determination

Exempt / Multiple Sources Determination

1.0 * When you extract data and record it for research purposes, will you collect/record any **identifiable information** in your data collection forms / records?

- ○ No (All information will be collected without any identifiers, codes, links or other means of linking the research data to the subjects identity) NOTE: you are certifying you will never record identifiable information or coded information even for a temporary period.
- ○ Yes identifiable information from a publicly available source
- ○ Yes (you will either collect identifiable information or you will have a code key/link that associates your data collection tools/research records with the identity of the subjects

Clear

2.0 * Do you need to examine **multiple sources** for each subject where one of the sources is specimens /tissue? (Usually in order to correlate information between multiple sources)

- ○ No None of the sources for this research include specimens or tissue
- ○ Yes you will examine multiple sources for each subject including specimens or tissue

Clear

2.1 If yes, Can you access all the sources and extract your research data at the **same time** on a per subject basis?

- ○ No you will need to look at the sources at different times and have a link or record identifiable information
- ○ No you certify all sources are publicly available and that you do not link the public data to a non-public data source
- ○ Yes you certify that you can assemble all of your sources including specimens for each subject and extract your research data from them at the same time and you will never have a link or use a code.

Clear

Exempt/Multiple Sources Determination (Continued)

- Read these questions and response options carefully.

- **Item 1.0**: If you answer 'No', you must include in you study description smart form **how** you will never record identifiable information or coded information (even for a temporary period).

- If you obtain data from IDR, they always keep a key code, so those studies are best submitted as Non-Human with a Confidentiality Agreement.

- **Item 2.0**: This should only be answered 'Yes' if specimens and tissue are involved. Answering 'Yes' changes myIRB branching, so it is critical that 2.1 be cleared of all responses if Item 2.0 is 'No'.

Exempt vs. Expedited Categories

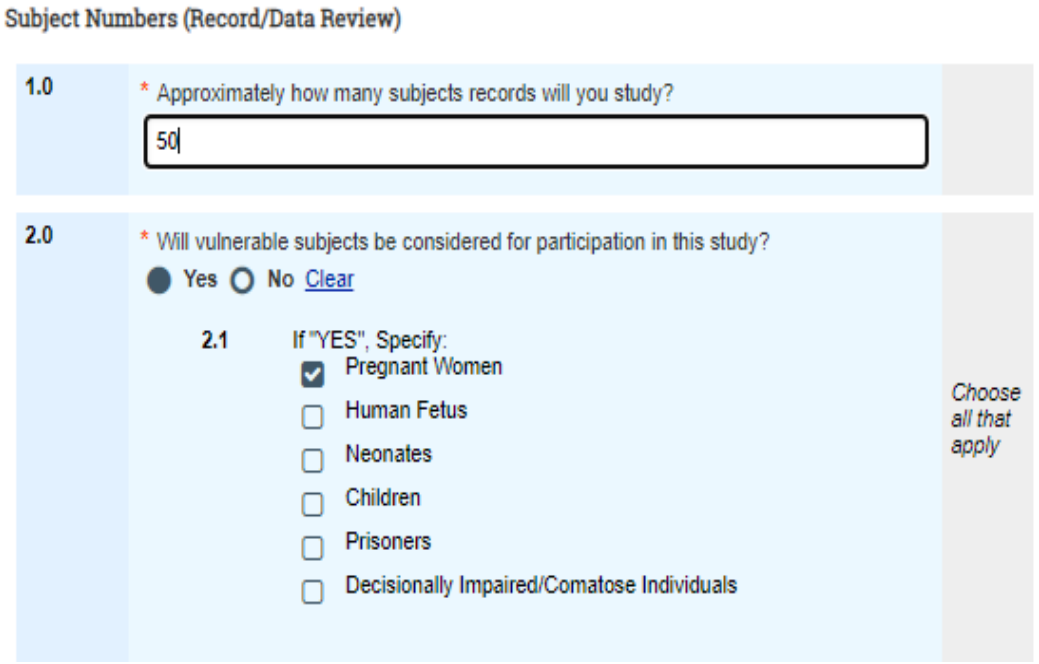
Exempt Regulation Confirmation Categories

- (4)(i) includes publicly available data. No HIPAA waiver required.
- (4)(ii) includes no identifiers or codes are being used. No HIPAA waiver required.
- (4)(iii) are the majority of the chart reviews. Identifiers are used. Therefore, a HIPAA waiver **is** required.

Expedited Regulation Confirmation Categories

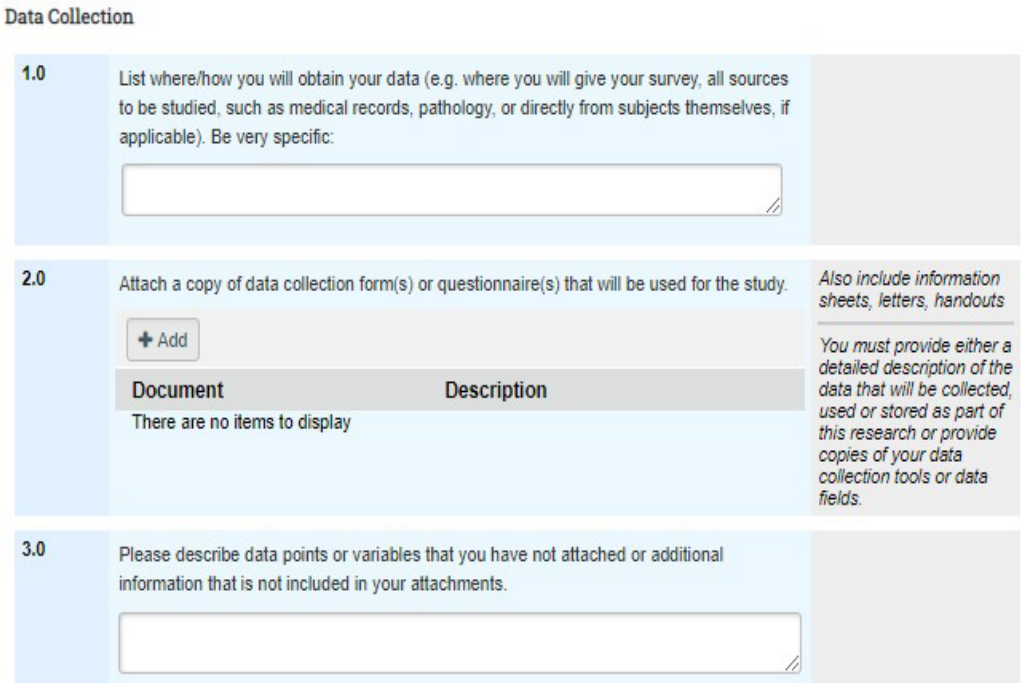
- (5) Research involving materials (e.g., data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **Note:** Some research in this category may be exempt from regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(4). This listing **only** refers to non-exempt research.
    - **REMINDER**: If you are working with *identifiable tissue that is not publicly available*, your record review will be approved under an expedited category.

Subject Numbers (Record/Data Review)



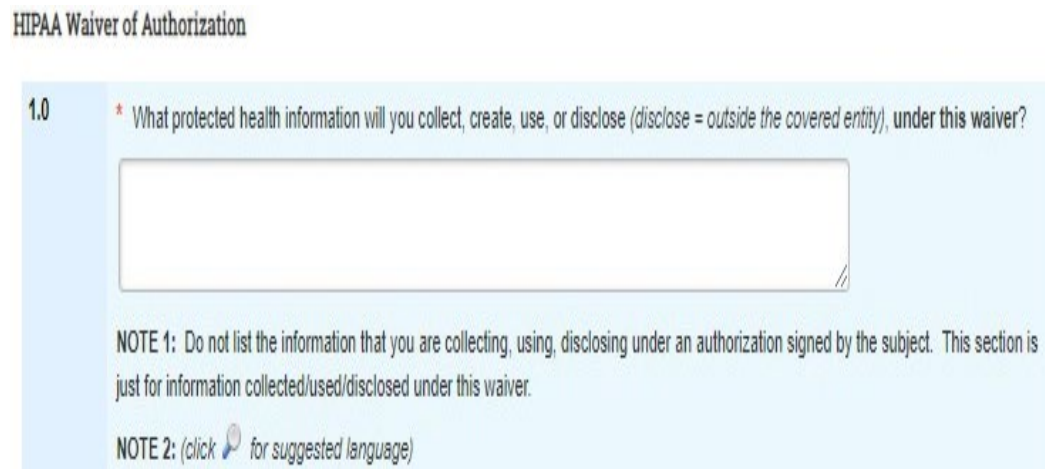
- Remember to **only** check the vulnerable subjects that you will record/analyze data/information for.

Data Collection Smartform



- Item 1.0 must state ***all*** sources of data.
- For items 2.0 and 3.0, only answer **one** of the two items. Remember that data collection must be consistent with what was stated on the study description as well as what will be included on the upcoming HIPPA waiver smartform.
- If this is a multi-center project, it must be clearly indicated. This can be done by attaching separate documents or clearly describing what data will remain at UF and what will be sent to external sites

HIPAA Waiver of Authorization Item 1.0

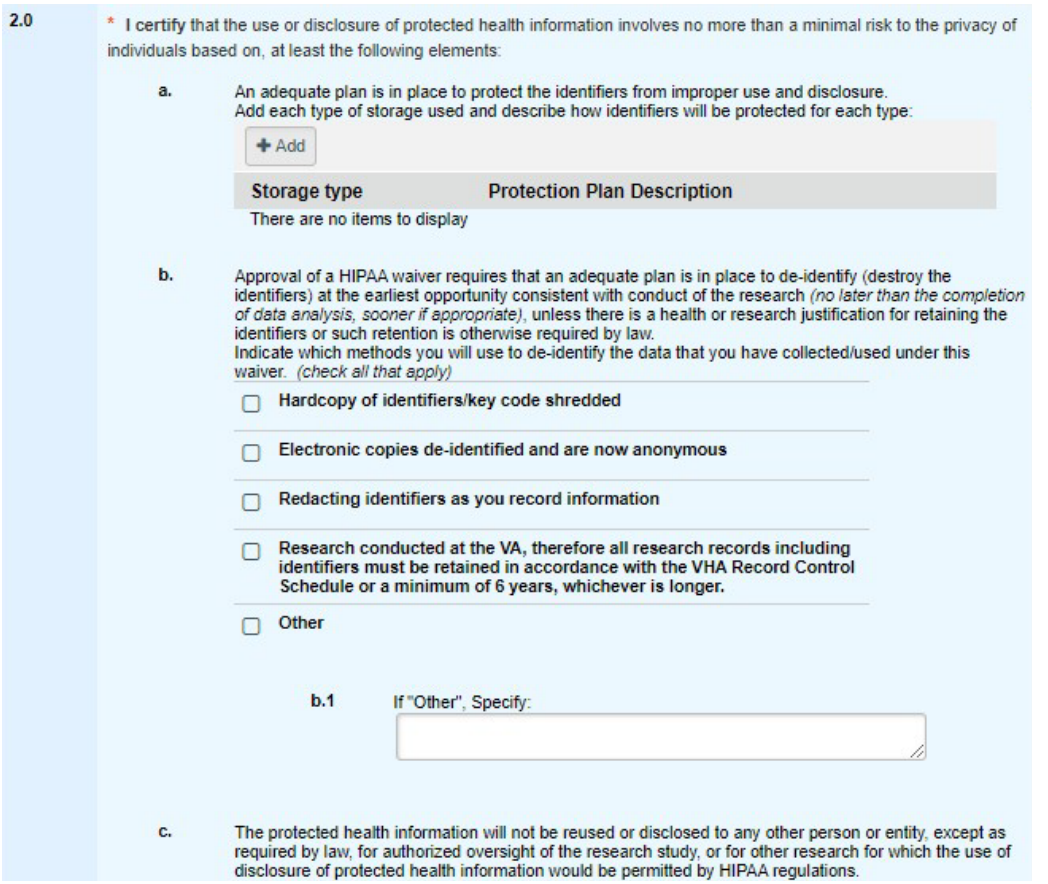


Additional instructions on smart form:

*If you are collecting Social Security Numbers for reasons other than compensation, you must complete the **SSN Exception Form***
*Attach form to this application on the **Miscellaneous Attachments** page in the Supplements section.*

- Please list all identifiers and a summary of the health variables you will be collecting. While the question asks for PHI, a name by itself is not PHI. This response must also be consistent with the Data Collection smartform.

HIPAA Waiver of Authorization Item 2.0



2.0 * I certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least the following elements:

a. An adequate plan is in place to protect the identifiers from improper use and disclosure.
Add each type of storage used and describe how identifiers will be protected for each type:

+ Add

Storage type	Protection Plan Description

There are no items to display

b. Approval of a HIPAA waiver requires that an adequate plan is in place to de-identify (destroy the identifiers) at the earliest opportunity consistent with conduct of the research *(no later than the completion of data analysis, sooner if appropriate)*, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
Indicate which methods you will use to de-identify the data that you have collected/used under this waiver. *(check all that apply)*

- ☐ Hardcopy of identifiers/key code shredded
- ☐ Electronic copies de-identified and are now anonymous
- ☐ Redacting identifiers as you record information
- ☐ Research conducted at the VA, therefore all research records including identifiers must be retained in accordance with the VHA Record Control Schedule or a minimum of 6 years, whichever is longer.
- ☐ Other

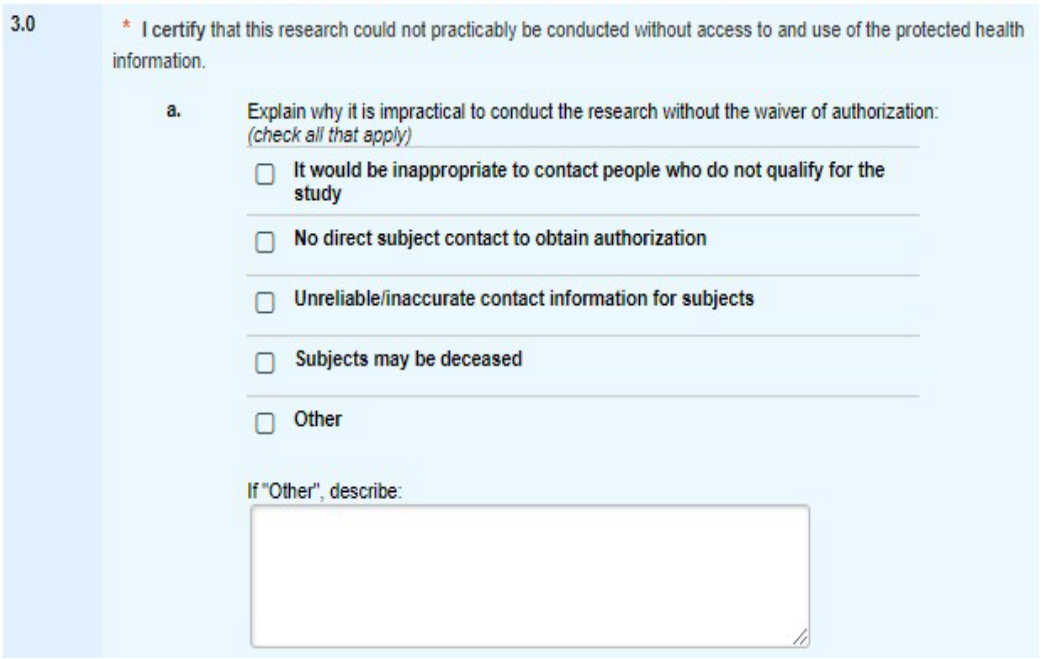
b.1 If "Other", Specify:

c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by HIPAA regulations.

- Item 2a **must** be consistent with previously stated storage and security plan (as outlined in item 3.0 on the "Study Description" smart form.

- For Item 2b, the plan to de-identify study data under this waiver **must** be consistent with what is stated in prior smart forms.

HIPAA Waiver of Authorization Item 3.0



- Item 3.0 **must** state why authorization is not practicable.
    - Please do not check the first box as patients are never contacted in a Data/Chart Review study.

Miscellaneous Smartform Hints

- No protocol document should be attached as the Study Description smartforms serve as the study protocol.
- Depending on source of data/specimens, you may need to upload IRB approvals.
- If applicable, the HIPAA authorization would be attached here.
- If obtaining or sharing a Limited Data Set outside the covered entity, you must request a Data Use Agreement (DUA). DUAs are handled by the Office of Clinical Research and are submitted for review via UFIRST: https://research.ufl.edu/ufirst.html
- If a Confidentiality Agreement is needed because you are sharing de- identified or coded data, it would be attached here.