University Of _____
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: ***<<Insert Title of the Research Study>>***

Principal Investigator: ***<<Insert the Name of the Primary Investigator>>***
<<Insert Address>>
<<Insert Phone Numbers>>

Co-Investigators:** ***<<Insert the Names of the Co-investigators>>
<<Insert Phone Numbers>>

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. This authorization form gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting the University of _____ Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of _____ Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study.

What personal health information is collected and used in this study, and might also be shared (disclosed)?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study: ***[Modify this list as appropriate-delete or add items as necessary]***:

- Name
- Address
- Telephone number
- Family medical history
- Allergies

- Current and past medications or therapies

- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature

- List all other tests and procedures that will be performed in the study ***[these tests and procedures should be fully described in the existing Informed Consent Form (ICF) along with the associated risks and discomforts of the tests and procedures]***

- ***[List any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites]***

Why is your personal health information being used?

Your personal contact information is important for the University of _____ Health System and School of Medicine research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- The University of _____ Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of _____ Office of Regulatory Affairs
- The University of _____ Office of Human Research (the office which monitors research studies)
- Authorized members of the University of _____ Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the University of _____ Health System and the School of Medicine, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following ***[Modify this list as appropriate- delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information {the examples below are suggestions only}.]***:

- Other collaborating academic research center(s) ***[list all academic centers including those at the University of _____ that may not be within the covered component or its associated support offices. This would include collaborators at other Schools and their roles in project {who are working with the investigators in studying the economic impact of this treatment}]***
- Research data coordinating office and/or their representative: ***[name that group or company {who will be responsible for collecting results and findings from all the centers}]***
- Research data management office and/or their representative: ***[name that group or company]***

- Pharmaceutical Company and/or their representative: ***[name that group or company {who will use the results for submissions to the Food and Drug Administration}]***
- Government agency and/or their representative: ***[name that agency {which needs to confirm the accuracy of the results submitted to the government or using government funds}]***
- Contract Research Organization: : ***[name that company {whose job is to review and correct any mistakes before the results are given to the sponsor or government}]***
- Others: ***[name the other group and why they will receive the results]***

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of _____ Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations.

[Depending on how personal health information will be handled for a specific study, the following notes some example language that might also be included (if applicable):]

- In all disclosures outside of the University of _____ Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

- In records and information disclosed outside of the University of _____ Health System and School of Medicine, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

How long will the University of _____ Health System and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of _____ Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of _____ Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care ***[will or will not]*** be included in your medical record.

Will you be able to access your records?

You will be able to request access to your medical record when the study is completed.

[If applicable, for the majority of blinded studies or other studies where access <u>will</u> be denied:]

During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

[If applicable, for open label studies and other studies for which access <u>will not</u> be denied:]

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

[ONLY USE THE FOLLOWING PARAGRAPH IF APPLICABLE]

If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of _____ Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document you are permitting the University of _____ Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

_____	_____	_____
Subject's Name **[print]**	Subject's Signature	Date

_____	_____	_____
Person obtaining authorization **[print]**	Person obtaining authorization Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	_____
Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person's authority to serve as the subject's authorized representative.

_____

HIPAA DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made and entered into as of this _____ day of _____, 20__ by and between the _____ ("Covered Entity") and _____ ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain Protected Health Information (PHI) to the Data Recipient as described below (insert a meaningful description of the data set):

   _____

   _____

   _____

2. Except as otherwise specified herein, Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described in the research application. The title of the research project has been provided below:

   _____

   _____

3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include:

   _____ _____

   _____ _____

   _____ _____

4. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

5. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.

6. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.

7. Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.

8. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.

9. Data Recipient will indemnify, defend and hold harmless Covered Entity and any of covered Entity's affiliates, and their respective trustees, officers, directors, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

COVERED ENTITY

_____

Name:_____

Title: _____

DATA RECIPIENT

_____

Name:_____

Title:_____

REQUIRED ADDITIONAL PROTOCOL INFORMATION (ADDENDUM)

The information **must** include a brief specific description of the procedure(s) involving the human subjects in sufficient detail to demonstrate to the IRB reviewer that the research project/protocol meets the requirements for waiver of authorization or prospective consent. The text should be provided on a separate sheet(s) and be in sufficient detail to allow the reviewer to judge waiver criteria. Please use the following headings as a guide to the preparation of your rationale. This information can be provided as an amendment to an existing protocol--if so, be sure to provide protocol number.

1. The objective (hypothesis) of the research project and a brief background for the study.

2. The rationale for the use of the selected subject population, record set, archives or material, and sources of information.

3. The specific type of protected health information (PHI) to be collected (must be specific and include a copy of a data collection sheet(s)).

4 If the recorded data contains a link to allow the re-identification of the individual, describe the procedures to protect the confidentiality and security of this linking data set, and specific plans as to the time point at which the link data set will be destroyed. If the linking set will not be destroyed, provide reasons.

5 Provision to destroy any identifiers at the earliest opportunity consistent with the conduct of the research, unless a health or research justification is provided for retaining the identifiers or such retention is required by law.

6 Provide a rationale as to why the use and/or disclosure of the PHI involves no more than minimal risk to the rights, welfare, and/or privacy of the individuals.

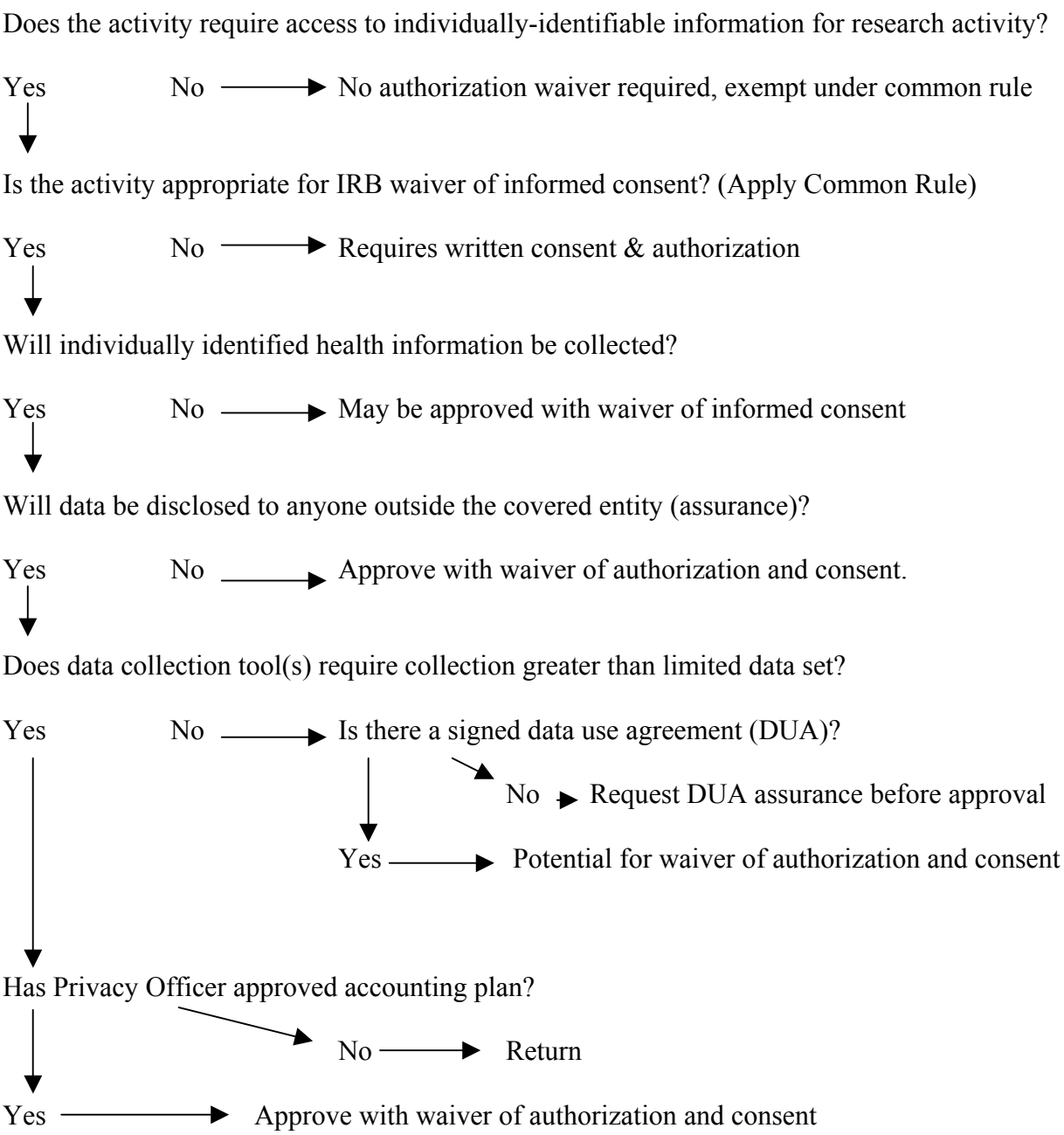
7 Describe the reasons why the research could not practically be carried out without the waiver of authorization or consent to review the PHI.

8 Provide a rationale as to why the research described in the research protocol could not be practicably conducted without the access to the health information.

9 If data containing PHI is to be disclosed outside the covered entity/component in a format other than de-identified, or as a limited data set with an appropriate Data Use Agreement between the parties, include your plan for recording and reporting to the covered entity/component each instance of: what information was disclosed, to whom the information was disclosed, the reason for the disclosure, and the date of each such disclosure for each individual's PHI (i.e., your plan for meeting the requirements for Accounting for Disclosures). This plan must receive approval from the Privacy Office before submission to IRB.

Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse: and (2) 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 health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

IRB HIPAA Authorization and Consent Waiver Algorithm - new studies and amendments



"Approve" implies that the submission may be forwarded to the IRB member or committee for review of complete addendum material. Satisfaction of the above submission requirements does not imply IRB approval of the waiver request.

Sample Letter Documenting Reviews in Preparation for Research
–to be on Official Covered Entity letterhead–

To: Covered Entity Privacy Officer
From: [Insert Name of Principal Investigator]
Date: [Insert Date]
Re: Request to Review Protected Health Information to Develop a Research Protocol

I, _____ (name of Principal Investigator) and/or my study staff would like to review [insert name of covered entity] records containing Protected Health Information in order to prepare a research protocol. The use of such PHI is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.

I understand and agree that no Protected Health Information will be removed from [insert name of covered entity] in the course of review, and the Protected Health Information being sought is necessary to develop the research protocol.

In the course of this review the following general description of the records sought is found below:

_____

_____

_____

Principal Investigator Signature: _____

Sample Letter Documenting Request to Review Decedent Health Information for Research
–to be on Official Covered Entity letterhead–

To: Covered Entity Privacy Officer
From: [Insert Name of Principal Investigator]
Date: [Insert Date]
Re: Request to Review Decedent Protected Health Information for Research

I, _____ (name of Principal Investigator) and/or my study staff would like to review [insert name of covered entity] records containing Protected Health Information of decedents for research purposes. The use of such PHI is sought solely for research on the Protected Health Information of decedents and that I able to provide evidence to [insert name of covered entity] that the Protected Health Information is only obtained from decedents and will provide the death certificate if it is requested by[insert name of covered entity].

The following general description of the records sought is found below:

_____

_____

_____

Principal Investigator Signature: _____