Tips for Investigators
~eIRB Submissions~

Department of Emergency Medicine
Research Division

University of
Massachusetts
UMASS. Medical School

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eIRB LINKS

- UMass Medical School, IRB Website: http://www.umassmed.edu/research/irb/index.aspx

- IRB Step-by-Step Job Aides Manual with Diagrams is available at:
  http://www.umassmed.edu/research/IRB/JobAids.aspx

- Forms & Templates: http://www.umassmed.edu/research/IRB/Forms_Templates.aspx
  - *Note:* It is recommended that you use the form templates created by the IRB which are currently listed on their website. These forms are up-to-date and have been formatted so they upload correctly to the eIRB system.

FORMS & TEMPLATES AVAILABLE ON THE IRB WEBSITE

- Non-UMass Personnel List
- HIPAA Waiver: (see HIPAA section below for further details)
- HIPAA Authorization
- Consent Form Template and Assent Template
- Consent Form Template – Short Version (for non-English speaking subjects)
- Fact Sheet Template (may be used when requesting a waiver of documentation of informed consent), (see HIPAA section below for further details).
- Investigator Study Plan Template with Instructions

ACCESSING YOUR eIRB ACCOUNT

Go to

- Log in using your assigned username and password.
- Navigate to the submissions workspace; follow the instructions for completing submissions.
- If you forgot your username or password there are two hyperlinks you can click on to retrieve your username and/or password.
- If you experience problems with the eIRB system call the IRB Office at 508-856-4261 for assistance.

ADDITIONAL CONTACT PERSONNEL

- The individual who is responsible for completing and/or updating the IRB study documents should be listed as an additional contact.
- This way when clarifications and/or changes are needed the IRB will notify both the PI and the person responsible for making the changes by Email.
- This individual will also need to be added to the research staff section in order to do so.
- If you designate more than one additional contact the names will be listed in alphabetical order.
- The default person for verbal communication is usually the first person on the list.

EDITING RESEARCH PERSONNEL

A. <u>UMass Personnel</u>
- If your changes in personnel do not affect your Investigator Study Plan, you can edit research staff without submitting a modification.

B. <u>UMass Personnel not Included in the Electronic List:</u>
- To add school personnel, other UMMS staff, or medical students to the IRB personnel list (if they are not already included in the electronic list embedded in the e-IRB system (under "edit research staff")),
- Submit a new user request form at http://www.umassmed.edu/irb/access.aspx
- You will need the person's legal name (as they are known to HR), email, department, and employee ID or student ID number.

C. <u>Non-UMass Personnel</u>
- To add non-UMass personnel, including volunteers from other colleges or volunteers with no current affiliation:
- Fill out the "HRP-215 FORM: Non-UMass Personnel List" located under the "Resources" section on the UMass IRB website to keep a running list of individuals who are study staff but whose names are not available in eIRB.
- Email irb@umassmed.edu your entire non-UMass personnel list with the name of the new staff(s) you are adding along with the new staff's CITI certificate(s), and confirmation that these individuals have gone through Volunteer Services or are part of the Academic Internship Program - The IRB will upload on your behalf.

- It is helpful to name the file "study ID_HRP215_date" so that when the IRB adds the file to the parent study it is easy to identify which study the form belongs to and which form is most recent.

- *! Note:* For individuals who are not affiliated with UMass Worcester, listing their names on this form does not automatically provide UMMS IRB coverage. As a general rule, a researcher is covered by his or her home institution. Please contact the IRB for more information.

- Below (p.5) is an example of a study that has submitted the form on 1apr13 and then submitted updated forms at the beginning of the May (Blodgett A., 2013):

1. H00000000_HRP215_1apr13.doc – The study has three research assistants who are not in eIRB.

FORM: Non-UMass Personnel List

	NUMBER	DATE	PAGE
	HRP-215	9/17/12	1 of 1

Use to report personnel outside University of Massachusetts who are not listed in the eIRB system and who are not covered under their institution's IRB

Protocol Name: All in the Family (H00000000)

Investigator: Lear

Names of personnel involved in this protocol's design, conduct, or reporting

Name	Role	Involved in consent?	Financial Interest Related to the Research? (see below)	
			Yes	No
Sally Struthers	Research Assistant	☒	☐	☒
Jean Stapleton	Research Assistant	☐	☐	☒
Rob Reiner	Research Assistant	☒	☐	☒

2. H00000000_HRP215_1may13.doc – The study adds a fourth research assistant not in eIRB.

FORM: Non-UMass Personnel List

	NUMBER	DATE	PAGE
	HRP-215	9/17/12	1 of 1

Use to report personnel outside University of Massachusetts who are not listed in the eIRB system and who are not covered under their institution's IRB

Protocol Name: All in the Family (H00000000)

Investigator: Lear

Names of personnel involved in this protocol's design, conduct, or reporting

Name	Role	Involved in consent?	Financial Interest Related to the Research? (see below)	
			Yes	No
Sally Struthers	Research Assistant	☒	☐	☒
Jean Stapleton	Research Assistant	☐	☐	☒
Rob Reiner	Research Assistant	☒	☐	☒
Sherman Hemsley	Research Assistant	☒	☐	☒

D. Deleting non-UMass Personnel

- Email irb@umassmed.edu your entire non-UMass personnel list minus the name of the staff(s) you are removing (see example below).

3. H00000000_HRP215_1jun13.doc – The study removes a research assistant either because the person has left the study or because her name became available in eIRB and she was added to the Project Personnel tab using EDIT RESEARCH STAFF.

FORM: Non-UMass Personnel List					
NUMBER	DATE		PAGE		
HRP-215	9/17/12		1 of 1		

Use to report personnel outside University of Massachusetts who are not listed in the eIRB system and who are not covered under their institution's IRB

Protocol Name:	All in the Family (H00000000)
Investigator:	Lear

Names of personnel involved in this protocol's design, conduct, or reporting

Name	Role	Involved in consent?	Financial Interest Related to the Research? (see below)	
			Yes	No
Sally Struthers	Research Assistant	☒	☐	☒
		☐	☐	☐
Rob Reiner	Research Assistant	☒	☐	☒
Sherman Hemsley	Research Assistant	☒	☐	☒
		☐	☐	☐

- *! Note:* The only time a student needs to get IRB approval from his/her home institution is if he/she is performing their own project here at UMass under your supervision, or if he/she is carrying out a "major qualifying project". If you have questions about this, please check with Ed Boudreaux at: (Edwin.Boudreaux@umassmed.edu).

STUDY SUBMISSIONS

- Once you begin your application, if you need to complete it at a later time, click "Save" and then "Exit" at the top of your form to save your work.

- When uploading tracked changed documents for modifications do not highlight changes in the document. The system does not recognize highlighting; therefore the document will remain highlighted.

- When you upload a document, you control the name that will appear in the determination letter through the title field.
  - a. If you leave the title field blank, eIRB will use the file name automatically.
  - b. Be sure there is a version date or number on each document (to the extent possible) and that this information appears as part of the title field or as part of the file name if you leave

the title field blank. That way, the determination letter will clearly list the documents that are part of the approved submission.

- c. When you revise a document, it's important to replace the existing document with the revised one using the UPDATE or UPLOAD REVISION function, as opposed to uploading revisions as entirely new documents. If you go to Section 7.0 and click on a file name, you can access the UPDATE/UPLOAD REVISION function for that document.
- For more file management tips see JOB AID: How to Manage Files in eIRB

- To remove a document that was uploaded in error, you should rename the document "DO NOT USE" and it will be ignored.

- If you need to flag an existing document as no longer in use, add NO LONGER IN USE to the title field.

A. All Study Submissions
- If you are not the PI, let the PI know that the submission is ready for them to review and submit. You can select "Ready for PI review" to notify the PI that they must log into eIRB using their username and password to submit.
- You can only submit one follow-on submission at a time. (Reportable New Information can be submitted at any time.)
- If you have submitted a continuing review only that has not yet been approved and you need to submit a modification, you can either wait for the continuing review to be approved or you can withdraw your continuing review and resubmit a combined modification and continuing review submission.
- Similarly, if you have submitted a modification that has not yet been approved and you need to submit an additional modification, you can either wait for the first modification to be approved or you can withdraw the submission and resubmit one that reflects all of the modifications for which you are requesting approval.

B. New Study Submissions
- To submit a new research study you will first need to "create new study."
- Once your study has been created it will provide you with your IRB docket number.
- You will need to insert the docket number on all study documents (where indicated) prior to uploading them to the eIRB (section 7).

- *Note:* When the IRB office adds documentation to a study, the Full History tab tracks the activity as "Documentation added." Documentation such as IRB authorization agreements and individual investigator agreements should appear on the Full History tab for the *parent study* even if the agreement was executed during a *follow-on submission*.

CONSUMER LAY SUMMARY

- Click on "Edit Consumer – Lay Summary"
- Provide a short summary of your research.
- These summaries should be no longer than 3 sentences (300 words).
- ***Example:*** *This patient-oriented study will determine the feasibility and acceptability of patients self-administering a core set of patient reported outcomes (PRO), such as tobacco, alcohol, and drug use, on a computer during their medical visit. Ultimately, this work will lead to improved*

patient-centered care and improved patient health through promotion of more consistent and
more accurate identification of high risk health behaviors and unaddressed mental health issues.
- Once you have entered the required information click on "OK" at bottom right to close.

INVESTIGATOR STUDY PLAN

- Investigator Study Plan Template available on the IRB website.
- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as "NA" and provide a brief description why.
- For any items described in the sponsor's protocol, grant or contract, submitted with the application, you may reference the title and page numbers of these documents. (*)
- Rather than repeating information, you can reference information that appeared in an earlier item.
- Although you should keep electronic copies, of all documents supporting the study, if you go to eIRB and download the most recent approved version, then you know that you're working from the most current document.

RESPONDING TO CLARIFICATIONS

- When responding to a clarification, use the Respond to Clarifications Requested link under My Current Actions at the left. You must insert text in the text box otherwise it will not be submitted.
- You will know that you have responded successfully when the blue box with the submission state changes state from Pre-Review Clarifications Requested to Pre-Review.
- If the state seems stuck in Pre-Review Clarifications Requested, make sure that you hit OK to UPDATE the response box and OK again to return the response. You can also see if there are clarifications requested with empty response boxes that need to be updated.
- ! Note: Make sure you make the revisions needed before responding to the clarifications requested.
- Any study staff can respond to a clarifications request. The eIRB requires that the PI be the one to submit an initial study or follow-on submission and to respond to an IRB determination (e.g., Modifications Required to Secure Approval).

EDITING STUDY SUBMISSIONS

- The available actions for a submission will alternate between Edit Study (when the submission is under PI control) and View Study (when the submission is locked for IRB review).

HIPAA – PROTECTED HEALTH INFORMATION & WAIVER OF HIPAA AUTHORIZATION

Protected health information (PHI): You will have PHI any time you collect health information in a clinical setting (e.g., recruiting in the ED) that is linked to any of the 18 identifiers listed in the table below (p18) -- even if you collect that PHI exclusively for research purposes.

- In order to create, use, or disclose an individual's PHI without their HIPAA Authorization the researcher must obtain a Waiver of HIPAA Authorization.
- There are typically 2 instances when you would need a Waiver of HIPAA Authorization:

1. Prescreening: When you want to determine who is eligible for the study prior to approaching them.
   - These individuals once approached and consented would sign a HIPAA Authorization (see p. 11 for templates with recommended language).

2. No patient contact: When you want to Waive HIPAA Authorization altogether such as in instances when there will be no patient contact (e.g. retro chart reviews)
   - *Note:* You need to justify in your application for HIPAA Waiver of Authorization why it is not feasible to obtain the HIPAA Authorization from the patients (see p. 13 for templates with recommended language).
   - *Note:* Make sure you use the HIPAA templates provided by the IRB on their website to ensure proper formatting for uploading to the eIRB.

3. Investigator Study Plan: In your Investigator Study Plan under the "Provisions to Protect the Privacy Interests of Subjects (HIPAA)" talk about the Waiver of HIPAA Authorization and explain your reasons for obtaining this waiver.

HIPAA – PROTECTED HEALTH INFORMATION: LIST OF 18 IDENTIFIERS			
1)	Names		
2)	All geographical subdivisions smaller than a State, including: • street address • city • county • precinct • Zip code, and their equivalent geocodes, except for the initial three digits of a zip code.		
3)	All elements of dates (except year) for dates directly related to an individual, including: • birth date • admission date • discharge date • date of death • All ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.		
4)	Phone numbers	5)	Fax numbers
6)	Electronic mail 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 & serial numbers
14)	Web Universal Resource Locators (URLs);	15)	Internet Protocol (IP) address numbers
16)	Biometric identifiers, including: • finger prints & voice prints	17)	Full face photographic images and any comparable images
18)	Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).		

DE-IDENTIFIED PROTECTED HEALTH INFORMATION

- To be non-identifiable the health information should not contain any of the 18 above listed elements and should not contain any subject IDs that are linked to identifiers.
- The IRB tends to refer to de-identified data as data that has no direct or indirect identifiers. It tends to refer to data with subject IDs as coded data (i.e., not completely de-identified).
- For studies that obtain a Waiver of HIPAA Authorization to determine if patients may be eligible for participation in a study prior to approaching them, and the PHI is recorded in documents such as enrollment logs:
  - If a patient **refuses** participation all PHI for these individuals must either be destroyed or convert to non-identifiable {e.g., recording age instead of DOB}.
  - Converting the information to non-identifiable will allow you to keep the information you need to assess population statistics while respecting the HIPAA regulations and the rights of individuals to decline participation.

WAIVER OF INFORMED CONSENT – SCREENING LOG DATA

- For studies that record PHI/PII in documents such as screening logs, in order to use any of the Personally Identifiable data that you collected for patients that were not enrolled in your research, you will need to obtain a (1) Waiver of Informed Consent and a (2) Waiver of HIPAA Authorization.
- In the applications for waivers you will need to explain why it is impracticable to obtain the consent and HIPAA Authorization of each of these individuals.
- Even though you have an approved Waiver of HIPAA Authorization to collect this data for screening purposes, you cannot use that information other than to determine the patient's eligibility for your study.
- If a patient **refuses** participation all PHI/PII for these individuals must either be destroyed or convert to non-identifiable {e.g., recording age instead of DOB} to respect the right of these individuals to refuse participation.

STORAGE OF PERSONAL IDENTIFYING INFORMATION (PII) IN RESEARCH - CONFIDENTIALITY

Storage of Study Data Containing PHI

 A. Paper Documents

- It is best to staple the subject's consent & HIPAA forms together.
- Write the subject's ID on the consent for ease of identification.
- It is good practice to store the subject's consent/HIPAA forms in a separate cabinet from the data collection form(s) to avoid a breach in confidentiality. This adds an extra level of security.
- All paper documents can be scanned into databases which are "housed on secure networks with password-protection," and then the study documents, including the consent & HIPAA forms, can then be shredded.
- *Note:* Although scanned copies are considered original copies according to IRB standards, it is important to check with your study sponsor to ensure they do not require you to keep the paper versions of the study forms.

B. Electronic Data Storage

- PHI may also be stored electronically.
- In your IRB application and under the "Confidentiality" section of your Investigator Study Plan you will need to present a brief description on what data you will store electronically and how your data will be secured.

- Paper Documents
  - All paper documents can be scanned into databases which are "housed on secure networks with password-protection."
  - Once scanned the study documents, including the consent & HIPAA forms can then be shredded.
  - *Note:* Although scanned copies are considered original copies according to IRB standards, it is important to check with your study sponsor to ensure they do not require you to keep the paper versions of the study forms.

- Automated Storage
  - For Investigators who utilize REDCap below is a sample boiler plate statement:
    Data collection will be automated such that research personnel will input their data on a secure web-based data collection system. This data, by necessity, will include personal identifiers, because {state reason for use of PI}. The Information Services (IS) Department at the University of Massachusetts Medical School (UMMS) will host the web-based data management system (REDCap). Below is a summary of the security measures used to protect data.

    REDCap is a secure, web-based application designed exclusively to support data capture for research studies. REDCap is hosted locally by UMMS and employs user authentication and role-based security. The REDCap application resides in an isolated secure network segment designed for PHI, PII and other types of regulated data. Web-based data entry is via an SSL cryptographic transport protocol. Additional security procedures are in place for data access. The environment logs are audited by IS.

THE RIGHT OF SUBJECTS TO REVOKE HIPAA AUTHORIZATION

- Research subjects have the right to revoke their consent to participate in research.
- In addition, the Privacy Rule permits a subject to revoke permission for researchers to use or disclose his or her identifiable information for research.
- *Note:* **The revoke of PHI needs to be done in writing**.

STEPS TO ENSURE PATIENTS ARE NOT PUT UNDER UNDUE INFLUENCE IN RESEARCH

- It is possible that patients may feel coerced into participation. In the Investigator Study plan under the "Recruitment" process, put in a paragraph describing the steps to ensure that patients are not put under undue influence (examples below):

The risk of potential undue influence will be minimized by the following standard procedures:
- The Research personnel will be trained to observe signs or symptoms that may suggest the patient is not suitable to approach {e.g. sleeping, too ill, and/or distressed}.
- The Research personnel will only approach the patient after he or she has been "cleared" to do so by the {insert according to study specific procedures, e.g., treating physician; treating nurse; mental health clinician}.
- The Research personnel will emphasize the voluntary nature of the considered participation.
- The Research personnel will explain the nature, purpose, risks and benefits of the considered participation.
- The Research personnel will explain that the patient can decline participation or withdraw at any time and they will still receive the usual clinical treatment with no prejudice.
- The Research personnel will wear blue lab coats to distinguish them from clinical staff.

TELEPHONE SURVEY STUDIES & CLINICIANS OBTAINING PHI FROM SUBJECTS

- A. Patient surveys conducted after the patient's ED visit can be categorized either as quality improvement/quality assurance, or as research. When post-visit telephone surveys are conducted for research purposes.

- B. If the PI is a clinician and the research includes obtaining PHI from subjects, then HIPAA applies here as well. Either the consent process would need to meet the HIPAA requirements or the study would need a waiver of authorization for any and all HIPAA requirements that are not met.

- You must include in the IRB application:
  - A waiver of HIPAA authorization for screening patients.
  - A request for a waiver of written documentation of consent
  - A description of the consent process
  - A fact sheet that would be available for patients who request information about the study. However, you do not have to mail a fact sheet to each patient who consents to be in the study.

MANDATED REPORTING IN RESEARCH

- Research staff are not mandatory reporters required by law to disclose.
- HOWEVER, physicians, social workers and other appropriate trained professionals are.
- From an ethical perspective, anyone who is conducting such an evaluation in which a patient discloses information such as child or elder abuse or a threat to harm themselves or others, would have an ethical responsibility to report it to someone.
- This usually gets wrapped up on the consent form by adding a few sentences in the confidentiality section that states " Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law.
- Examples of information that we are legally required to disclose include abuse of a child or elderly person, threatened harm to self or others, or certain reportable diseases."

SAMPLE HIPAA LANGUAGE FOR PRESCREENING SUBJECTS

UMass Memorial Medical Center
HIPAA IRB WAIVER OF AUTHORIZATION

Principal Investigator:
IRB Study ID #: H
Protocol Title:
_____

1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

Patient information will be reviewed and/or documented in order to determine eligibility of potential subjects and to compare the study sample with the population from which it was drawn.

2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).

To help identify prospective participants for research and to help document the characteristics of the population from which the study sample was chosen, the patients' names, {insert additional prescreening criteria or remove those listed as needed by the study} will be abstracted from medical records and documented on paper enrollment logs.

We are collecting only those identifiers necessary to determine eligibility and sample representativeness. Without these we would be unable to perform these tasks.

3. Explain why the research could not practically be conducted without this PHI.

The PHI is necessary because without it, we cannot determine eligibility or report on the sample's representativeness, which is a required component for scientific publications.

4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the

study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law). We plan to protect identifiers by the following plan:

1. Only trained research personnel who have been educated on HIPAA regulations and who have been given password-protected access to clinical health systems and medical records will have access to this information.
2. All paper-based forms will go directly into a locked file cabinet in a locked office at the end of the research personnel's shift.
3. All databases into which the data will be stored will be housed on secure networks with password-protection.
4. The paper-based forms will be stored in locked filing cabinets in a locked room (room: xxx), both before and after the identifiers are removed.
5. The electronic data will be stored on a server managed by UMass Medical School. Access to the server is restricted to only those with IRB approval for the study, and it is password protected. {Add any other locations electronic data is stored}
6. The following people and organizations will have access to the <u>identified</u> PHI:
   1. The research staff approved to be on the study.
   2. The UMass IRB.
   3. Any organization that is required for ensuring patient safety, data quality and good conduct of study, including auditors, data safety monitoring boards etc. (*Note*: important to include).
   4. {List other agencies as appropriate}.
7. The following people and organizations will have access to the <u>de-identified</u> PHI:
   1. The research staff approved to be on the study.
   2. Statisticians and investigators who analyze the data.
   3. {List other agencies as appropriate}.

Identifiers used for pre-screening are only recorded on paper enrollment logs. All identifiers collected during the study will be removed from the paper enrollment logs once the data has been collected and validated through quality assurance review. Additionally, the enrollment logs will be shredded three years after the study has been completed. Identifiers will not be stored electronically. We will only maintain de-identified data for those who decline to participate by destroying PHI from these individuals.

5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

Research personnel will need to review patients' records prior to offering consent to determine if the patients meet the minimum study requirements. In addition, data on the population from which the sample will be recruited is required to describe the sample's representativeness. The waiver is necessary because without it, we could not practicably collect the data required to determine eligibility, since this would require actually approaching every single patient treated in the ED at the time of the study. In addition, without documenting data on the population, the investigators will be unable to report on the sample's representativeness, which is a required component for scientific publication.

By submitting this form, the PI attests the following:
a) The information listed in the waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria.
b) Protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

UMass Memorial Medical Center
HIPAA IRB WAIVER OF AUTHORIZATION

Principal Investigator:
IRB Study ID #: H
Protocol Title:
_____

1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

Patient information will be reviewed and/or documented in order to complete retrospective chart reviews.

2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).
For this study, medical records will be reviewed. We will document information needed to answer the research questions, including: {insert data being abstracted for the study}.

We will use the following method to determine which patients' medical records to abstract: {insert method for case identification}.

We are collecting only those identifiers necessary to answer the study's research questions. Without these, we would be unable to answer the research questions.

3. Explain why the research could not practicably be conducted without this PHI.

The PHI is necessary is necessary to identify the individuals' whose charts we need to review and to answer the research questions inherent in the study. {Provide an example of the data needed. Ex: For example, this study is examining suicide screening in the ED. Without the ability to access ED patients' charts and document whether they were screened for suicide, we would be unable to answer the research question pertaining to the prevalence of suicide screening}

4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law).
We plan to protect identifiers by the following plan:

8. Only trained research personnel who have been educated on HIPAA regulations and who have been given password-protected access to clinical health systems and medical records will have access to this information.
9. All paper-based forms will go directly into a locked file cabinet in a locked office at the end of the research personnel's shift.
10. All databases into which the data will be stored will be housed on secure networks with password-protection.

11. The paper-based forms will be stored in locked filing cabinets in a locked room (room: ==xxx==), both before and after the identifiers are removed.
12. The electronic data will be stored on a server managed by UMass Medical School. Access to the server is restricted to only those with IRB approval for the study, and it is password protected. =={Add any other locations electronic data is stored}==
13. The following people and organizations will have access to the <u>identified</u> PHI:
    5. The research staff approved to be on the study.
    6. The UMass IRB.
    7. Any organization that is required for ensuring patient safety, data quality and good conduct of study, including auditors, data safety monitoring boards etc. (*Note:* Important to include).
    8. =={List other agencies as appropriate}.==
14. The following people and organizations will have access to the <u>de-identified</u> PHI:
    4. The research staff approved to be on the study.
    5. Statisticians and investigators who analyze the data.
    6. =={List other agencies as appropriate}.==

Identifiers used for chart reviews are only recorded on =={insert where identifiers are recorded; electronic, paper etc}==. All identifiers collected during the study will be removed from the =={insert where identifiers are recorded; electronic, paper etc}== once the data has been collected and validated through quality assurance review. The =={insert where identifiers recorded; electronic, paper etc.}== will be destroyed three years after the study has been completed.

5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

The waiver is necessary because it would be impracticable to collect the needed data. Due to the retrospective nature of this data collection, the records are old enough that some subjects are likely to have moved or died making it difficult to obtain consent. The time and resources it would take to try and locate and contact each potential subject for consent would be very difficult. Not only would it be very difficult, it is likely that we would not be able to locate 100% of the sample. This would lead to inadequate data sampling, which would introduce bias, such as selection bias of only studying patients with reliable telephone access. Such bias would render the data useless.

By submitting this form, the PI attests the following:

c) The information listed in the waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria.
d) Protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

REMINDER: The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. The relevant forms are available on the IRB website and additional information regarding these obligations is available by contacting the Office of the Vice Provost for Research or the UMass Memorial Medical Center Privacy Officer.

 **Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive the use of authorization forms if all of the criteria listed above are met.