Massachusetts Eye and Ear Infirmary

HUMAN STUDIES COMMITTEE
Application for Research Using Medical Records/Secondary Uses of Tissue/Data

Protocol Number: _____

Submit the completed application to HSC_Submission@meei.harvard.edu

Please use this form ONLY if your research involves RETROSPECTIVE DATA COLLECTION, which are data that already exist at the time this application is submitted. If your research includes any form of patient contact or involves PROSPECTIVE DATA COLLECTION, which are data that are not yet in a record but will be collected in the future and put in a record, use the HSC Full Protocol Application instead.

Project Title: _____

Principal Investigator: _____

Laboratory: _____ Extension: _____

Email: _____

Additional Contact: _____ Email: _____

Co-Investigator/Study Staff who will have access to identifiable data:

Name and Degree	Precise Role	Date Passed CITI/HSC training

As Principal Investigator, I assure that the information I obtain as part of and for purposes of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed in this form, except as required by law or for authorized oversight of the research project. I certify that the anonymity and confidentiality of patients where tissue or records are reviewed for this research will be maintained under all circumstances. If at any time I want to reuse this information for other purposes, or disclose the information to other individuals or entity I will seek approval by the Human Studies Committee.

Signature of Principal Investigator: _____ Date: _____
(Please complete entire form before signing)

1) In layperson's language please state the purpose of this study in 3-5 sentences:

2) How long do you anticipate it will take you to complete this research? _____

3) Study Population (Describe study population, i.e. diagnosis, age group, surgical/medical, etc.):

4) How many individuals' records are needed for this study? _____ Over 49 ☐

5) Specify the time period involved (e.g. patient records from November 2006 to November 2007).

_____

6) Funding Source: ☐ If Federal, provide InfoEd proposal record # below

Sponsor Name: _____ # _____

MEEI Account Number: _____

7) If your study proposes to use tissue, what is the source (e.g. New England Organ Bank or patient specimens)?

_____

8) Was the material obtained from patients as part of their clinical care?
(i.e. a clinically indicated procedure or intervention) ☐ Yes ☐ No

9) What type of record/chart/database will be reviewed for research?

- ☐ Medical Record/Chart Review
- ☐ Films/X-rays
- ☐ Computer/Database
- ☐ Hospital Administrative/Billing Records
- ☐ Other types of record (please specify): _____

10) If records will be reviewed, please specify the source.

- ☐ Hospital Paper Based Medical Records
- ☐ Hospital Electronic Medical Records (LMR)
- ☐ Departmental/Office Paper Records
- ☐ Departmental/Office Electronic Records
- ☐ IDX
- ☐ Other Please Specify: _____

11) Please check all categories of data that will be obtained for this study.

- ☐ Demographics (age, sex)
- ☐ Diagnosis
- ☐ Lab Values
- ☐ Radiology Testing/Images
- ☐ Procedures/Treatment
- ☐ Billing/Charges
- ☐ Drug/Device Utilized
- ☐ Length of Stay
- ☐ Location of Service
- ☐ Clinic/Office Notes
- ☐ Provider of Record
- ☐ Tissue Samples
- ☐ Other, please specify: _____

12) Please check any identifiers collected for this study that will be recorded with or linked by code to the data.

If any of the categories are checked, you will need to obtain HIPAA authorization or waiver to perform research.

- ☐ None of the listed identifiers will be recorded as part of the study.
- ☐ Name
- ☐ Social Security Number
- ☐ Medical Record Number
- ☐ Address by Street Location
- ☐ Address by Town/City/Zip Code
- ☐ Elements of Dates (Admission/ Discharge Date, Procedure Date, Date of Birth or Death)
- ☐ Ages Over 89
- ☐ Telephone Number
- ☐ Fax Number
- ☐ Email Address
- ☐ Web URL's
- ☐ Internet Protocol (IP) Address
- ☐ Health Plan Beneficiary Number
- ☐ Account Number
- ☐ Certificate/License Number
- ☐ Vehicle ID Number and Serial Number, including License Plate Number
- ☐ Medical Device Identifiers and Serial Number
- ☐ Biometric Identifiers (finger and voice prints)
- ☐ Full Face Photographic Image
- ☐ Any other unique identifiers or code that can be used to identify the participant

Note: PHI (protected health information) means any data in #11 linked with any identifiers in #12.

LDS (limited data set) - is health information that may include town or city, state, zip code, elements of dates except year and indirect identifiers. Use of data under the provisions of a 'limited data set' may require the signing of a data use agreement.

13) Will PHI (as defined in #12 above) be sent with data/tissue to individuals or institutions outside MEEI?

☐ Yes

☐ No

If Yes:

a. Where specifically will the PHI be sent? _____

b. Why is it necessary to send PHI outside of MEEI?

c. How will the PHI be sent? Describe actual methods and include plans for coding and/or encryption.

14) a. Investigators are allowed only to obtain the minimum necessary PHI in order to achieve the goals of the research. Please justify why the PHI you are obtaining is the minimum necessary to achieve the goals of the research.

b. If the research will use PHI, explain why the research could not practicably be conducted without access to and use of PHI:

15) What is the risk to subjects whose information is used in this research? Specifically address the risk to the privacy of the subjects' PHI. Describe the steps taken to assure the privacy and confidentiality of subjects' PHI and to protect the identifier/link to identifiers from improper use or disclosure.

16) You are required to destroy identifiers or link to identifiers (as listed in #12) at the earliest possible time. Please describe your plans and specify when this will occur. If you require retaining the identifiers for any significant length of time, please provide justification.

17) Please check here if you are requesting a waiver of consent/authorization for the use of retrospectively collected data (which already exists in the record at the time this protocol is submitted) and complete the questions below). ☐

ALL the following conditions must be justified:

a. Explain why the proposed use of this data/document/record presents no more than minimal risk to the privacy of individuals:

b. Explain why the research could not practicably be conducted without the waiver of informed consent and authorization: *(It is not enough to explain that there are insufficient resources or time available. Common reasons include, patients are lost to follow-up, may have been seen years ago so there is not current contact information, patients may be deceased, etc. If all the subjects are currently seeking care at the hospital it would be possible to ask their consent to review their record for research purposes. Therefore it may not be possible to satisfy this criterion).*

c. Explain why waiving informed consent will not adversely affect the subjects' rights or welfare:

For HSC Use Only

RESEARCH DETERMINATIONS

☐ **Does not meet regulatory definition for human subject research. BOTH** must apply:

- ☐ The data were/are not collected specifically for the currently proposed research through intervention and interaction. Applies to existing data or data to be collected in the future for purposes other than the research (medical records).
- ☐ The investigator cannot readily ascertain the identity of the individual to whom the coded private information pertains because the PI never sees identifiers **AND one** of the following:
  - ☐ Key to code is destroyed before research begins.
  - ☐ The PI and holder of key enter into agreement prohibiting the release of the key to the PI.
  - ☐ There are written IRB approved procedures and operating procedures for the data repository that prohibit release of key to identifiers to the PI.

☐ ***Exempt Human Subject Research***, Category Number _____

- ☐ Data are publicly available

  OR

- ☐ Data exist at the time this protocol is submitted, **AND:**
  - ☐ Data are recorded in such a way the PI cannot identify the subjects either directly or indirectly, because the PI either never saw the identifiers, or if they were seen, the data is recorded in such a way that the PI cannot go back and determine who the data belongs to (no codes).

☐ **Expedited Approval**, Category Number _____

WAIVERS OF CONSENT/AUTHORIZATION

☐ **Consent/ Authorization is required** in accordance with the regulations of the Common Rule and HIPAA Privacy Rule.

☐ **Waiver of Consent/Authorization is granted** in accordance with the regulations of the Common Rule and HIPAA Privacy Rule.

HIPAA WAIVER DETERMINATIONS

☐ **De-identified**

☐ **Identified**

- ☐ Waiver of Authorization granted
  - ☐ Use
  - ☐ Disclosure (outside MEEI)

☐ **Preparatory**

☐ **LDS**

The request has been approved.

_____ _____

Approval for the Human Studies Committee Date