

Review Preparatory to Research and Recruitment

1). All human subjects research requires IBRA review to determine either a) exempt status or b) need for further review.

As a matter of IBRA policy only individuals who have access to PHI as part of their care or administrative duty to patients may access their PHI without prior IBRA Privacy Board review and approval.

2). Reviews preparatory to research that are permitted under HIPAA may or may not be human subjects research depending on the investigation being conducted.

a.) Only those reviews of a database by an individual entitled to access that database intended to enumerate an available data set without reviewing PHI and for which no PHI is recorded do not require review. For example: medical records may be queried for information such as: In the year XXXX how many patients had a discharge diagnosis of [indicate disease/diagnosis]. IBRA Privacy Board Review is required for all other uses of PHI as indicated.

b.) If the research involves a de-identified data set, defined as removing the following identifiers:

Names	Account #s
Geographic info. (city, state, and zip)	Certificate /License #s
Elements of Dates (except years)	VIN and Serial #s, license plate #s.
Telephone #s	Device identifiers, serial #s
Fax #s	Web URLs
E-mail address	IP address #s
Social Security#	Biometric identifiers (finger prints)
Medical Record, prescription #s	Full face, comparable photo images
Health Plan Beneficiary #s	
Unique identifying #s	

, then a de-identified data set certification form must be completed submitted for administrative review and certified prior to accessing the data set. This activity also requires an IBRA determined exemption from review.

c.) If the research involves a limited data set, defined as removing the following 16 identifiers:

Names	Certificate/license #s
Postal address info. (if other than city, state and zip)	Vin and serial #s, license plate #s
Telephone and fax #s	Device identifiers, serial #s
Email addresses	Web URLs
Social Security #s	IP address #s
Medical record, prescription numbers	Biometric identifiers (finger prints)
Health plan beneficiary #s	Full face, comparable photo images
Account #s	

The following are required:

- Information on the Creation of a Limited Data Set
- Data Use Agreement
- Human Subjects Application (Application for New Protocol)
- Consent and Authorization or properly justified request for a waiver or modification of consent and/or authorization.

IBRA Privacy Board review and approval is required prior to initiating this research. Investigators are not authorized to contact potential research subjects identified in reviews preparatory to research unless they are directly responsible for care of the potential subject and entitled to PHI as a result of that duty.

Investigator's who have previously obtained full consent and authorization to contact a research subject as a result of a previously approved research project, may contact his or her former research subjects provided that the subject agreed to be contacted for information on future research conducted by the same principal investigator or co-investigator (s). The following standard language can be used to include in current approved consent documents to obtain the subjects permission to be contacted by the principal investigator or co-investigator for future research conducted by original principal investigator or co-investigators:

I authorize the principal investigator and his or her co-investigators to contact me about future research on (specify type of research) within the (insert department, division, or center) provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from Dr. (insert)'s research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating [*am interested in having my child participate*] in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

____ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: (insert title of study)

____ I **do not** want to be contacted by the Principal Investigator or Co-Investigator of the research study titled:

Signature

Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care [*or your child's care*] at any of the NYUSM facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you [*your child*] must join in any study.

If the investigator intends to recruit potential subjects with which the investigator has no professional relationship, the following procedures are prescribed:

- Obtain permission of the patient's physician other healthcare provider known to the patient, and
- Provide IRB-approved study information (brief) to the patient's physician or other healthcare provider known to the patient, and
- Healthcare Provider/physician or their agent provides the patient with an introduction to the study and the name of the investigator (staff member), to contact if the prospective subject is interested in the research.