

Mount Sinai School of Medicine Institutional Review Board
Guidance on Research Limited to the Use of Medical Records

Executive Summary: For research projects that are limited to the use of medical record data (i.e. the investigator is not interacting with any individual subject) the IRB will now permit completion of a "MEDICAL RECORD REVIEW" application form (referred to hereafter as the "MRR FORM") instead of the standard protocol summary form (IRB Form 1) and waiver of informed consent form (Form 7). Along with applicable GCO forms and the "MRR form", the PI should attach a protocol (if it exists, as in NIH-sponsored or industry-sponsored projects), and any applicable HIPAA forms. Guidance about which additional forms may be required is provided both in the "Guidance" and the application form. Submissions for all types of medical record review projects should be logged in with the GCO office; no additional copies will be necessary for the IRB.

The following document contains:

1. Guidance about the medical record data review policies
2. Flow chart depicting the process of determining the status of a project
3. A sample application form entitled "MEDICAL RECORD REVIEW".

Guidance on Research Limited to the Use of Medical Record Data

DATE: 9/21/04

SCOPE: This guidance is intended to accomplish 3 objectives: 1) to explain recent clarifications made by OHRP (Office of Human Research Protections) regarding the “status” of certain kinds of research involving private health information; 2) to provide a “flow chart” demonstrating the decision-making process involved in determining the status of such research and what is required of researchers; and 3) to provide a new specialized application form to be used in lieu of a standard protocol summary and waiver of informed consent form (Form 7) when submitting projects that solely involve private health information.

This guidance applies to research projects that are limited ONLY to the review of private health information on patients. This guidance does NOT apply to any research in which data is obtained through intervention or interaction with individual patients/subjects, nor does it apply to the creation of data repositories, or to any research subject to FDA regulations.

This new policy is applicable to all research conducted under the auspices of the Mount Sinai IRB, whether federally funded (except FDA), foundation or industry funded, or internally (MSSM) funded projects.

BACKGROUND

Due to a lack of specificity in some of the federal human research protection regulations (e.g. 45 CFR 46.101, 45 CFR 46.102), historically there has been confusion and inconsistency in interpreting whether research involving certain kinds of medical data, in fact, was considered “research” at all, or if such research fell within the definition of research on “human subjects”. OHRP has just issued a guidance on 8/10/04 called “OHRP Guidance on Research Involving Coded Private Information or Biological Specimens” to shed some light on areas of common questioning. The MSSM IRB’s policies will now reflect the impact of this OHRP guidance on research involving medical data.

This guidance provides information about when research involving the use of medical information is not considered “human research” at all, when it is considered to be “exempt” from the federal policy for the protection of human subjects (45 CFR 46), and when it may be considered to require “expedited IRB review” or review by IRB committees (“full board review”).

GUIDANCE

In order to determine the “status” of proposed research (i.e. when is it “not human subject research”, or meets exempt, expedited, or full board review criteria) a series of questions must be answered, and they must be answered sequentially (as there is a hierarchy of decision making involved).

1) The first question to be asked is: **Does the activity involve research?**

HHS regulations define *research* at 45 CFR 46 102(d) as follows:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Activities that are purely for operational purposes, such as quality assurance activity are not considered research. However, if there is a design to contribute to generalizable information, e.g. there is a plan to publish the information, the activity is considered research.

2) If the study involves research, the second question is: **Does the activity involve “human subjects”?**

HHS regulations define *human subject* at 45 CFR 46.102(f) as follows:

“Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) data through intervention or interaction with the individual, or*
- (2) identifiable private information.”*

OHRP provides some guidance in interpreting the terms of the above definition:

(1) Obtaining data through intervention or interaction. Intervention includes both physical procedures by which data are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject.

For the purpose of this guidance, any research that involves obtaining data through intervention or interaction with individuals is not eligible for use with this MSSM Medical Record Review policy and form.

(2) Obtaining identifiable private information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. *Obtaining* means receiving or accessing identifiable private information for research purposes. OHRP interprets *obtaining* to also include an investigator's use, study, or analysis for research purposes of identifiable private information already in the possession of the investigator.

Coded Private Health Information

In general, OHRP considers private information to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly, or indirectly through coding systems. Conversely, OHRP considers private information or specimens not individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

For example, OHRP does not consider research involving **only** coded private information to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

- (1) the private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; AND
- (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertain because, for example:
 - (a) the key to decipher the code is destroyed before the research begins; OR
 - (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators, until the individuals are deceased; OR
 - (c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; OR

(d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Important points about these conditions:

An investigator includes anyone involved in conducting research. However, the act of solely providing coded private information does not constitute involvement in research per OHRP. This is true ONLY if the “coder” who is providing the information is not involved in the study (e.g. interpretation or analysis of the data resulting from the coded information). Likewise the “coder” cannot be involved in the authorship of presentations or manuscripts related to the research.

In order for the coded information to be considered HIPAA de-identified the code cannot be derived from the subject’s name, Medical Record number, Social Security Number, or other identifiers. Investigators are therefore strongly urged to use a “non-derived” code.

While the investigators will need to indicate their assertions of whether obtained private information is not individually identifiable in the application process, the ultimate determination will be made by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

NOTE: It is possible that an investigator who obtains coded private information about living individuals under the above conditions may 1) unexpectedly learn the identity of one or more living individuals or 2) for previously unforeseen reasons now believe that it is important to identify the individuals. If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information pertain, then the research activity now would involve human subjects under HHS regulations. A revised application form will need to be submitted to the IRB who will determine if the project is exempt or expedited criteria.

In summary, in analyzing a particular activity under the second question, one must focus on what is being obtained by the investigators. If the investigators are not obtaining identifiable private information, then the research activity does not involve human subjects. For research of this status, a submission is still required (including GCO forms, the new MRR application form, etc.). If the IRB concurs with the determination, the investigators will receive a notice certifying that the research is not considered to be human subject research.

(3) If human research is occurring the next question is: **Is the activity “exempt” from the human subject protection regulations?**

With respect to research involving private information, the exemption that is most frequently relevant is the exemption under HHS regulations at 45 CFR 46.101(b)(4):

“Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

Having determined under the second question above that a research activity involves human subjects because the investigators are obtaining identifiable private information, unless the sources are publicly available, the assessment under the exemption at 45 CFR 46.101(b)(4) focuses on: (1) whether the data or specimens are **existing** at the time the research is proposed to an institutional official or IRB for a determination of whether the research is exempt, and (2) how the data or information is **recorded** by the investigators. If the information to be collected will be recorded with direct identifiers (e.g. name) this exemption category would

not apply. If the information to be collected is being recorded with indirect identifiers or codes linked to identifying source material), since this information could enable subjects to be re-identified, this exemption would not apply. An example of a code that would be acceptable under this exemption criteria would be to record “1, 2, 3” or “A, B, C” to mark separate records. *However*, if you maintain a “key code list” indicating the association between the code (“#1”) and information that does or could identify the individual (e.g. #1=John Smith; #2=Mary Johnson, etc.) that would not meet the criteria for exemption #4.

Once a project submission is received (including GCO pages, the MRR application form, etc), if the IRB concurs that the project meets exemption criteria, the IRB will issue a certificate of exemption.

4) If the activity does not meet exemption criteria, the next question is: **Does the activity meet “expedited review” criteria?**

Most projects that do not fit the exemption #4 criteria mentioned above, but involve simply medical record review, will fall into Expedited category #5 (under 45 CFR 46.110):

“Research involving materials (data, documents, records...) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)”

Once the PI submits a project (including GCO pages, the MRR application form, etc), the IRB will review whether the project in fact meets the expedited review criteria.

5) The next question is: **Will a waiver of informed consent be requested?**

When doing human subject research, the default expectation is that informed consent be obtained from the humans on whom the research is to be conducted prior to the conduct of the research. However, there are situations in which the IRB has the authority to grant a waiver of informed consent. In order to do so, the IRB has to find and document that: (per §46.116.d):

- (1) the research involves no more than minimal risk to the subjects;*
- (2) the waiver will not adversely affect the rights and welfare of the subjects;*
- (3) the research could not practicably be carried out without the waiver or alteration; and*
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

If the investigator believes that the above conditions can be satisfied, s/he should thoughtfully answer the questions in the MRR application that deal with waiver of informed consent.

6) The next question is: **Does the project involve a review of HIV/AIDS information AND informed consent will not be obtained?**

If researchers wish to do research specifically involving records of patients with HIV infection and also to apply for a waiver of informed consent, there are legal implications under the New York State HIV confidentiality laws. Based on consultation with MSSM’s Legal Department, the following conclusions have been reached:

A) MSSM’s Legal department’s interpretation is that, under New York State law, a clinician who has a right to access HIV data for clinical reasons can also use the data for research purposes without obtaining a new consent from the patient. Assuming the research has IRB approval, HIPAA waivers etc, this means that a waiver of informed consent for chart reviews can be granted by the IRB if other necessary criteria are met.

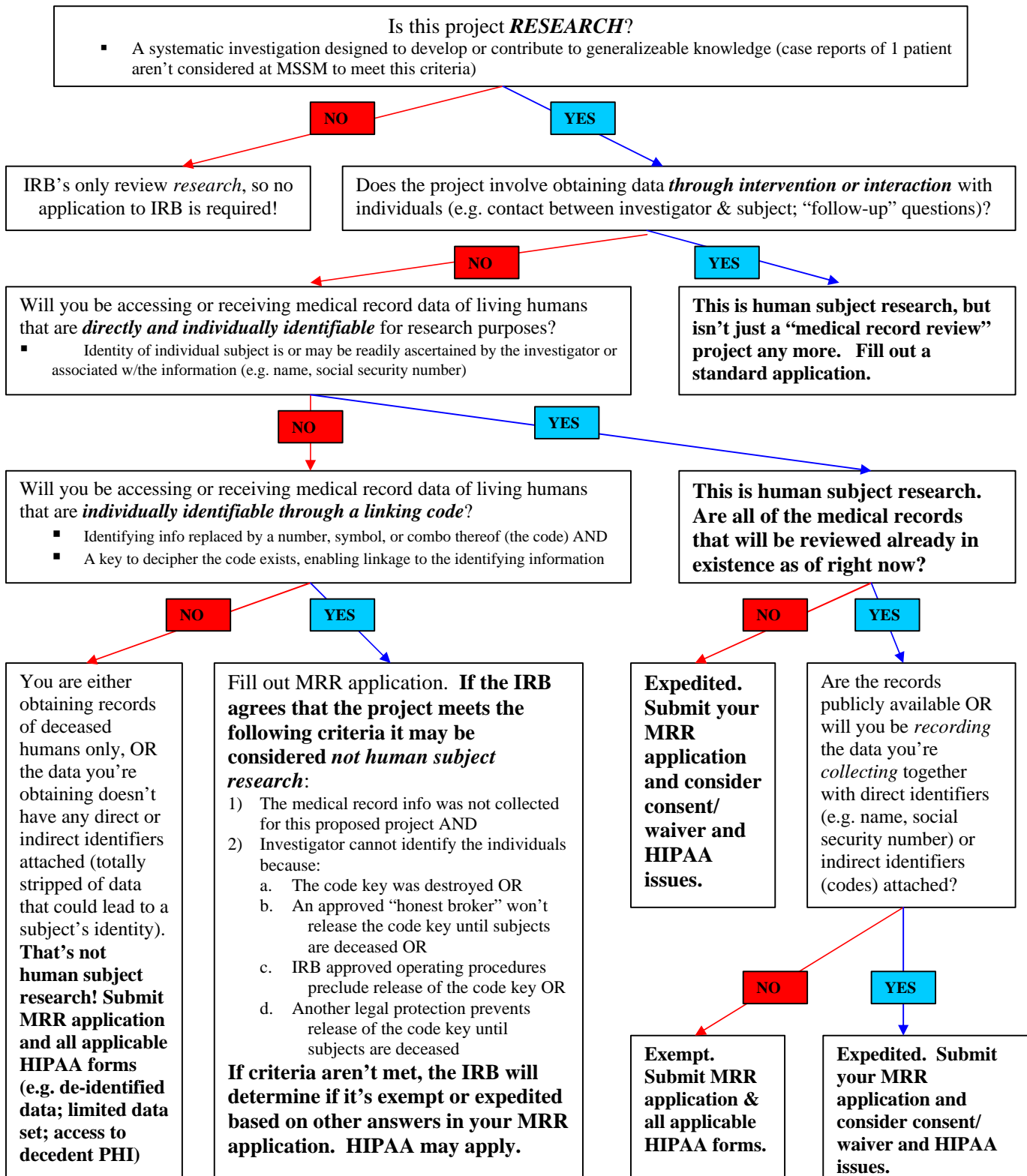
But this waiver of informed consent is only applicable to those who have legitimate clinical access to the HIV information. It would, for instance, allow a clinician working in a true group clinical practice with cross coverage responsibilities to access the group's charts, since s/he has true clinical access to the information.

B) Conversely, someone who does not have a right to the HIV data would not be allowed to see the identified data. This would be true for anyone—from those who simply supervise those who treat those with AIDS (like a department chair or head) but do not have a right to the clinical data themselves, as well as research staff who are not treating clinicians.

C) However, clinicians and their day-to-day clinical support staff would be able to abstract data in an anonymized fashion for use by those without clinical access! The catch is that the research data would have to be recorded in a strictly confidential manner (totally anonymized) though not necessarily HIPAA de-identified (e.g. dates of service can be maintained). Legal does not believe researchers can maintain HIV data with along with a code that links back to the identifiable information, even if the link was kept securely on a another computer, etc. The exception is that a temporary code for short-term use (at most hours) to be held just long enough to pull data from the chart or the EMR would be permissible, but not a code to be maintained for days.

If researchers are interested in pursuing a research project of this type, a separate IRB form for HIV research will also need to be completed, which will deal with key issues of who will have direct access to the records and the method of recording the data.

Medical Record Review (MRR) Flow Chart*



Research related to HIV may have additional requirements. An HIV application form should accompany the submission.

THE MOUNT SINAI SCHOOL OF MEDICINE
MEDICAL RECORDS REVIEW APPLICATION FORM

Please answer each question starting at the beginning, and follow the instructions below each question based on your answer.

1. PURPOSE OF THE STUDY: (describe briefly, including hypothesis and analysis plan)

2. RESULTS OF THE STUDY ARE TO BE USED FOR:

- Publication
- Oral/Poster Presentation Pilot
- Other, please specify

3. STUDY POPULATION: (describe study population, i.e., diagnosis, age group, surgical/medical, etc.)

4. WHAT MEDICAL INFORMATION IS TO BE ACCESSED/RECORDED? (Be specific)

5. WILL ANY HIV RELATED INFORMATION BE ACCESSED PURPOSEFULLY WITHOUT SPECIFIC INFORMED CONSENT FROM THE PATIENTS? YES NO

If YES, you will need to fill out an HIV form in addition to this application and continue to next question.
If NO, continue to next question.

6. THE MEDICAL RECORDS OF HOW MANY PATIENTS ARE TO BE STUDIED?

7. IS THERE TO BE ANY CONTACT OR COMMUNICATION WITH PATIENTS IN THIS STUDY? (This would include contacting patients to fill in missing data from the records or requesting permission to release medical records housed elsewhere) YES NO

If YES, discontinue filling out this form and submit a standard IRB application.
If NO, continue with next question.

8. IS THIS STUDY FUNDED BY FDA OR SUBJECT TO FDA REGULATIONS?

YES NO

If YES, discontinue filling out this form and submit a standard IRB application.
If NO, continue with next question.

9. WILL THIS STUDY INVOLVE COLLECTION OF DATA TO FORM A DATA "BANK" OR DATA REPOSITORY? YES NO

If YES, discontinue filling out this form and submit a standard IRB application.
If NO, continue with next question.

10. INDICATE THE SOURCE OF MEDICAL RECORD INFORMATION TO BE ACCESSED:

(check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Paper Hospital Medical Record | <input type="checkbox"/> Clinical Database |
| <input type="checkbox"/> Office Records | <input type="checkbox"/> Research Database GCO # _____ |
| <input type="checkbox"/> Electronic Medical Record | <input type="checkbox"/> Other, please specify: _____ |
| <input type="checkbox"/> Laboratory Records | |

Continue with next question.

11. WILL THE MEDICAL DATA TO BE ACCESSED BY THE RESEARCH TEAM BE LIMITED TO ONLY DECEASED HUMAN INFORMATION? YES NO

If YES, stop here. This is not human subject research. Sign this document in #22 and submit this application along with the HIPAA Access to Decedent PHI Form.

If NO, continue with next question. If part of the medical records you will access will be from individuals known to be decedents, you will need to submit the HIPAA Access to Decedent PHI Form with your application, along with any other form recommended in this application process.

12. WILL THE MEDICAL DATA TO BE ACCESSED BY THE RESEARCH TEAM CONTAIN ANY OF THE FOLLOWING DIRECTLY IDENTIFYING INFORMATION? YES NO

- | | |
|---|--|
| <input type="checkbox"/> Name | <input type="checkbox"/> Health plan beneficiary number |
| <input type="checkbox"/> Social Security Number | <input type="checkbox"/> Account number |
| <input type="checkbox"/> Medical Record Number | <input type="checkbox"/> Certificate/license number |
| <input type="checkbox"/> Address by street location | <input type="checkbox"/> Vehicle Identification number and serial number, including license plate number |
| <input type="checkbox"/> Telephone number | <input type="checkbox"/> Medical Device Identifiers and serial numbers |
| <input type="checkbox"/> Fax number | <input type="checkbox"/> Full face photographic images |
| <input type="checkbox"/> Email address | <input type="checkbox"/> Biometric Identifiers (finger and voice prints) |
| <input type="checkbox"/> Web URLs | |
| <input type="checkbox"/> Internet protocol (IP) address | |

(This list contains only 16 of the 18 HIPAA identifiers)

If YES, check off which ones and continue to question 15.

If NO, continue to question 13.

13. DOES THE MEDICAL DATA TO BE ACCESSED BY THE RESEARCH TEAM CONTAIN ONLY “CODED” DATA? *This means that identifying information (as detailed in the question #12 above) is not present in the data being accessed, but a “linking code” (a number, symbol or combination thereof) is present which is connected to the information that could lead to ascertaining the identity of individual subjects. Answer yes if a code is present, even if you personally don’t have access to the key code.* YES NO

If YES, proceed to question 14.

If NO, stop here. You’ve indicated you will be accessing data neither directly nor indirectly identifiable to individual subjects (according to Common Rule/MSSM guidelines) which is not human research. Sign this document in #22 and submit it along with applicable GCO forms. Additionally, the data you are accessing may qualify as de-identified data or a limited data set according to HIPAA. It is possible it will require a full HIPAA waiver. Therefore fill out the appropriate HIPAA form (refer to HIPAA wizard and those forms to determine which one to complete.) NOTE: In order for data to be considered de-identified the code used cannot be derived from another identifier (e.g. initials, SSN, MR #, zip code, etc.)

14. IF THE MEDICAL DATA TO BE VIEWED BY THE RESEARCH TEAM IS ONLY CODED INFORMATION, DO THE FOLLOWING CONDITIONS APPLY? YES NO

- A) The medical information was not collected for the current proposal AND
- B) The information cannot be identified because:
 - o The code key was destroyed (Please attach a statement from the holder of the key code attesting to its destruction along with this form) OR

- An agreement is in place between the PI and the provider of the coded information (a.k.a. “honest broker) prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (Please provide this signed agreement along with this form) *OR*
 - IRB approved operating procedures preclude release of the key *OR*
 - Another legal protection prevents release of the key (Please provide a statement indicating this)
- C) The maker of the coded data cannot be part of the research team. The coder cannot be involved in the data analysis, the publication/presentation of the research, etc.

If YES, stop here. Print out and sign this document in #22. Provide detailed written confirmation/statements regarding which criteria apply along any supporting documentation, along with this form and applicable GCO and HIPAA forms.

If NO, then continue with question 15.

15. IS ALL OF THE INFORMATION TO BE REVIEWED PUBLICLY AVAILABLE?

YES NO

If YES, proceed to question 17.

If NO, proceed to question 16.

16. IS ALL THE MEDICAL INFORMATION THAT WILL BE VIEWED ALREADY IN EXISTENCE AS OF TODAY’S DATE? YES NO

If YES, proceed to question 17.

If NO, proceed to question 18.

17. WILL THE MEDICAL INFORMATION BE RECORDED BY THE RESEARCH TEAM (E.G. WRITTEN DOWN, DATA-ENTERRED, ETC.) WITH IDENTIFIERS (DIRECT OR INDIRECT VIA CODES THAT COULD LEAD TO THE IDENTITY OF AN INDIVIDUAL)? Consider carefully whether you need to retain the identity of the subject, or a link to the identity of the subject, with your data in order to accomplish the research goal. YES NO

If YES, continue with question 19.

If NO, this means that you will never be able to link a piece of your collected data back to an individual subject’s identity. This is exempt from human subject review. Stop here. Print out and sign this document in #22. Submit this application form, along with a HIPAA waiver of authorization form, and your data collection sheets, and applicable GCO forms.

18. WILL THE MEDICAL INFORMATION BE RECORDED BY THE RESEARCH TEAM (E.G. WRITTEN DOWN, DATA-ENTERRED, ETC.) WITH IDENTIFIERS (DIRECT OR INDIRECT VIA CODES THAT COULD BE LEAD TO THE IDENTITY OF AN INDIVIDUAL)? Consider carefully whether you need to retain the identity of the subject, or a link to the identity of the subject, with your data in order to accomplish the research goal. YES NO

If YES, continue with question 19.

If NO, continue with question 20.

19. HOW WILL THE INFORMATION BE STORED (where specifically, with what confidentiality measures, etc.)?

Once answered, continue to next question.

20. IS A WAIVER OF INFORMED CONSENT BEING REQUESTED? YES NO

If NO, an informed consent document will need to be submitted. Continue with #21.

If YES, respond to the following issues:

A) Explain why the research could not practicably be done if informed consent was required.

B) Explain why subjects' rights and welfare will not be adversely affected by the waiver of consent

C) Is it reasonably foreseeable that the results of this study could yield information important to the care or treatment of individual subjects whose records are to be reviewed? YES NO

If YES, the PI must agree to contact the IRB in the event of discovering such findings in order to receive counsel on how to proceed. Affirm your understanding of this by signing here:

Signature of Principal Investigator _____ **Date** _____

D) Submit a HIPAA request for Waiver of Authorization along with this form. Continue with #21.

21. LIST THE INDIVIDUALS' NAMES WHO WILL HAVE ACCESS TO IDENTIFIABLE MEDICAL DATA AND THEIR ROLE IN THIS STUDY (e.g. attending physician, research coordinator)?

Once answered, continue with #22.

22. WRITTEN ASSURANCE AND SIGNATURE

As Principal Investigator, my signature below provides written assurance that I will collect the specific information I have indicated above in the method I have indicated above. I will not modify the content or method of conducting my research without obtaining prior IRB approval in the form of a modification to the research. Information collected as part of this project will not be reused or disclosed except as required by law, except as authorized oversight of the research, or for other research use except when that research has also been reviewed and approved (or designated as not human subject research) by the MSSM IRB.

Signature of Principal Investigator _____ **Date** _____

23. ATTACHMENTS

Please attach the following items:

- Protocol (where applicable such as an NIH application or industry sponsored protocol)
- Data Collection Form (when available)
- Statements related to inaccessibility to key codes for coded data (as applicable)
- HIPAA forms (as applicable)
- HIV form (if HIV/AIDS research is proposed)