# HRP-503R Record Review or Specimen Analysis Application Form

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| * This simplified application form is for the submission of studies that do not involve any study participant interaction (in-person / remote survey, questionnaire administration or consenting for record / sample review) or intervention. * The HRP-503R Form is for the following specific study designs only: 1) retrospective or prospective clinical record/clinical data review, 2) retrospective of other types of records/data 3) retrospective specimen review associated with identifiers or some clinical information, 4) prospective review of clinical specimens associated with identifiers or some clinical information, or 5) case-series analysis. A study can be comprised of a combination of the aforementioned research designs. * The HRP-503R is a standalone application and does not require a protocol. If there is one that has been prepared, usually as part of a grant submission, please provide it within the RUTH submission. * All other observational studies should use the standard HRP-503 Protocol Supplement Form. * If your record/ specimen review study cannot meet the requirements for a waiver of consent, then you cannot use this form for your application. You must provide a protocol and an HRP-503 full application form. * All exempt studies should use the HRP-503E Form. * NOTE: The investigator must demonstrate that the study is consistent with “sound scientific design” and that the design is sufficient to achieve the study objectives. The investigational plan, study procedures, and analysis plan must provide sufficient detail to provide the IRB with a basis for its decisions. Even though the risks of the research may be minimal, the IRB will not approve studies with insufficient information. * Depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. If the question is not applicable to the study, mark the section “N/A”. Do not delete any sections or leave them blank. * Be sure to complete any supplement questions from one or another ancillary office that you receive during the RUTH application process. Please make certain that this HRP-503R Application and responses to ancillary offices do not contradict each other and the information is incorporated in all documents where appropriate. Be sure to save the Ancillary office responses you provided within REDCap as a PDF and upload it into RUTH. * Throughout this application are references to checklists. These are located in the RUTH Portal under the Library tab > Checklists. These tools are used by the IRB to make specific regulatory findings. To allow us to do that it is the applicant’s responsibility to ensure that your protocol has sufficiently addressed these additional regulatory criteria for approval, and that the applicant identifies those protocol specific findings required by the checklist. * Keep an electronic copy of this version of the document. You will need to modify this copy when making changes. * Throughout this document, use the pink italicized text as a guide for your responses and delete the text in your final document. |

# Study Overview

*The study overview should include:*

# *Objectives of the research*

* *Population, disease, current standard of care (if one exists), knowledge limitations or available therapy for the study problem or question being addressed.*
* *Background information including existing literature and previous research efforts*
* *Study Duration (how long is the study expected to be open for once it begins?)*

# Setting of the Human Research

*Where within the Mount Sinai health system or its affiliates will research activities take place including participant recruitment?*

*For research conducted outside MSSM and its affiliates (to be listed in the RUTH smart form) under the supervision of the Sinai investigator, please indicate the following:*

* + - Site(s) name(s) and location.
    - Site-specific regulations, laws or customs affecting research.
    - Local scientific and ethical review structure.

1. Resources Available to Conduct the Human Research

*The aim here is to assess if the research is likely to be successful and thus justify the efforts and risks taken by the subjects.*

* *Explain the feasibility of meeting the goals of this project in the expected study duration.*
* *For research involving considerable data extraction or mining describe who will be providing those services.*
* *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol*
* *If an honest broker will be used for obtainment of data/ samples, provide their information here and explain how they have primary access to the data/ samples needed for this study.*

### Total Number of Records/Samples/Cases to be accessed for Eligibility Review

* *For record review primarily, it is often the case where many more records will need to be accessed and reviewed for eligibility than the number of evaluable records required. Please be sure to indicate the total number of records/data/samples to be accessed for eligibility review.*
* *If this is a multicenter study, also indicate the total number of records/cases/specimens to be accessed for eligibility review across all sites.*

1. Number of Records/Samples/Cases for Acquisition and Review

* Indicate the number of records/samples/cases to be reviewed locally.
* If this is a multicenter study, also indicate the total number of records/cases/specimens to be reviewed across all sites.

### Date Range(s) of Study Data/ Samples

*Indicate the range of dates (i.e., time-period) when the data/ samples that are included in this study were originally collected or will be collected for a non-research purpose.* *For example, “Records will be included from mm/dd/yyyy to mm/dd/yyyy.” Also indicate the review period. For example, you may identify cases from 2023, but plan on following outcomes for 5 additional years. Both periods have to explicitly be reported here.”*

Data/samples to be requested from the following time-period:

## **Inclusion and Exclusion Criteria**

## *Define the study population using inclusion and exclusion criteria. These are the criteria that will be used to determine whether to include a chart/specimen/case is to be included (eligible) within the study.*

* *Any exclusions based on race, sex/gender, preferred language must be explained.*
* *Per institutional policy, special status patients (e.g. employees, VIPs, celebrities, public figures) must be excluded from research unless they will be consented prior to research participation. This must be added to your exclusion criteria if you will not be consenting potential participants.*
* *(NOTE: You may not include members of vulnerable populations as participants in your research unless you indicate this in your inclusion criteria).*

### Inclusion Criteria (list):

### Exclusion Criteria (list):

# Study Procedures

*Briefly describe the study procedures. Procedures are limited to review of records and/or analysis of leftover biological samples (if applicable).* *For example, indicate if samples were collected for clinical purposes, or for another research study, and will undergo further analysis as part of this study.*

### Record/ Data/Specimen Sources

* *The description should be specific. Please indicate the source of the records/data/samples for your study. If multiple sources are involved, indicate each.*
* *If this study involves the secondary use of research data/specimens from an IRB-approved protocol at Mount Sinai, the original IRB project number and, if applicable, include the source study consent form indicating subject permission for this use.*
* *If an honest broker will be used for obtainment of data, please explain how this will be accomplished.*
* *If data are to be obtained from another (internal to Mount Sinai) source (e.g., EPIC, Mount Sinai Data Warehouse, etc.), please indicate.*
  + *It is recommended that you use the Mount Sinai Data Warehouse as your data source. If this is not possible to do, provide an explanation.*
  + *How excluded patients will be kept out of the data analysis has to be explained.*
  + *The staffing, location, and data security during manual chart review must be addressed.*
* *If data are to be obtained from a source outside of Mount Sinai (e.g., NYC DOH, SPARCS, please indicate and note that a DUA will be needed and whether that process has been started. Contact GCO as part of your application process for receipt of outside data.*

Does this protocol involve any information leaving Mount Sinai? [ ] Yes [ ] No

*If “Yes” - Please indicate the following:*

*Recipient of data transfer, how will data be shared/transmitted, and whether or not these data will be linked.*

*Please be sure to contact* [Mount Sinai Innovation Partners (MSIP)](https://ip.mountsinai.org/request-an-agreement/) *as part of your application process in order to transfer data or specimens from ISMMS.*

### Data Elements

**Protected (Identifiable) Health Information**

*PHI refers to health/medical information that is accompanied by any of the listed 18 HIPAA identifiers or by a code where the key to the code that links to the identifiers is accessible to investigators. DE-IDENTIFIED DATA or anonymous (without any identifiers or codes that link back to individuals) are not considered PHI, and are not subject to HIPAA regulations.*

*For your reference, below is a complete list of the 18 HIPAA identifiers. When a study records ANY of these of data, the study involves PHI.*

* *Name*
* *Social Security Number*
* *Medical record number*
* *Address by street location*
* *Address by town / city / zip code*
* *Dates (except year), e.g., date of birth; admission / discharge date; date of procedure; date of death*
* *Telephone number*
* *Fax number*
* *Electronic email address*
* *Web URLs*
* *Internet protocol (IP) address*
* *Health plan beneficiary number*
* *Account number*
* *Certificate / license number*
* *Vehicle identification number and serial number, including license plate number*
* *Medical device identifiers and serial numbers*
* *Biometric identifiers (finger and voice prints)*
* *Full face photographic image*
* *Any other identifier; or combination of identifiers likely to identify the subject (e.g., Pathology Accession #)*

For this study, will you be **recording** any of the 18 HIPAA identifiers with the data or using a code to link the data to any of the identifiers?

[ ] Yes [ ] No

*If “Yes”, then under the HIPAA Privacy Rule provisions the data cannot be considered de-identified and authorization from the subject or a waiver of authorization must be granted by the IRB. When answering this question, consider the need for recording dates or retaining direct identifiers, such as name and/or medical record number, to link data from multiple sources, to avoid duplicating records, or for QA purposes.* ***NOTE: If you are recording medical record number or other identifiers, even if temporarily for QA purposes or to avoid duplicating records, then answer "Yes".[[1]](#footnote-2)***

**Check the identifiers that will be recorded with or linked by code to the data**.

Name

Social Security Number

Medical record number

Address by street location

Address by town / city / zip code

Dates (except year), e.g., date of birth; admission / discharge date; date of procedure; date of death

Telephone number

Fax number

Electronic email address

Web URLs

Internet protocol (IP) address

Health plan beneficiary number

Account number

Certificate / license number

Vehicle identification number and serial number, including license plate number

Medical device identifiers and serial numbers

Biometric identifiers (finger and voice prints)

Full face photographic image

Any other identifier; or combination of identifiers likely to identify the subject (e.g., Pathology Accession #)

Will identifiers be removed from the data and destroyed after all of the data has been collected, the study has been completed, or all regulatory and sponsor obligations have been met, consistent with regulatory and institutional research record keeping requirements?

[ ] Yes [ ] No

1. Statistical Considerations

## **Statistical Methods**:

*Briefly describe statistical methods for this study. The statistical methods should address each endpoint addressed. If the study is purely descriptive, it is appropriate to state the data will be summarized using descriptive measures.*

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## **Sample Size and Study Power**

*For some descriptive studies, the sample size will be one of convenience (i.e., easily accessible and all of the available cases). If that applies to your research, then simply state that you will use a convenience sample. Ensure you indicate the date range(s) for accessing records/data/specimens. (See query #2).*

*Study power refers to the ability of a study to detect a difference or effect, should a difference/effect actually exist. Sample size estimation is a good way to ensure that a study has adequate statistical power. A sample size estimate, while not required, is recommended.*

1. Consent Process and HIPAA Authorization

**To use this HRP-503R, consent will not be obtained.** Justification is necessary for not obtaining consent and appropriate waivers are required. It is possible to request waivers for prospective activities but then the hurdle of practicality must be carefully and comprehensively addressed. It is permissible to ask for a waiver for a large retrospective review and then obtain consent/authorization for a smaller prospective component. If waivers cannot be granted for your entire study, you cannot use this HRP-503R and instead will need to use the HRP-503-Full RUTH Application template.

If your study meets criteria for a waiver, proceed to the **Waiver or Alteration of the Consent Process** section below.

To request a waiver of HIPAA Authorization, complete the relevant HIPAA form as directed by the HIPAA wizard and attach it to your RUTH application.

*NOTE: Federal regulations mandate that, under a Waiver of Consent / Authorization, identifiers must be destroyed as early as possible.*

**Waiver or Alteration of Informed Consent / Authorization**

**Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk.**

*When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Mount Sinai network with password protections enabled and anti-virus software or an encrypted laptop, with access to data limited to study staff; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.*

RESPONSE:

**Explain why the research could not practicably be carried out without the waiver of consent / authorization.**

*When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.*

RESPONSE:

**Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization.**

*When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.*

RESPONSE:

**If the research involves using identifiable private information or identifiable biospecimens, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format. (N/A if research does not use identifiable private information or biospecimens)**

*When addressing this question, consider the research question(s) and how using identifiable information or biospecimens is necessary to answer the research question(s).*

RESPONSE:

**Explain that whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.**

*When addressing this question, please mention incidental findings that might arise from reviewing patient records e.g. new findings triggered by a second look at radiology images or pathology slides. These incidental findings must be provided to the subjects or their legally authorized representatives and/or their physician(s). Provide a plan for what efforts will be made to contact the subjects or their legally authorized representatives and how the information will be provided.*

RESPONSE:

1. **Sensitive Information and Certificates of Confidentiality**
2. Will any *sensitive* personal information be collected?

[ ] Yes [ ] No

If “Yes”, *Please check data elements below (all that apply)*

HIV Status

Mental Health

Reproductive History (e.g., abortions)

Sexual Behavior/Sexually Transmitted Diseases

Substance Abuse (e.g., drug or alcohol abuse)

Other potentially stigmatizing behaviors *(please specify)* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Why are the sensitive/ personal data checked above needed to achieve the goals of the study?
2. If this project will collect sensitive information and is not funded by the NIH, will a Certificate of Confidentiality (CoC) be obtained?

[ ] Yes [ ] No

If “No”, please explain why a CoC is not warranted.

If you will apply for a CoC, note that the NIH considers the following when reviewing CoC requests:

* *If the study is collecting or using identifiable, sensitive information*
* *If the research data/ samples in the study are collected, used, or stored in the United States.*
* *If the study is a single, standalone study and not part of a research program or involves multiple projects.*
* *If the study is not establishing a research bank/ repository where the main source of the data/ samples was originally obtained for clinical care or other non-research purposes.*

If you have questions about whether you should apply for a CoC, please contact the PPHS at [irb@mssm.edu](mailto:irb@mssm.edu) and be sure to put COC in your subject line.

1. **Data Storage, Transmission, Security and Confidentiality**

* *Where and how will the data/ samples to be analyzed be stored? Provide data standards where known.*
* *How long will they be stored for?*
* *What are the SOPs that govern data sharing?*
* *How will you ensure the confidentiality of the data, from the beginning of the abstraction process though analysis?*
* *Include a statement that all record/data/samples used during this study will be kept confidential in accordance with Institutional research policies and HIPAA law.*
* *Confirm that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.*
* *Describe the safeguards to maintain data confidentiality.*
* *If the investigator leaves the institution and plans transfer the data, or share the data with an outside colleague/institution, additional HIPAA and institutional requirements must be satisfied.*
* *Details of the data sharing plan for multicenter studies.*

1. [↑](#footnote-ref-2)