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

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| * *This simplified application form is intended for the submission of studies that do not involve any subject interaction (in-person or remote survey or questionnaire administration is considered subject interaction) or intervention.* * *The HRP-503R Form is to be used for the following specific study designs only: 1) retrospective record/data review, 2) retrospective specimen review, 3) prospective record/data review, or 4) 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. * *All other observational studies should use the standard HRP-503 Form.* * *All exempt studies should 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 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 (HRP-410 and HRP-411). These located in the RUTH Portal under the Library tab/SOPs. 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. |

# Study Overview

Please provide a *brief description* of the purpose of this research, including the study design *(record review, analysis of previously collected specimens, prospective data review, or case-series)*. Include the study duration, enrollment goals and indicate the number of sites (*internal, as well as external to the Mount Sinai Health System).*

1. Number of records/cases/specimens for acquisition and review

Specify local number of records/cases/specimens for retrieval and review.

Indicate the total number of records/cases/specimens to be reviewed locally.

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

### Date Range(s) of Study

Indicate the range of dates (i.e., time-period) during which data collection/review will occur. *For example, “Records will be included from mm/dd/yyyy to mm/dd/yyyy.” For studies involving the collection of prospective (future) data, use the anticipated project end date.*

Retrospective data/specimens to be requested from the following time-period (retrospective means that the data and/or specimens exist at the time that this study is submitted to the IRB):

Prospective data collection time-period:

### Total Number of Records/Specimens/Cases to be accessed for 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/specimens to be accessed for eligibility review**.*

1. **Study Population**

## 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.

### 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 specimens (if applicable). *For example, indicate if specimens 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/specimens for your study. If multiple sources are involved, indicate each.

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| For a Case-Series ONLY:  The patients within this case-series are from my practice :  [ ] yes [ ] no IF “no”, describe how they were identified and how you will use the data.  The reported cases will not contain any identifiers of descriptors, which could reveal patient identity:  [ ] yes [ ] no  Number of cases to be reported within this case-series study: \_\_\_\_  \_\_\_\_\_\_\_\_\_\_ |

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.

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.

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

If “Yes” - *Please indicate: 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. Contact GCO as part of your application process to receipt of outside data.*

1. **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”, than 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

Either informed consent must be obtained or the investigator must request a waiver of informed consent and a waiver of HIPAA Authorization

For this research, will you obtain informed consent?

[ ] Yes [ ] No

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| **If Yes** - **See Consent SOP 090 and 091 and Consent at a Distance Policy in the RUTH Portal under the Library tab/SOPs**.  Describe the procedures that will be used to obtain informed consent. Include: who will obtain consent, where will consent process take place, how will privacy be assured, how much time will subjects be permitted, how will the investigators assure that subjects comprehend the nature of the study, the study procedures and the risks-benefits of participation, steps that will be taken to avoid coercion and documentation of consent. |

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| **If No**- Justification is necessary and appropriate waivers are required. Proceed to the **Waiver or Alteration of the Consent Process** section of this form. (below)  **NOTE: Federal regulations mandate that, under a Waiver of Consent / Authorization, identifiers must be destroyed as early as possible. De-identified datasets may be retained indefinitely.** |

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| **Waiver 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 Partners 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.  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.  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. |

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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Explain why the sensitive/personal data checked above are needed to achieve the goals of the study:

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.

# Confidentiality of Data

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/specimens used within this 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.*

1. **Data Security**

How will data or specimens be stored? Provide data standards where known.

How long will data be stored?

What are the SOPs that govern data sharing?

1. [↑](#footnote-ref-2)