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**HRP-503C – MEDICAL RECORD REVIEW ONLY PROTOCOL**

**(2022-2)**

**Protocol Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**Version Date:** Click or tap here to enter text.

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| **INSTRUCTIONS** |
| This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:**1. Use this protocol template for a Medical Record Review Application only. Additional templates for other types of research protocols are available in the system Library.
2. If a section or question does not apply to your research study, type “Not Applicable” underneath.
3. Once completed, upload your protocol in the “Basic Information” screen in IRES IRB system.
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## Section I: Research Plan

**Requests for medical records should be made through JDAT as described at** <http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx>

1. **Will information be collected from sources other than Yale School of Medicine or Yale-New Haven Hospital?**

NO [ ]  YES [ ]

**Important Note:**  Yale-New Haven Health System partners, e.g., Greenwich Hospital, Bridgeport Hospital, Northeast Medical Group and Lawrence & Memorial Hospital, are not under the Yale HIC; therefore, IRB approval from those sites may also need to be obtained if their records are intended to be reviewed.

If you checked **Yes** to the above, indicate **sources**: Write here

a. Is the information from international sources? NO [ ]  YES [ ]  (this may require that you coordinate with that facility for access to the records).

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested and describe the research plan and possible risks and benefits. Write here
2. **Probable duration of study:** (Please state the expected duration of the project, including all data analysis activities). Write here
3. **Estimated number of records to be reviewed:**  Write here
4. **Criteria for inclusion/exclusion (state if minors, pregnant women, or prisoners will be included)**: Write here
5. **Does the PI or any other member of the research team have a direct existing clinical relationship with the subjects whose records will be reviewed?**

 [ ]  Yes, all subjects

 [ ]  Yes, some of the subjects

 [ ]  No

 If yes, describe the nature of this relationship: Write here

1. **Nature of the data** (check applicable and answer the associated questions):

[ ]  **Retrospective** (data already in existence)

Dates of the medical records that will be reviewed: Write here to Write here

[ ]  **Prospective** (records that will be created in the future)

Dates of the medical records that will be reviewed: Write here to Write here

[ ]  **Both retrospective and prospective**

Dates of the medical records that will be reviewed: Write here to Write here

If at all **prospective,** consider whether verbal or signed consent should be obtained.

Should consent be obtained? Yes [ ]  No [ ]

If consent is to be obtained, see **Appendix I** for required additional questions.

1. **Type of data**.

Only those items listed below may be requested from JDAT. Note that only the minimum information necessary to conduct the research should be used.

1. **Check off all identifiers listed below that will be collected. Check “N/A” if none are being collected**

[ ] N/A

[ ] Name

[ ] Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)

[ ] All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)

[ ] Telephone numbers

[ ] Fax number

[ ] Email address

[ ] Social Security Number

[ ] Medical record number

[ ] Health plan beneficiary number

[ ] Account number

[ ] Certificate or license number

[ ] Vehicle identifiers and serial numbers, including license plate numbers

[ ] Device identifiers and serial numbers

[ ] Web URL

[ ] Internet Protocol (IP) Address

[ ] Finger or voice print

[ ] Photographic image - Photographic images are not limited to images of the face.

[ ] Any other characteristic that could uniquely identify the individual (please describe)

1. **Other information requested through JDAT from medical records (e.g.., health information, diagnosis, test results, imaging results).**
2. **Other information from medical records not requested through JDAT (e.g.., clinician notes)**
3. **Identify the type of medium that will be used to record the information and the plans for maintaining confidentiality and security of the data.**
4. **Indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored. State if those individuals will see identifiable or de-identified data.**

***Note****: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media.  Identifiers and code keys must be stored in a secure manner, e.g., Yale network servers.  All portable devices must contain encryption software, per University Policy 5100.  If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url* [*http://its.yale.edu/egrc*](http://its.yale.edu/egrc) *or email* *it.compliance@yale.edu*

1. **How will the data and/or identifiers be destroyed when no longer needed for research purposes?** If it will not, please explain why data must be retained, for how long and how it will be kept secured.

## Section II: Consent and HIPAA Authorization Waivers

 **If you are requesting a Waiver of Consent/Waiver of HIPAA Authorization, complete the following (if not requesting a waiver, state N/A and fill out questions in Appendix I):**

* 1. Does the research pose greater than minimal risk to subjects? Yes [ ]  No [ ]
	2. Will the waiver adversely affect subjects’ rights and welfare? Yes [ ]  No [ ]
	3. Explain why the research could not practicably be carried out without the waiver.

Write here

* 1. Are there any plans to provide subjects with additional pertinent information after their records have been reviewed? [ ] No [ ] Yes

 If yes, how will pertinent information be returned to subjects, if appropriate at a later date? Write here

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the “accounting for disclosures log”, by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer*.*

**The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.**

***Waiver of signed consent:*** (Verbal consent from subjects will be obtained. Note that an information sheet may be required.) [ ]  N/A

 **For a waiver of signed consent, address the following:**

* Would the signed consent form be the only record linking the subject and the research?  **YES** [ ] **NO** [ ]
* Does a breach of confidentiality constitute the principal risk to subjects? **YES** [ ] **NO** [ ]

 **OR**

* Does the research pose greater than minimal risk? **YES** [ ]  **NO**[ ]
* Does the research include any activities that would require signed consent in a non-research context? **YES** [ ]  **NO** [ ]

**APPENDIX I: Consent Considerations**

***If consent will be obtained (verbal or written), please address the following:***

1. **Process of Consent/Assent:** Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects’ independent decision-making.

Write here

1. **Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent:** Indicate how the personnel obtaining consent will assess the potential subject’s ability and capacity to consent to the research being proposed.

Write here

1. **Documentation of Consent/Assent:** List the documents that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given to subjects.

Write here

**Non-English Speaking Subjects:** Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. Translated copies of all consent materials must be submitted for approval prior to use.

Write here

As a limited alternative to the above requirement, will you use the short form\* for consenting process if you unexpectedly encounter a non-English speaking individual interested in study participation and the translation of the long form is not possible prior to intended enrollment? YES [ ]   NO [ ]

**Note\*** If more than 2 study participants are enrolled using a short form translated into the same language, then the full consent form should be translated into that language for use the next time a subject speaking that language is to be enrolled.

Several translated short form templates are available on the HRPP website (yale.edu/hrpp) and translated HIPAA Research Authorization Forms are available on the HIPAA website (hipaa.yale.edu). If the translation of the short form is not available on our website, then the translated short form needs to be submitted to the IRB office for approval via modification prior to enrolling the subject.  ***Please review the guidance and presentation on use of the short form available on the HRPP website.***

**If using a short form without a translated HIPAA Research Authorization Form, please request a HIPAA waiver in the section above.**