**The University of Vermont Committees on Human Research**

**Health Records Review Protocol**

This form is to be used when the only procedure involving human subjects is review of identifiable Protected Health Information (PHI) from a covered entity. Health Information includes EMR, pathology slides and radiographic images. The UVM IRB Privacy Board covers the following covered entities: The University of Vermont Medical Center (UVMMC), and the UVM Eleanor M. Luse Center.

If prisoners are the target population for this record review, **STOP** and contact the IRB office for further guidance.

If any other procedures are being included, **STOP** and contact the IRB office for further guidance. Note: Non-health record reviews (e.g. student educational records) require completion of a Protocol Exemption Review and Determination form utilizing exempt category #7.

As long as no other procedures are being conducted, the protocol review meets expedited **Category #5**: *Research materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).*

**Indicate the source/custodian of the records (check all that apply)**

|  |  |
| --- | --- |
|  | Documentation of permission from the source/custodian must be attached to this submission.  |
|  | *Acceptable documentation can range from an approval from the Jeffords to an email from the person responsible for oversight of UVM records.* |
|  | University of Vermont Medical Center  |
|  | Jeffords Institute for Quality (JIQ) or Business Intelligence ***(You must submit a JIQ Research Resource Request to Jeffords (***[***UVMHealth.org/MedCenter\_Research***](https://www.uvmhealth.org/medcenter/Pages/Clinical-Trials-and-Research/Research-at-The-University-of-Vermont/Research-Resource-Request.aspx)***) and obtain their acceptance prior to IRB review and approval.)***  |
|  |
|  | I will be reviewing individual medical records *(****Submit simultaneously to both the Jeffords and the IRB if you are not a UVM Medical Center Employee nor on the Medical Staff.)*** |
|  |
|  | Clinical Database | Identify |  |
|  | Research Database  | List CHRMS#: |  |  |
|  | University of Vermont |
|  | Eleanor M. Luse Center for Communication |
|  | Unaffiliated (private practice) list below name of practice(s) |
|  |  |
|  | Other source, list below |
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| **1. Project Title**  |
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| **2.** | **Investigator Information** |
|  | Principal Investigator (PI): |  | Degree: |  |
|  | Department |  | Subspecialty |  |
|  | Phone |  | E-Mail: |  |
|  | Campus/Office Address: |  |
|  | Department Chair |  |
|  | Identify the PI’s role(s) |
|  | UVM Faculty |
|  | UVMMC Employee or Medical Staff |
|  | UVM Employee *(not faculty)* |
|  | Student *(check applicable status)* |
|  |  |  | Fellow |  | Resident |  | Graduate |  | Undergraduate |
|  | List Faculty Sponsor Name |  |
|  | Faculty Sponsor Department |  |

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|  | **Do you want to appoint a primary contact other than the PI?** | Yes |  | No |  |  |
|  | Investigators wishing to appoint a contact for **all** IRB communications should complete the contact information requested below. **Primary contacts are considered “key personnel” and must complete required human subjects training.** |
|  | Contact Full Name |  | Email |  |
|  | Department /Address |  | Phone |  |

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| **3.** | **Personnel Roster** |  |
|  | Because the data are identifiable, key personnel are required to complete Human Subjects training. More information about required training can be found at <http://www.uvm.edu/irb/?Page=training_faqs.html> Any persons who are accessing any UVMMC medical records for research are required to complete [credentialing](https://www.uvm.edu/medicine/clinicaltrials/?Page=uvmresearchcredentialing.html) through UVMMC or Office of Clinical Trials Research. |
|  | **Personnel Name** | **Email Address** |
|  | PI: |  |
|  | Contact Person: |  |
|  |  |  |
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| **4.** | **Source of Support**  |
|  | Is there any external funding for this project?  | Yes |  | No |  |
|  | **If yes, list sponsor name here** |  |
|  | If it is a federal sponsor list InfoEd # herePlease attach the grant if applicable |  |

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| **5.** | **Purpose**  |
|  | State the purpose of this record review project, including the primary and secondary objectives. |
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|  **6.**  | **Data Collection** |
| **a. Describe the data elements you will be collecting.** |
|  |
| **b. Indicate how many records you intend to review and how you will select records.**  |
|  |
| **c. Is the data you wish to collect prospective or retrospective?** |
|  | **Prospective data** are data that are not currently available |
|  | **Retrospective data** are data that exist at the time of this application  |
| **d. Provide the start and stop dates [mm/dd/yyyy] for the data collection period of interest. *Note:*** *Often times, researchers may need to request additional date ranges. If a change to your requested dates is necessary, you must submit an amendment, update this form, and submit to the IRB for approval.**Provide the start and stop dates [mm/dd/yyyy] for the collection period of interest.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Start Date…** |  | **Stop Date** |
|  | *01/01/2012* |  | *12/31/2012* |
| **Period\_1** |  |  |  |
| **Period\_2** |  |  |  |
| **Period\_3** |  |  |  |

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|  **e.**  | **Are you collecting any sensitive research data?** *(e.g. criminal behavior, illicit drug use or alcohol abuse, sexual habits where identifiers are attached)* |
|  |  | Yes |  | No |
|  | **If yes, describe the sensitive data that will be collected.**  |
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|  | e.i. Will sensitive, directly identifiable data with PHI be moved or transferred? |
|  | Yes |  | No | If yes, continue. |
|  | If yes, the media which is used to transfer the data must be encrypted. Has this been done for all media? *(encrypted thumb drives can be purchased with a PIN pad right on the device and are not dependent on software being installed)* |
|  |  | Yes |  | No |
| e.ii. Will sensitive, directly identifiable data with PHI be transferred via email? *(will require encryption of the file(s))* |
|  |  | Yes |  | No |
|  | If yes, explain why it is necessary to include identifiable information in an email. |
|  |  |
|  | Explain the process for encrypting the files that will be sent via email.  |
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| **7. Protection of the Data**  |
| **a. Who will have access to the identifiable PHI?** |
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| **b.** | **Will the research data be shared with anyone other than the approved research team?**  |  | **Yes** |  | **No If no, skip to c.** |
|  |  |
|  | If yes, describe the process for ensuring that the research data are protected. Include the process for obtaining appropriate IRB approvals, stripping of individual identifiers, and/or justification to maintain identifiers, even if coded.  |
|  |  |
|  | ***Sharing data outside of our institutions may require that a data use agreement be executed. UVM investigators should contact Sponsored Projects Administration at 656-3360 to speak with the AVP for Research. UVMMC investigators should contact the Office for Clinical Trials Research at 847-8990.*** |

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| **c. What identifiers will you need?** *Check off below which identifiers will be included with the PHI. Any of these elements, under Privacy rule provisions, cannot be considered de-identified. Either an authorization must be signed or a waiver of authorization must be granted by the IRB.* |

|  |  |
| --- | --- |
|  | Patient/Subject Name |
|  | Address street location |
|  | Address town or city  |
|  | Address state |
|  | Address zip code |
|  | Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death |
|  | Telephone number |
|  | Fax Number |
|  | Electronic mail (email) address |
|  | Social security number |
|  | Medical record numbers |
|  | Health plan beneficiary numbers |
|  | Account numbers |
|  | Certificate/license numbers |
|  | Vehicle identification numbers and serial numbers including license plates |
|  | Medical device identifiers and serial numbers |
|  | Web URLs |
|  | Internet protocol (IP) address |
|  | Biometric identifiers (finger and voice prints) |
|  | Full face photographic images |
|  | Any unique identifying number, characteristic or code, that may identify individual |

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| **d. How will you protect the identifiers?** |
| d.i. Describe how the research team will record the data.  |
|  |
| d.ii. Describe the coding mechanism *(separate master list that contains the code that links the data to the identity of the person)* |
|  |
| d.iii. Confirm by checking below that the master list with the code will be kept in a totally separate location from research data. *(i.e., separate computers, files cabinets)* |
|  | I confirm that I will keep the master list separate from the research data. |

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| **e. How will you store the data?** |
|  | **For hardcopy data** |  | **For electronic data** |
|  |  | Locked office |  | Local computer hard drive *(will require encryption if data contains sensitive, directly identifiable private information)* |
|  |  |  |
|  |  |  |
|  |  | Locked file cabinet |  | Secure network/server List:  |  |
|  |  |  |  | Password protected  |
|  |  |  |  | Other types of storage (e.g. thumb drives, media, external hard drive*) (will require encryption if data contains sensitive, directly identifiable private information)* |
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|  |  | Other explain or comments: |  | Online data (i.e. forms, surveys) complete below |
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| **8.** | **Consent and HIPAA Authorization** |
|  **a.** | Are you requesting approval for written informed consent and authorization **or** a waiver of consent and authorization? |
|  | Written Informed Consent and Authorization *Proceed to 8.b.* |
|  | Waiver of Informed Consent and Authorization *Proceed to 8.c.* |

*This request means that you will not be obtaining verbal or written consent.*

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|  **b. Process for obtaining Consent/Authorization** |
| b.i. | Once a prospective subject is identified, who initiates the informed consent and HIPAA discussion and answers questions presented by the subject or the subject’s family? |
|  |
| b.ii. | Where (in what setting) is the process initiated? How much time is the subject given to decide? |
|  |
| b.iii. | Is the principal investigator present for the initial and subsequent informed consent discussions with the subject? |
|  |
| b.iv. | What other method of documentation is used to record the informed consent process, in addition to the executed consent form? *See an* [*example of documentation*](http://www.uvm.edu/irb/?Page=forms_all.html) *of the informed consent* ***process*** *under consent templates on our forms page.* |
|  |
| b.v**.** Do you plan to retain the research data once the protocol is closed?  |
|  |  | Yes, continue |  | No, continue to section i. |
|  | If yes, will you keep identifiers of any kind, direct or coded?  |  | Yes |  | No |
|  | If yes, explain how you will maintain security around the identifiers. |
|  |  |
|  | If you intend to maintain identifiers, any subsequent secondary analysis after protocol closure requires prior IRB review and approval. Please acknowledge this requirement by checking below.  |
|  |  | I understand subsequent data analysis requires prior IRB review and approval.  |

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| **c. Consent Waiver Criteria** |

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| c.i. Explain why the research involves no more than minimal risk\* to the individual |
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| *\*The probability and magnitude of harm is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of the general population.* |
| c.ii. Explain why the research will not adversely affect the rights\* and welfare of subjects |
|  |
| *\*The rights of participants include, for example, the rights to be informed about research activities, to make a voluntary decision whether or not to participate, to privacy, and to confidential management of personal information.* |
| c.iii. Explain why it would be scientifically or logistically impracticable (not possible) to conduct the research without the requested waiver or alteration of consent  |
|  (*Inconvenience or difficulty is not justification.)* |
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| c.iv. Will information be provided to the subjects once the research is complete, when appropriate?  |
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| **d. HIPAA Authorization Waiver Criteria** |

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| d.i. Minimum Necessary*Investigators are required to only obtain the minimum necessary data in order to achieve the goals of the research. Please explain why the data you are obtaining is the minimum necessary to achieve the goals of the research.*  |
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| d.ii. Destruction of Identifiers*You are required to destroy identifiers (or links) at the earliest possible time. Please describe your plans and specify when this will occur. If there is a justification for retaining the identifiers, please provide this information.* |
| a. Will the identifiers be destroyed?  |  | Yes, continue. |  | No, go to 3. |
| 1. Identifiers will be destroyed upon completion of  |
|  | Data collection |
|  | Data analysis |
|  | Specimen processing |
|  | Other, explain below |
|  |  |
| 2. Describe the plan to destroy the identifiers. |
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| 3. If identifiers will be retained indefinitely, check why and justify where indicated |
|  | Health or research justification, explain below |
|  |  |
|  | Federal requirements, explain below |
|  |  |
|  | Retention of identifiers is required by law |
|  |  |
| 4. If you intend to maintain identifiers, any subsequent secondary analysis of this data after protocol closure, requires prior IRB review and approval. Please acknowledge this requirement by checking below. |
|  | I understand subsequent data analysis requires prior IRB review and approval.  |
| d.iii. Describe why the research could not practicably be conducted without access to and use of PHI. |
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| d.iv. Describe why the research could not practicably be conducted without the waiver or alteration(*explain why it would not be practical/possible to obtain signed authorizations from the researcher subjects).* |
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| **9. Future Research** **Do you intend to bank any identifiable research data obtained from this protocol for future unspecified research?** *(must have authorization or meet authorization waiver criteria)* |
|  | No If no, skip to 10. |
|  | Yes | If yes, do you have an IRB approved research repository protocol?  |  |  |
|  |  | Yes |  | No |
| If yes, list the IRB number |  | AND amend the repository protocol to include this new source of information. |
| If no,you will need to submit a Biological Specimens/Repository protocol for review and approval. *This form can be found on the forms page of our website.* |

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| **10. AGREEMENT PRINCIPAL INVESTIGATOR** |
| **As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity, I will seek prior approval by UVM IRB. I understand subsequent data analysis requires prior IRB review and approval.  |
| x |  |  |  |
| Signature of PI |  | Date |
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| **FACULTY SPONSOR (if applicable and referenced on page one of this form)** |
|  |  |  |
| Advisor’s Name: |  | Telephone Number: |  |
|  |  |  |
| Department/Address: |  | E-mail: |  |
|  |  |  |
| Date of Human Subjects Tutorial Completion |  |  |
| ***Policy Statement from the Research Manual:*** *“As the responsible investigator, the faculty sponsor or course instructor is required to complete the Human Subjects in Research tutorial. Protocol approvals will not be released until that requirement has been met.” The training can be found at* [*http://www.uvm.edu/irb/tutorial/index.html*](http://www.uvm.edu/irb/tutorial/index.html) |
|  |
| **As the faculty sponsor for this protocol,** I certify that the student will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all University of Vermont and Federal Regulations relating to human research as outlined above and in the Human Subjects Research Manual. |
| x |  |  |
| Signature of Faculty Sponsor |  | Date |
|  |  |  |
| Printed Name |  |  |

All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information.