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

**Request for Waiver or Alteration of Informed Consent/Authorization/Documentation**

This form needs to be completed when you are requesting a waiver or alteration of consent procedures or HIPAA authorization, or the documentation required for either of these permissions.

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| **Protocol/Project Title** | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **Principal Investigator (PI):** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
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| **I. Waiver of Consent OR Alteration of Consent** | | | | | | | | | | | | | | | | | | | | |  | | | Not applicable | | | | | | |
| *A waiver of consent means that you will not be obtaining verbal nor written consent. An alteration of consent means you plan to alter the informed consent process or elements of informed consent (often times used in deception studies or when PIs cannot provide signature).* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is this request for a waiver of consent or an alteration of typical consent procedures? | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Waiver | | |  | | Alteration | | | | | | | | | | | | | | | |
| If an alteration, describe how it deviates from typical consent procedures. *(i.e., phone screening, deception)* | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2. Does this request apply to the entire subject population? | | | | | | | | | | | | | | | | | Yes | | | |  | | No | |  | |
| If no, describe the subpopulations for which the waiver or alteration is being requested. | | | | | | | | | | | | | | | | | | | | | | |
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| 3. Does the request meet the regulatory criteria? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| a. 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* | | | | | | | | | | | | | | | | | | |
| b. Explain why the research will not adversely affect the rights\* and welfare of subjects: | | | | | | | | | | | | | | | | | | | | | | | |
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| *\*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. 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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| d. Will information be provided to the subjects once the research is complete, when appropriate? | | | | | | | | | | | | | | | | | | | | | | | |
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| 4. Will you use protected health information received from the University of Vermont Medical Center (UVMMC)? | | | | | | | | | | | | | | | Yes | | |  | | | No | |  | |
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| If yes, complete Section II and IV. If no, check not applicable in Section II and proceed to Section III. (*If obtaining PHI from an outside institution, please check with the privacy officer of that institution for further guidance.)* | | | | | | | | | | | | | | | | | | | | | |

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| **II. Waiver of Authorization or Alteration** |  | Not applicable |

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| **1. Protected Health Information Requested**  *Please list all protected health information (PHI) that will be accessed under the waiver (for example, specific tests, medical history, diagnosis):* | |
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| **2. Data Collection Period(s)**  *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** |  |  |  |
| ***Note:*** *Often times, researchers may need to request additional date ranges. If a change to your requested dates is necessary, you must amend this form and submit to the IRB for approval.* | | | | | | |
| **Add additional periods below if you are amending** | | | |
| **Period\_2** |  |  |  |
| **Period\_3** |  |  |  |

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| **3. Access to the PHI**  *Describe who will have access to the PHI, and the individuals to whom it will be disclosed.* | |
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| **4. Identifiers**  *Check off below which identifiers will be included with the PHI. Any of these elements, under Privacy rule provisions, cannot be considered de-identified. 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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| **5. 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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| **6. Identification**  *Describe how the research team will record the data. If links to identifiers are used, please describe the coding mechanism. (i.e. separate master list that contains the code that links the data to the identity of the person)* | |
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| **7. Protection of Identifiers**  *Describe the steps taken to assure privacy and confidentiality of subject data and to protect the identifiers/links to identifiers from improper use or disclosure.* | |
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| **8. 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.* | | | | | | | |
| Will the identifiers be destroyed? | | |  | Yes, go to 8.a. |  | No, go to 8.c. |
| 8.a. Identifiers will be destroyed upon completion of | | | | | | |
|  | Data collection | | | | |
|  | Data analysis | | | | |
|  | Specimen processing | | | | |
|  | Other, explain below | | | | |
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| 8.b. Describe the plan to destroy the identifiers below. | | | | | | |
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| 8.c. If identifiers will be retained indefinitely, check why and justify where indicated: | | | | | | |
|  | Health or research justification, explain below | | | | |
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|  | Federal requirements, explain below | | | | |
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|  | Retention of identifiers is required by law | | | | |
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| 8.d. 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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| **9. Describe why the research could not practicably be conducted without access to and use of PHI.** | |
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| **10. Describe why the research could not practicably be conducted without the waiver (explain why it would not be practical/possible to obtain signed authorizations from the researcher subjects).** | |
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| **III. Waiver of Documentation of Consent** | | | | | | | |  | Not applicable |
| *This request means you are obtaining verbal or implied consent without obtaining the subject’s signature on a consent form.* Check the applicable regulatory criterion below **and then describe the process for obtaining verbal or implied consent:** | | | | | | | |
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|  | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. | | | | | |
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|  | OR | | | | | |
|  | The only record linking the subject and the research would be the consent document and the | | | | | |
|  | principal risk would be potential harm resulting from a breach of confidentiality. | | | | | |
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| **Describe process:** | | | | | | |
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|  | *(If a written summary of the research will be given to participating subjects, it must be reviewed and approved by the IRB.)* | | | | | |
| **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 protocol, 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. | | | | | | | | |
| x | | | |  |  |  | | |
| Original Signature of PI | | | |  | Date | | | |
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