### The University of Vermont Committees on Human Research

### Protocol Exemption Review and Determination

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.

|  |  |
| --- | --- |
| **1. Protocol Title** |  |
|  |
| **Principal Investigator (PI):** |  | **Degree:** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |
| --- |
| **Checklist to Determine Whether Submission Meets Exemption Criteria** |
|  |
| **A. Does the project involve intervention or interaction with prisoners?**  |  | Yes |  | No |
| If yes, stop. You must apply for either an expedited or full committee review. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **B. Do you plan to use deception in the project?** |  | Yes |  | No |
| If yes, this project may require expedited or full committee review. Contact the office for guidance. |
| **C. Does the project involve intervention or interaction with any of the following vulnerable**  |
| **populations?**   |  | Yes |  | No |  |
|  | Cognitively Impaired |  | Mentally Ill |  |  | Pregnant Women |
|  | Wards of the State |  | Non-English Speaking  | Fetuses |
| If yes, stop as regulations require that IRBs give special consideration for particularly vulnerable participants. Contact the office for guidance.  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **D. Will your research involve children under age 18?** |  | Yes |  | No, continue to E. |
| If yes, indicate below all the criteria under which exempt research is allowable with children.  |
|  the research involves normal educational practices, or  the project involves use of educational tests, or observation of public behavior when the investigator(s) do not participate in the activities being observed, or  collection or study of existing data or specimens, when the data are recorded in such as manner that subjects cannot be identified, or collection or study of existing data or specimens, when the data are identifiable and the project is not federally funded.(Non-Federal Exemption #7) |
| Please explain why you feel that the inclusion of minors meets the criteria you have chosen.  |
|  |
| If none of these situations apply, stop. You must apply for either an expedited or full committee review. |
| **E. Will the project utilize educational tests, survey procedures, interview procedures, observations of public behavior?** |
|  | Yes, continue. |  | No, continue with F. |  |

|  |
| --- |
| Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND**Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation, or deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug abuse, sexual behavior or the use of alcohol. |
|  | Yes |  | No, continue with F. |
| If yes,stop.You must apply for either an expedited or full committee review. |
| **F. Will the project use existing or archived data, documents, records, or specimens (in existence at the time of this protocol submission) that are collected in such a manner where subjects cannot be identified?**  |
|  | Yes, continue to 2. |  | No, continue to G. |  |
| **G. Will the project use existing or archived data, documents, records, (in existence at the time of this protocol submission) that are collected in such a manner that subjects can be identified?**  |
|  | Yes |  |  | No |
| If yes, is this project federally funded?  |  | Yes  |  | No, continue |
| If yes, stop. You must apply for either an expedited or full committee review. |
|  |
| **H. Do you need to keep identifiable data that includes Protected Health Information (PHI) from UVM Medical Center?** |
|  | Yes |  | No |
| If yes, stop. Data that includes any of the 18 HIPAA identifiers (see addendum A) must be reviewed by either expedited or full committee review.  |
| If no, continue. |

 |

|  |  |
| --- | --- |
| **2.** | **Principal Investigator Information** |
|  |  |  |  |  |
|  | Dept. |  | Contact Phone: |  | E-Mail: |  |
|  | Campus/Office Address: |  |
|  | PI’s Dept. Chair(s) |  |
|  | Date of Human Subjects Tutorial Completion |  |  |
|  | Is PI UVM Employee? | Yes |  | No |  |  Is PI UVM Medical Center Employee? | Yes |  | No |  |
|  | Is PI a Fellow, Resident, or Student? | Yes |  | No |  |  |
|  | Please check graduate status if applicable: |  |  | Graduate |  | Undergraduate |
| **Faculty Advisor/Sponsor** (if fellow, resident, or student research) |
|  |  |  |
| Name: |  | Title: | Phone: |  |
| Dept/Address: |  | E-mail: |  |
| Date of Human Subjects Tutorial Completion |  |  |
|  | ***\*NOTE:*** *Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If you are not affiliated with either UVM nor UVM Medical Center, you must stop here and contact the RPO office for additional guidance.* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **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 |  |

|  |  |
| --- | --- |
| **3.** | Other Key Personnel |
|  |  |  |
| **🡺** | Definition: All individuals who will have contact with subjects or with research data locally.Key personnel are encouraged to take our human subjects in research training. Any persons who are accessing any medical records for research are required to complete required [credentialing](https://www.uvm.edu/medicine/clinicaltrials/?Page=uvmresearchcredentialing.html) through UVMMC or Office of Clinical Trials Research. |
| 1 |  | **3** |  |
| 2 |  | 4 |  |

|  |  |
| --- | --- |
|  **4.** | **Brief Lay Language Summary** *(Use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) objectives or aims, and (2) a brief but specific description of the procedure(s) involving the human subjects. Do not exceed one single-spaced 8 ½ X 11” page.* |
|  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **5.** **Does the research involve the study of cancer or is it cancer-related?** | Yes |  | No |  |  |
| **If yes,** this research is also subject to a separate review by the University of Vermont Cancer Center. Click here, [Protocol Review and Monitoring Committee (PRC)](http://www.vermontcancer.org/getpage.php?pid=101) ,for the requirements.  |
| **6.** | **Source of Support** |
|  |  |
|  | **a. Do you have any source of support for this project?**  |
|  |  | No, this is a research requirement with no monetary or other support.  |
|  |  | Yes, check below all that apply. |
|  |  | **Internal (Dept, Honors College, Pilot funds)**  | Specify |  |
|  |  | **Project processed through Sponsored Project Administration (SPA)**  |
|  |  | *(e.g. NIH, DOD, cooperative groups, other state or local ,private foundations, etc.)* |
|  |  | Name of Funding Agency |  |
|  |  | InfoEd Proposal # |  |

|  |  |
| --- | --- |
| **7.** | Participant Information |
| a. How many participants are anticipated to enroll locally? |  |
| Note: This requested number should equal the number of individuals, medical records, or specimens necessary. |
|  b. Identify the targeted classes of subjects (check all that apply) |
|  | Male or |  | Female |
|  | Adults, provide age range |  |  or |  | Minors, provide age range |  |
|  | Healthy or |  | Persons with a specific disorder list disorder |  |
|  |
| c. Will participants be compensated? | Yes |  | No |  |
| If yes, explain which participants in your pool will be compensated and the payment method. (e.g. cash, gift cards) |
|  |
| Provide monetary value of compensation and specify funding source. *Note: Principal investigators are not allowed to use their own personal funds to compensate participants.* |
|  |

|  |  |
| --- | --- |
| **8.** | **Recruitment** |
| a.  | Summarize process of recruiting potential subjects. Specify inclusion and exclusion criteria when relevant. *If you are recruiting anyone who is subordinate to you (students or employees), additional protections may be necessary. Please contact the office.* |
|  |  |
|  | \*Attach any recruitment announcements such as flyers, or other advertisements. |
| b.  | Provide the specific name of the schools, country, clinic, or other agency from which subjects will be recruited and/or where research procedures will be conducted.  |
|  |  |
|  | \*Provide letter(s) of support or permission letter(s) from the other agency(ies).  |

|  |  |
| --- | --- |
|  **9.** | Exemption Categories and Procedures |
|  | a. Check the Federal Exemption Category or the Non Federal Exemption Category that you are applying for and complete the related questions.*NOTE: Cancer-related studies, although exempt from IRB review, MAY not be exempt from Vermont Cancer Center Protocol Review and Monitoring Committee review. Please refer to their* [*website*](http://www.vermontcancer.org/) *for further information on submission criteria.* |
|  | **Exemption 1, 2, & 3 - Interviews, Surveys, Audiotaping, Observation**  |
| **Exemption #1: Normal Educational Practices and Settings** Research conducted in established, or commonly accepted educational settings, involving normal educational practices, such as 1. research on regular and special education instructional strategies, or

research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.**Exemption #2: Educational Tests, Surveys, Interviews, or Observations**Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior, unless: 1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
2. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects’ financial standing, employability, or reputation, or deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug abuse, sexual behavior or the use of alcohol.

**\*Note: This exemption does not apply to research involving minors except for research involving educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed. All other research projects with minors require either expedited or full committee review.****Exemption #3: Identifiable Subjects in Special Circumstances**Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under exemption #2, if: 1. the human subjects are elected or appointed public officials or candidates for public office; or

Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |
| **If exemptions 1, 2 or 3 complete questions below.**  |
| i. Describe all procedures which will be completed during this study |  |
| ii. Time estimation for subjects to complete procedures |  |
| iii. Frequency of procedures |  |
| iv. Describe potential risks (e.g. accidental breach of confidentiality) and efforts to reduce any risks or discomforts |  |
| v. Will photos, audio recordings, images be made during the study? Explain |  |
| vi. Describe procedures to secure all research data. How long will it be maintained? |  |
| vii. Describe plan for follow-up if necessary |  |
|  | \*Attach a copy of questionnaires, rating scales, or other instruments to be used. |

|  |  |
| --- | --- |
|  | Exemption #4: Use of Existing Data (unidentifiable) |
| Research involving the collection or study of ***existing*** data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects. All data or specimens have to exist at the time you request this exemption. **Note: This may not constitute “human subjects research” if the investigators/collaborators will not have access to the identities of the subjects. See guidance on Research Involving Coded Private Information or Biological Specimens.** |
|  |
| If using existing data, is the data publicly available?  |
|  | No |  | Yes | If yes, skip to question 10. |  |  |
| **Note:** If you require any PHI to identify the records or if you have access to the identifiers while you are recording the unidentifiable information you require for the research, you must complete the following questions and complete Addendum A. Certification of De-Identification. |
|  |  |
| i. Identify the specific time period that the data/specimens were collected (be specific e.g. 1/1/2013 – 12/31/14). The End date cannot extend beyond the date of this exemption request. |  |
| ii. Describe in detail the existing data/specimens to be collected for this research aim. Please note that temporarily recording a name or other identifier(s) that allow individual subjects to be identified will exclude this type of activity from meeting the Exemption #4 criteria. |  |
| iii. Describe the source of the data/specimens. |  |
| iv. Under what authority do you now have access to the data/specimens (explain if there was prior consent to the use of the data/specimen for research) |  |
| v. Describe potential risk and efforts to reduce risk  |  |
| vi. Describe how the research data will be recorded by the investigator(s) in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects. (not coded in any way) |
|  |

|  |  |
| --- | --- |
|  | **Exemption #5: Public Benefit or Service Programs** |
|  | Research and demonstration projects which are conducted by or subject to the approval of the [Federal] Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: 1. Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs; 1. possible changes in or alternatives to those programs or procedures; or
2. possible changes in methods or levels of payment for benefits or services under those programs.
 |

|  |  |
| --- | --- |
|  | **Exemption #6: Taste and Food Evaluation and Acceptance Studies** |
|  | Taste and food quality evaluation and consumer acceptance studies, 1. if wholesome foods without additives are consumed or
2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food and Safety and Inspection Service of the U.S. Department of Agriculture.
 |

|  |  |
| --- | --- |
|  | Non-Federal Exemption #7 - Research involving collection or study of existing  |
|  | data, documents, records, when this information is personally identifiable or coded. |
| **Note:** Do you have federal funding for this project? |  | Yes |  | No |
| If yes, **stop**. You must apply for either an expedited or full committee review, otherwise continue. |
| **Note:** Will there be any PHI associated with the data? |  | Yes |  | No |
| If yes, **stop**, this form does not apply. You must submit for either any expedited or full committee review. If no, continue. |
| i. Identify the specific time period that the data were collected (be specific e.g. 1/1/2013 – 12/31/14) |  |
| ii. Describe in detail the existing data to be collected for this research aim. |  |
| iii. Describe the source of the data. |  |
| iv. Under what authority do you now have access to the data (explain if there was prior consent to the use of the data for research). |  |
| v. Describe potential risk and efforts to reduce risk. |  |
| vii. Describe how the research data will be recorded by the investigator(s) in such a manner that protects and ensures subjects’ confidentiality (i.e. master list with link to a code separate from the coded data).  |
|  |

|  |  |
| --- | --- |
| **10.** | Consent and HIPAA |
| a. Are you requesting a Waiver of Informed Consent? |  | Yes |  | No |
| *This request means that you will not be obtaining verbal, nor implied, nor written consent.* |
| If yes, does the project meet the following criteria necessary to allow for a waiver of consent? |
| -Involves no more than minimal risk -Will not adversely affect the rights and welfare of subjects.-Research cannot be conducted without the waiver of consent AND-Whenever appropriate the subjects will be provided information once the research is complete. |
| Yes |  | If yes, continue. |
| No |  | If no, a consent process is necessary. Proceed to 9.c. |
| b.Are you requesting a Waiver of HIPAA Authorization? |  |  Yes |  |  NA |
| *This only applies if you are 1) collecting Protected Health Information (PHI) from a Covered Entity (hospital or other healthcare entity) or 2) accessing PHI through a Covered Entity in order to collect or extract de-identified data, thus making the data protected under the HIPAA regulations. This request means that you will not be obtaining verbal, nor implied, nor written authorization.* |
| If yes, does the project meet all of the consent waiver criteria plus the following additional HIPAA criteria? |
| (a) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following criteria:(1) An adequate plan to protect the identifiers from improper use and disclosure;(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; (3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted under the HIPAA privacy rule.(b) The research could not practicably be conducted without the alteration or waiver; and;(c) The research could not practicably be conducted without access to and use of the protected health information. |
| Yes |  | If yes, continue to 11. |
| No |  | If no, a consent process is necessary. Continue to 10.c. |
| c. Are you requesting a Waiver of Documentation of Informed Consent? |  | Yes |  | No |
| *This request means you are obtaining verbal or implied consent without obtaining the subject’s signature on a consent form.*  |
| If yes, describe the consent process below:  |
|  |
| \*If an information sheet will be provided to the subjects, attach the sheet for review. |

|  |  |
| --- | --- |
| **11.** | LOCATION OF RESEARCH ACTIVITIES (complete all that apply) |
|  |  |  |
|  | UVM Medical Center | University Campus (specify locations below) |
|  |  | Main Hospital/ACC |  |
|  |  | Clinical Research Center |  | School/School System |
|  |  | 1 South Prospect (UHC) |  | Correctional Facility |
|  |  | Other UVM Medical Center Location(s)  |  |
|  | Specify location(s): |
|  | **Other Location** |
|  | Specify location(s): |

|  |
| --- |
| **12. Assurances** |
| **Principal Investigator****As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:I will seek prior approval of any changes to this exempt project which may change the original exemption.I will report any unanticipated problems. |
|  |  |  |  |
| Original Signature of PI |  | Date |
|  |  |  |
|  |  |  |
| **Faculty Advisor/Sponsor (if applicable)** |
| **As the faculty advisor/sponsor for this protocol,** I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound;The student has the necessary training, experience and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles; I will oversee and monitor the conduct of this research by communicating regularly with the student investigator; Assist with any resolution of any problems or concerns encountered during the research;The UVM IRB is notified in the event of an adverse event or protocol deviation.  |
| Is there is a thesis or dissertation committee reviewing this research? | Yes |  | No |  |  |
| If yes, date of approval:  |  |  |
|  |
|  |  |  |
| Original Signature of Faculty Sponsor |  | Date |
|  |  |  |
| Printed Name |  |  |

RPO Use Only

I have reviewed and approve of the requested process and compensation for this project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Member

Behavioral and Social Sciences

**If you are applying for Exempt 4 determination you must also complete Addendum A below, otherwise you may remove this sheet as well as Addendum A from your submission.**

**Addendum A**

**Certification of De-Identification When Applying for Exempt 4**

Research that involves the use of de-identified protected heath information (PHI) is exempt from HIPAA requirements. Methods by which data may be classified as de-identified are **1)** by certifying that none of the 18 HIPAA-defined identifiers are used, reviewed or recorded by the researchers or staff **2)** by certifying that as a member of our covered entity the individual using PHI to create a de-identified data set a) keeps all information seen in the process of creating the de-identified data strictly confidential, b) does not record any of the identifiers defined by HIPAA, and c) cannot link the data back to the individual in any way or **3)** by certifying through statistical analysis on each identifier that is contained within the data that the likelihood of an individual being identified by using the data in whole or in part is very small. Statistical de-identification must be done be a qualified statistician and the methods and results of the analysis must be documented.

**Check if any of these HIPAA-defined identifiers are necessary to conduct your research.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. Names |  | 10. Certificate/license numbers |
|  | 2. All geographic subdivisions smaller than a state\* |  | 11. Vehicle identifiers and serial numbers, including license plate numbers |
|  |  |
|  | 3. Telephone numbers |  | 12. Device identifiers and serial numbers |
|  | 4. Fax numbers |  | 13. Web Universal Resource Locators (URLs) |
|  |  |
|  | 5. Electronic mail addresses |  | 14. Internet Protocol (IP) address numbers |
|  | 6. Social Security numbers |  | 15. Biometric identifiers, including finger and voice prints |
|  |  |
|  | 7. Medical record numbers |  | 16. Full face photographic images and any comparable images |
|  |  |
|  | 8. Health plan beneficiary numbers |  | 17. All elements of dates (except year)\*\* |
|  | 9. Account numbers |  | 18. Any other unique identifying number, characteristic or code |
|  |  |

\*including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

\*\*for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

**Certify Use of Either Method 1, 2, or 3**

**Method 1 – No Identifiers Used, Reviewed or Recorded** (45 CFR 164.514(b)(2))

I certify that the PHI used, reviewed or recorded by research personnel for this research project does not include any of the 18 above HIPAA-defined identifiers as related to the individual, relatives, employers or household members of the individual.

|  |  |
| --- | --- |
| Signature of Principal Investigator  | Date |

**Method 2 – No Identifiers Recorded During the Creation of a De -identified Data Set** (45 CFR 164.502(d)(1))

I certify that the PHI recorded by research personnel to create a de-identified data set for this research project does not include any of the above 18 HIPAA-defined identifiers and that no link can be made back to the individual. Personnel reviewing records have agreed to keep any PHI seen during the course of records review as strictly confidential.

|  |  |
| --- | --- |
| Signature of Principal Investigator  | Date |
|  |
| List all others that will be conducting record review.  |
| Printed Names | Signature and Date |
|  |  |
|  |  |
|  |  |
|  |  |

**Method 3 – De -identification Via Statistical Analysis** (45 CFR 164.514(b)(1)(i and ii))

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable has performed such analysis on each of the identifiers (checked above) included in the data set. It has been determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the intended recipient to identify an individual who is the subject of the information.
2. **I have attached** documentation from the statistician that indicates 1) the date of the analysis, 2) the method(s) used, 3) the results obtained, 4) a statement that the likelihood of re-identification is very small, 5) the name of the statistician, 6) the credentials of the statistician 7) the signature of the statistician, and 8) the date signed

|  |  |
| --- | --- |
| Signature of Principal Investigator  | Date |

\* 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.