

# - INSTRUCTIONS -

## Protocol Exemption Review and Determination

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**Note:** All the necessary forms for submission are located in the forms section of our website and should be downloaded each time you need one. This will ensure that the most recent version is submitted. Outdated versions will not be accepted.

The data fields within the form automatically expand to allow additional text. Use the required fields for all comments –this may expand the form to additional pages - which is acceptable.

### Section 1: Protocol/Project Title:

The title should reflect the title on the research protocol.

### Section 2: Investigator Information:

**1. Principal Investigator:** The name of the local principal investigator.

**2. Degree:** The degree of the principal investigator (i.e., MD, PhD etc.).

Enter the following contact information for the PI.

**Dept:**

**Phone:**

**E-mail:**

**Campus/Office Address:** Location where the Committee should send correspondence. This could be the PI or the designee for the study.

**Fax #**

**Department Chair** List the chair at time of submission.

**Is PI UVM Faculty?** If the PI is a UVM faculty member, please check “Yes”. Many employees share appointments at both UVM and FAHC.

**Is PI FAHC Employee?** If the PI is a FAHC employee, please check “Yes”. Many employees share appointments at both UVM and FAHC.

**Is PI UVM Employee only?** Check yes if applicable.

**Is PI UVM Fellow, Resident or Student?** Check “Yes” if applicable and complete section 15 once the rest of the form is complete. If the principal investigator is a student indicate whether Graduate or Undergraduate.

**\*NOTE:** Under normal circumstances only UVM or FAHC individuals can be PI. If you are not affiliated with either UVM nor FAHC, you must stop here and contact the RPO office for additional guidance.

**Do you want to appoint Primary Contact other than PI?**

Investigators wishing to appoint a contact for all IRB communications related to this protocol should check “Yes,” and complete the contact information in the sections provided. Often times the **research coordinator** is the person who handles most of the administrative responsibilities of a study, acts as a liaison between the principal investigator, the sponsor, if applicable, and the IRB. These responsibilities can be assigned to someone on the study team, an administrator, or the principal investigator but is more often a data manager, clinical research associate, or research nurse. Regardless of the primary contact, the PI is still ultimately responsible for all aspects of the research and IRB submissions.

### **Section 3: Other Key Personnel:**

Anyone who has contact with subjects or their identifiable data

**“Key Personnel” Must Include:**

PIs

Researchers in contact with subjects

Clinical research associates or coordinators (data managers and research nurses)

Anyone in contact with personally identifiable research information and

Anyone consenting subjects

**“Key Personnel” Might Include:**

Other clinicians in the clinic conducting the research or  
Other laboratory staff in the lab conducting the research

**“Key Personnel” Never Includes:**

Cooperative group or sponsor staff (unless they are directly contacting our locally enrolled subjects).

**Note:** Please do not include people who are only expected to provide cross-coverage unless there is a very high likelihood that they will actually see or contribute to the research data of at least one subject. If you have any questions as to whether or not someone should be listed as Key Personnel, please contact the IRB staff.

It is strongly recommended that Key Personnel must complete the UVM / FAHC Protections of Human Subjects in Research Tutorial before the protocol approval or re-approval.

The names of all persons fitting the above descriptions should be listed in alphabetical order, by last name, if possible. Use an additional sheet if there are more than 12 key personnel.

**Faculty Sponsor:** Fellows, residents, post-doctoral fellows, post-doctoral associates, post-doctoral trainees, and students (graduate or undergraduate) cannot conduct human subject research without having a faculty sponsor/instructor who is responsible for overseeing the research activities.

**Section 4: Source of Support:**

Indicate all applicable sources of support by checking the appropriate box(es). If you have any questions about what source of support should be checked contact our office.

**Section 5: Category of Exemption:**

In this section we determine if the project meets the criteria for exemption.

**A. Provide justification below for the exemption category(ies) chosen above.**

**NOTE:** Cancer-related studies, although exempt from IRB review, MAY not be exempt from Vermont Cancer Center Protocol Review Committee review. Please refer to their website for further information on submission criteria.

**Check one or more of the categories listed below if you feel the research is exempt from IRB review.** This section is self-explanatory, however if you have questions contact our office.

## **Section 6: Subject Information:**

Recording an accurate list of the subject populations targeted for the research allows the Committees to ensure all applicable federal regulations are met. All of the following information should be provided in the protocol.

**A. Subject Information:** Enter the total number of subjects that are expected to enroll in the research study locally. This should be an estimate of the total accrual over the lifespan of the research. It should include an estimate that accounts for subjects who decline after consent or are screen failures as these subjects are considered “enrolled”. This information should be reflected somewhere in the protocol (usually the section for statistical analysis).

**B. Type of Subjects (check all that apply)** The following elements should be included in the inclusion/exclusion section of the protocol.

- **Male**
- **Female**
- **Students or Employees**
- **Normal Volunteers:** If the research expects to include subjects without a specific disease or condition, check this box. (Check this box for research that is only enrolling normal volunteers and for research that will include normal volunteers in the control group.)
- **Other potentially vulnerable subjects:** Describe any other potentially vulnerable subjects not checked or listed above.
- **Persons with specific disorder:** In the protocol, if specific disorders are included in the eligibility section, please check this box and summarize the disease or condition. If there is a normal control group, check Normal Volunteers as well.
  
- **Adults:** Are 18 years old or older, specify ages

- **Minors (17 years or less):** Are 17 years old or younger, specify ages
- **\*Wards of the State**
- **\*Non-English Speaking**
- **\*Cognitively Impaired or Mentally Ill**
- **\*Pregnant Women**
- **\*Fetuses**
- **\*Prisoners**

**\*Note subjects with an asterisk can't be included in exempt research. You must submit a full protocol for review. Contact the office if you have any questions.**

- C. Will Subjects be compensated?** If there is any compensation (compensation may be in the form of money or in other forms such as health care benefits, course points or course credit, travel expenses, bonuses, etc.) check "Yes".  
**If "Yes" Amount:** Enter the dollar amount given to subjects, if any.  
**Other types of compensation:** If there is any other compensation such as health care benefits, course points or course credit, travel expenses, bonuses, etc., please provide details in the box provided.

## **Section 7: Protocol Information:**

In order to facilitate the rapid review of exempt research, this form requires that the proposed research be summarized in addition to the attached research proposal. All of the following information must be provided about the proposed research.

**A. Study will begin:** Enter the proposed start date of the research locally.

**Study will end:** Enter the projected end date of the research.

**B. Describe the purpose of the study/project.** Detail the objective or hypothesis of the research.

**C. Describe the study / project procedures.**

**Surveys** – Use of written, electronic, or verbally administered surveys.

**Observation** – Participant or group observation without interaction.

**Interview** – Oral interview. Open-ended or closed (fixed-response), informal (conversational), or formal (standardized).

**Use of Existing Data (collected prior to this submission)**

– Data about human subjects that has already been collected for other purposes.

**Tests** – Educational, Psychological, Physiological, etc.

**Use of Existing Tissue Specimens (collected prior to this submission)** – Tissue samples (including blood and any human pathology specimens) that have already been collected for other purposes.

**Other** – List any procedures which do not fall in the above categories.

**D. If you will be analyzing existing data (must be existing at the time of protocol submission), identify the source of the data, describe the content of the data, clarify whether the data are publicly available, and whether the data will be recorded in an unidentifiable manner (not coded in any way). If you are not analyzing existing data, please check “Not Applicable.”**

**E. If the project involves review of medical records or charts, describe the types of records that will be accessed (departmental data base or records, MAPLE, HIM, etc.), how many records/charts will be accessed, whether you normally have clinical access to such records, how potential records will be identified, who will review the records, and what information will be recorded. NOTE: If you are recording information from medical records or charts with any type of identifiers or codes which could link back to the subjects’ identity, the project cannot be exempted under the federal regulations. Submit a protocol utilizing expedited review guidelines. 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 you are not reviewing medical charts, please check “Not Applicable.”**

**F. If your project involves the study of existing (must be existing at time of protocol submission) human tissue (e.g. pathological or diagnostic specimens): Describe the source of the tissue, what information is linked with the samples, and, if known, whether consent was obtained to use the tissue for research purposes. 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 you**

are not studying existing human tissues, please check “Not Applicable.”

**G. Are you utilizing a questionnaire, survey, or interview procedure?** If yes, describe the procedure below, including whether consent with or without documentation will be obtained and attach copies of the instruments.

**H. Describe the target population, how subjects will be identified, how subjects will be recruited, number of participants to be enrolled, and how participants’ confidentiality will be protected.** This is the eligibility, recruitment, and confidentiality section of the research protocol.

**I. Are you obtaining consent? Yes or No**

**I.1.a. If yes, check the appropriate box.**

If Consent Form is checked you must confirm that the required basic elements of informed consent are included in the consent document. We do not review the consent content, however, the subjects must be afforded the same protections as if participating in non-exempt research. Confirm that all of the following are included in your consent document.

- (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) a description of any reasonably foreseeable risks or discomforts to the subject;
- (3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

If Verbal or Implied Consent is checked the following applies:

Research has to meet one of the following for waiver of documentation (i.e. a signed consent).

- 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

**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.

**b. Describe the consent process.** (If unclear about what should be here, reference our consent module for clarification.) If a written summary will be provided to those subjects who are not signing a consent form, attach the summary.

**I.2. If no, does the project meet the criteria necessary to allow for a waiver of consent?** (See waiver of consent section 8.B.4 of the Research Manual.) If **no**, a consent process is necessary. Return to above question.

**J. Describe any risks to human subjects associated with participation in this project (e.g. breach of confidentiality) and how these risks will be minimized.** If there are no risks involved in the research, state “No risk involved.”

## **Section 8: Data Security:**

Research data, with or without PHI, should be kept secure. Record the ways in which the research data will be maintained and stored.

**For Hardcopy Data:** All paper and physically stored materials including research charts, films, x-rays, pictures, drug logs, computer disks and CDs, slides, and other specimens. List the security methods used for the research project’s hardcopy data:

**Locked Suite:** The suite is generally inaccessible to the public and locked whenever the data is unattended.

**Locked Office:** The office is generally inaccessible to the public and locked whenever the data is unattended.

**Locked File Cabinet:** The cabinet is generally inaccessible to the public and locked whenever the data is unattended.

**Data Coded by PI or Research Team with a master list secured and kept separately:** For security issues, the

hardcopy data is de-identified and requires a master list to identify the subjects. The master list is kept separately and accessible only to key personnel listed in section 3 of the Common Protocol Cover Form.

**Deidentified:** No link to subject identity

**Other:** Describe any other security protections for hard copy research data.

**For Electronic Data:** All electronically stored materials (especially databases). Note that computer disks and CDs containing research data are considered hardcopy data. List the electronic data security methods used for the research project's electronic data, if applicable:

**Secure Network:** The data is on a secured database that requires a user ID and password. Provide the network or server name where the data resides.

**Password Access:** The data is contained in a program or electronic folder that has password protection.

**Other:** Describe other security protections for the electronic research data.

## **Section 9: Location of Research Activities:**

Please check the following locations where research is expected to take place.

**FAHC / UHC Campus:** University Health Center, 1 South Prospect St.

**Gen. Clinical Research Center:**

**FAHC / MCHV Campus:** 111 Colchester Avenue. Specify department within FAHC.

**FAHC Outpatient Facilities:** Such as Timberlane, or Fanny Allen. Specify offsite location.

**UVM Campus:** University of Vermont, non-FAHC setting. Specify location.

**Other Locations:** All locations not captured above. Specify location.

## **Section 10: Faculty Sponsor:**

**Faculty Sponsor:** If this is a student's, resident's or fellow's research project, the project must have a Faculty Sponsor. The Faculty Advisor

must review the proposal, sign off on the form, and understand that they are responsible for the overall conduct of the research project. Please list the name, phone number, address, and email of the Faculty Sponsor. The faculty sponsor must sign and date this form in the lines provided.

**Thesis or Dissertation Committee:** In addition, please list the date of the committee review (if applicable). [All research which requires a Thesis or Dissertation Committee review must be reviewed and approved by that committee **before** it may be sent to the IRB for review and approval.]

### **Section 11: Investigator's Agreement:**

By signing this agreement, the PI is agreeing to a list of PI Responsibilities that reflect the Common Rule regulations.

### **Section 12: Attachments to this Exempt Study Protocol Cover Form**

This section provides a way for you to track which documents were submitted along with the initial paperwork. This is an optional section.