

# - INSTRUCTIONS -

## Research Not Involving Human Subjects Review and Determination

Section 1: Protocol/Project Title: .....	1
Section 2: Investigator Information: .....	1
Section 3: Source of Support: .....	2
Section 4: Brief Lay Language Summary: .....	2
Section 5: Determination Questions: .....	2
Section 6: Faculty Sponsor: .....	4
Section 7: Investigator's Signature: .....	5

---

**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 Outdated versions will not be accepted.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: 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 4: Brief Lay Language Summary:**

Summarize the proposed research project. 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). Do not exceed one single-spaced 8 ½ X 11” page.

### **Section 5: Determination Questions:**

In this section we determine if the project meets the criteria for research "not involving human subjects."

**A. Does the activity involve research?** This section is self-explanatory, however if you have questions contact our office.

**If yes**, continue to next question.

**If no**, then the project does not require review by the IRB.

**B. Are you obtaining data about living individuals through intervention or interaction with those individuals?**

**If yes**, the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

**If no**, continue to next question.

**C. Does this research involve only obtaining information from the individual about non-human issues, such as community water quality, local infrastructure, business practices, etc.?**

**If yes**, stop and skip to #5. This type of research does not meet the definition of human subjects and therefore doesn't require ongoing review. Sign and submit this form to the Committee. You will receive a formal notification that it meets the criteria from the IRB.

**If no**, continue.

**D. Does this research activity involve only the use of ANONYMOUS (i.e., no identifiers or code) information or biological specimens?**

**If yes**, stop and skip to #5. This type of research does not meet the definition of human subjects and therefore doesn't require ongoing review. Sign and submit this form to the Committee. You will receive a formal notification that it meets the criteria from the IRB.

**E. Does this research activity involve only the use of coded private information or biological specimens?**

**If yes**, continue to the next question.

**If no**, the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

**F. Are the data or specimens being collected at UVM/FAHC specifically for this research?**

**If yes**, the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

In some cases, there are data or specimens being collected elsewhere and shipped here. You would answer this no as this does not constitute human subjects locally.

**If no**, continue to the next question.

**G. Are the data or specimens individually identifiable to you as the investigator or research team?**

**If yes**, the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

**If no**, continue to next question.

**H. Will the key to the individual's identity be available to you as the investigator or research team?**

**If yes**, the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

**If no**, check below how the individual's identity will be protected.

- The key to decipher the code is destroyed before the research begins;
- The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
  
- There are IRB-approved written policies and operating procedures for a repository or data with the management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

If none of these apply, then the research involves human subjects and either falls into the exempt or expeditable review categories. Refer to the research manual for guidance about which review may be necessary and the appropriate submission materials.

## **Section 6: 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 7: Investigator's Signature:**

By signing this agreement, the PI is confirming that the information provided for the determination of "research not involving human subjects" is accurate.