**Exempt 4 Determination**

**Secondary Research**

**Secondary research for which consent is not required: Secondary research uses of identifiable private**

**information or identifiable bio-specimens that are publicly available.**

**Secondary research with biospecimens without direct identifiers may meet the criteria of Not Human Research. Please refer to the IRB policies and procedures manual, Section 3.5:** [**https://www.uvm.edu/rpo/irb-policies-and-procedures#Not\_Human**](https://www.uvm.edu/rpo/irb-policies-and-procedures#Not_Human)

The Exempt 4 category covers the re-using of identifiable data that are collected for some other “primary” or “initial” activity. Research covered by this exemption would generally be found in medical or research records or a registry. It does not cover any primary collections of data or specimens.

**Restrictions on Exemption 4**

* Studies that are greater than minimal risk do not qualify for this exemption.
* Exemptions do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. [45 CFR 46.104(b)(2)].
* Biospecimens with direct identifiers (PHI) from the UVM Health Network do not qualify for this exemption. Please complete the [Human Subject Protocol Form](https://www.uvm.edu/sites/default/files/Research-Protections-Office/Human_Subjects_Protocol_Form_9.28.202210.docx).

**Protocol/Project Title** Click or tap here to enter text.

**Principal Investigator Name** Click or tap here to enter text.

**Faculty Sponsor Name (if applicable)** Click or tap here to enter text.

What type of data or tissue specimens are you collecting? Check all that apply.

[ ]  Private Information with direct identifiers (4iv)

[ ]  Private Information without direct identifiers (4ii)

[ ]  Protected Health Information with direct identifiers (4iii)

[ ]  Protected Health Information without direct identifiers (4ii)

[ ]  Biospecimens with direct identifiers that are publicly available (4i)

[ ]  Biospecimens without direct identifiers (4ii)

Who is providing the data or biospecimens to you?

[ ]  PI will be reviewing the UVMMC EPIC record and extracting PHI

[ ]  UVMMC Data Management Office will provide the PHI

[ ]  Non UVMMC Hospital data registries or tissue repositories

[ ]  UVMMC approved research data registries or tissue repositories. Please include the IRB ap proved CHRMS Study# below.

Click or tap here to enter text.

Is the data coming from a covered entity?

UVMMC and other hospitals in the Health Network are considered covered entities. Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

Click or tap here to enter text.

How will the data or biospecimens be provided to you?

Click or tap here to enter text.

If obtaining deidentifed specimens, where will they be stored?

Click or tap here to enter text.

1. State the purpose of this secondary data use, including the primary and secondary objectives.

Click or tap here to enter text.

1. Describe the data or biospecimens you wish to obtain for this project.

Click or tap here to enter text.

1. Describe inclusion and exclusion criteria for the information or biospecimens.

Click or tap here to enter text.

Check which one of the following Exempt 4 criteria applies to this research project: (key words are bolded to help you)

[ ]  4 (i) The identifiable private information or identifiable bio specimens are **publicly available**;

(Publicly available refers to data and/or specimens that are accessible to anyone in the general public, without the need for special permissions or privileges.  In these cases, the subjects do not have a reasonable expectation of privacy of their data/specimens. Examples include data/specimens available for purchase, searchable online, or available at a library.  Researchers may be subject to an agreement with the entity releasing data/specimens.)

[ ]  4 (ii) Information, which may include information about bio specimens, **is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects**, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

**(Readily identifiable** does not mean potentially identifiable or identifiable with substantial effort.)

[ ]  4 (iii) The research involves only information collection and analysis involving the investigator's **use of identifiable health information** when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b).

**4iii only applies to the use of protected health information (PHI).** Direct access to identifiable medical records (PHI) by the researcher/team requires submission of a request for Waiver of HIPAA Authorization. The justifications used in the Waiver of Authorization request must address all subject populations, dates of data requested (both retrospective and prospective), and variables that are to be collected.

[ ]  4 (iv) The research is **conducted by, or on behalf of, a Federal department or agency** using government-generated or government-collected information obtained for nonresearched activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(Pertains to research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected data obtained for non-research activities.  The study team must demonstrate compliance with the policies detailed in the regulation, specified above**.**)

***NOTE****: If you are applying for exempt 4 (iii)*

1. *Click Yes to question #3* to *request a waiver of HIPAA Authorization on the UVMClick Consent/HIPAA Information page,*
2. *the Research Data Management and Security Plan form is required to be attached to the Click record under Local Documents*

*If you are requesting a large research data set from EPIC, the Data Management Office (DMO)**within the UVM Health Network is a shared service to assist with your data and analytic needs. Both the DMO website and ServiceNow Portal are**found on your hospital intranet and provide easy access to the Data and/or Reporting**form, which are used for submitting and monitoring the status of your data request. Please submit to the DMO prior to submitting to the IRB. Questions can be emailed to:* ***AskDMO@UVMHealth.org***

Glossary of Data Terms

**Coded Data Set** - Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists that would enable linkage of the identifying information to the data or biospecimens.

***Coded data sets are not considered “de-identified” when the “code” is the study subject number.***

**Direct Identifiers** - An identifier that links to one specific person, can be used by itself to identify the person (e.g., name, social security number, medical record number, medical device number, email address).

**Indirect Identifers** - An identifier that does not link to one specific person but can be used in combination with other information to identify a person (e.g., dates including dates of birth, dates of death, zip codes, cities, counties).

**Private Information** - Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual, and that individual can reasonably expect will not be made public, such as a medical record.

**Protected Health Information (PHI)** - Individually identifiable health information, regardless of format, that is collected by a Covered Entity and relates to the past, present, or future physical or mental condition of a patient, the provision of healthcare or past, present, or future payment for the provision of healthcare. Protected health information can include demographic information (such as names, email addresses, telephone numbers) as well as information relevant to a person’s health such as dates of disease onset, testing, treatment, a particularly rare health condition, rash, birthmark, or any other information that could be used to identify the patient (or members of the patient’s family, employer and others who live in the patient’s household. Protected health information excludes individually identifiable health information in (i) Education records covered by the Family Educational Rights and Privacy Act (FERPA); (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and Employment records held by a covered entity in its role as employer; however, those records are covered by other privacy laws and requirements. Additionally, data generated by a Part 2 entity (federally assisted entities that hold themselves out as providing and do provide substance use disorder treatment) are protected by heightened privacy rules set forth in separate regulations. The University of Vermont Health Network has two Part 2 programs—UVMMC’s Addiction Treatment Program and UVMMC’S DayOne Program.