**University of Vermont**

**Exemption Category 4 - Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens**

Sec.\_\_.104(d)(4) Secondary research for which consent is not required. The initial determination for exemption 4 requires an expedited (limited) review by an IRB member.

**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.

1. **Is the research target population prisoners?**

[ ] Yes – [This project does not qualify for Exemption 4.]

[ ] No – (continue to 2)

1. **Does the research involve ONLY SECONDARY use of identifiable information/bio specimens?**

If one of the following criteria is met you are conducting secondary use.

(i) The identifiable private information or identifiable bio specimens are publicly available;

(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;

(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); or

(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.

[ ] Yes, the research involves ONLY SECONDARY use of identifiable information/bio specimens (continue to 3)

[ ] No [The project does not qualify for Exemption 4.]

**3. Indicate the source/custodian of the data (check all that apply)**

[ ] University of Vermont Medical Center

 [ ]  UVMHN Data Management Office

 [ ]  I will be reviewing individual medical records

*(Submit simultaneously to both the UVMHN DMO and the IRB if you are not a UVM Medical Center Employee nor on the Medical Staff.)*

 [ ]  Clinical Database IdentifyClick or tap here to enter text.

 [ ]  Research Database List CHRMS#:Click or tap here to enter text.

[ ] University of Vermont

[ ] Eleanor M. Luse Center for Communication

[ ] Unaffiliated (private practice) list below name of practice(s)Click or tap here to enter text.

[ ] Publically available, list Click or tap here to enter text.

[ ] Other source, list Click or tap here to enter text.

**3.1. Documentation of permission from the source/custodian must be obtained. Acceptable documentation can range from an approval from the UVMHN Data Management Office to an email from the person responsible for oversight of UVM records or other source**

**4. Provide the purpose of this secondary data use, including the primary and secondary objectives.**

Click or tap here to enter text.

**5. Describe the data elements that you will be collecting.**

Click or tap here to enter text.

**6. Indicate how many records you intend to review (this should correspond to your response to Question 14 on the Study Scope page in Click).** Click or tap here to enter text.

**7. Describe how you will select records.**

Click or tap here to enter text.

**8. Is the data being collected prospectively and/or retrospectively.**

[ ] **Prospective (data that are not currently available)**

[ ] **Retrospective (data that exist at the time of this application)**

**9. Provide the start and stop dates [mm/dd/yyyy] for the data collection period of interest.**

**Note:** Often times, researchers may need to request additional date ranges. If a change to your requested dates is necessary, you must submit an amendment, update this form, and submit to the IRB for approval.

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** | Click or tap here to enter text. |  | Click or tap here to enter text. |
| **Period\_2** | Click or tap here to enter text. |  | Click or tap here to enter text. |
| **Period\_3** | Click or tap here to enter text. |  | Click or tap here to enter text. |

**10. Check which HIPAA identifiers that will be required.**

Any of these elements, under Privacy rule provisions, cannot be considered de-identified. A waiver of authorization must be granted by the IRB.

 1.[ ]  Names.

2.[ ]  All geographic subdivisions smaller than a state, 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:

The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people, and the initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.

3. [ ] All elements of dates (except year) 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. The population of a zip code can be identified on the web site of the U.S. Census Bureau at the following url: http://www.census.gov/popfinder/

4. [ ] Telephone numbers.

5. [ ] Facsimile numbers.

6. [ ] Electronic mail addresses.

7. [ ] Social security numbers.

8. [ ] Medical record numbers.

9. [ ] Health insurance plan beneficiary numbers.

10. [ ] Account numbers.

11. [ ] Certificate/license numbers.

12. [ ] Vehicle identifiers and serial numbers, including license plate numbers.

13. [ ]  Device identifiers and serial numbers.

14. [ ] Web universal resource locators (URLs).

15. [ ] Internet protocol (IP) address numbers.

16. [ ] Biometric identifiers, including fingerprints and voiceprints.

17. [ ]  Full-face photographic images and any comparable images.

18. [ ] Any other unique identifying number, characteristic, or code, unless permitted by the individual

**NOTE**: Request for waiver of Consent and a waiver of HIPAA Authorization are to be completed in the UVM Click SmartForm

UVM Consent/HIPAA Information

Question #2: For waiver of consent, check “yes” and page will open to complete request for Waiver of Consent.

Question #3: For waiver of authorization, check “yes” and page will open to complete request for Waiver of Authorization