**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

**CPHS@Dartmouth.edu** **• 603-646-6482**

**DATA, SPECIMENS, AND REGISTRIES RESEARCH PLAN**

CPHS template v. 3/22/2021

**PI:**

**Title:**

**\*\*IMPORTANT NOTE: Please review the criteria for determining whether a project should be submitted to the D-HH IRB rather than CPHS.**

**\*\*Research involving DHMC data must be reviewed by the D-HH IRB*.\*\****

**For the purposes of this application, the term “registries” may also refer to databases, banks, and repositories.**

* **Respond to each item, even if to indicate N/A (not applicable)**
* **Upload this form as the ‘Investigator Protocol’ in Rapport**
* **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. **Type of Research:** this application is for (check one or more as applicable):

[ ]  Research using health information from clinical records / clinical data (e.g., electronic or paper medical records, imaging studies)

[ ]  Research using specimens obtained for clinical use

[ ]  Research using specimens collected solely for the purposes of this research

[ ]  Research using previously collected data or specimens from another research study

[ ]  Establishment of a registry for research projects (and potentially Quality Improvement projects; if primary intent is QI, indicate below in description)

1. **Description of Research:** describe the research and/or registry, addressing the purpose, relevant background information, objectives and hypotheses, and data analysis plan, including qualitative and quantitative methods.
2. **Data Collection Methods:** Indicate all sources from which you will be obtaining the data and/or specimens you are reviewing and describe your data collection plan. Please be as specific as possible.
* **Source of Data:** Please check all that apply. **(NOTE: Research involving DHMC data must be reviewed by the D-HH IRB rather than CPHS)**

[ ]  Existing CPHS-approved Registry or Database. Please provide the CPHS study number and upload any required agreements or documentation of permission from the manager of the database. CPHS #: \_\_\_\_\_\_\_\_\_\_\_

[ ]  Other: Please describe the source of data:

* **Data Collection:** Describe the methods you will use to collect the data.
* **Data Elements:** Specifically list each data field and/or specimens necessary for this project, or upload your data collection form. Describe your collection methods. Please note that in submitting this application, you are agreeing to use and access the minimum necessary data to complete your research goal.

 **Do all of the data and specimens exist as of today’s date?**

[ ]  Yes

[ ]  No

**Provide the inclusive dates of the data or specimens that will be requested or retained in the registry:**

1. **Privacy and Security of Data**
* **Check as applicable:**

[ ]  Data contains PHI (protected health information) please review the PHI list in the appendix of this form.

[ ]  Datacollected has the potential to damage financial standing, employability, insurability, or reputation (e.g., HIV/AIDS status, substance abuse disorders, genetic testing)

[ ]  Certificate of Confidentiality will be obtained.A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in sensitive health-related research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

* **Will the data or specimens be shared with anyone outside of Dartmouth College?**

[ ]  Yes [ ]  No

**If yes, provide the following information in the space below:**

* Names and affiliation of individuals who will be receiving the data or specimens
* The purpose of disclosing the information (e.g., for analysis, archival, etc)
* Will only a Limited Data Set be shared? Please review the LDS list at the end of this form. If so, is a Data Use Agreement in place? (contact Office of Sponsored Projects or Office of General Counsel for further information about DUAs)

* **Describe the safeguards employed to maintain the privacy and security of the data during the study. Address the following (as applicable):**
* Saving or storing data
* Sharing among study team members
* De-identifying data
* **Describe how you will destroy identifiable information at the conclusion of the study:**
* **Describe how you will communicate your privacy and security plans to other study team members (please note the PI is always responsible for control of the data):**
* **For registry, database or bank creation only:**

 List individual(s) who will have direct access to the database and describe how, or by whom, access will be provided:

 Describe the plan for internal review of future use of the registry or database, considering the following:

* Will the Principal Investigator be contacted for their approval prior to IRB review?
* Can IRB submissions come from any of the individuals listed above?
1. **Informed Consent (and Assent):**
* **Please describe the consent and/or assent process,** addressing who will obtain consent/assent from participants, where the consent/assent process will take place, the timeframe, any precautions taken to minimize the possibility of coercion or undue influence, and how comprehension will be ensured. Please upload any forms to Rapport.
* **Waiver(s) or alteration(s) of consent: Waivers may be requested for research that involves no more than minimal risk.**
1. [ ]  **Waiver of the entire consent process: consent will not be obtained**

**-or-**

[ ]  **Alteration of consent: consent will be obtained but not all** [**required elements**](http://www.hhs.gov/ohrp/policy/consentckls.html) **are present**

**Provide the justification for your above request. The justification must address all of the following:**

* A description of why the waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
* A description of why the research could not practicably be carried out without the waiver or alteration of consent
* A description of whether the subjects will be provided with additional pertinent information after participation
1. **Waiver of consent documentation: no signature will be obtained**

[ ]  **A script will be used to inform participants of the research and obtain consent**

[ ]  **An information sheet will be provided**

**Provide the justification for requesting a waiver or authorization of consent documentation. The justification must address *at least one* of the following:**

* 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. Each subject will be asked whether the subject wants any documentation linking the subject with the research, and the subject's wishes will govern.
* The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
1. **HIPAA Authorization waivers**

[ ]  **Waiver of HIPAA Authorization for recruitment**

[ ]  **Waiver of HIPAA Authorization for study activities**

**-or-**

[ ]  **Alteration of HIPAA Authorization; not all** [**required elements**](http://privacyruleandresearch.nih.gov/authorization.asp) **or** [**statements**](http://privacyruleandresearch.nih.gov/authorization.asp) **are present**

**Provide a justification for requesting a waiver or alteration of authorization. The justification must address the following:**

* The research could not practicably be conducted without access to and use of the PHI, nor without the alteration or waiver
* A description of why the privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
* A description of the whether identifiers will be destroyed or maintained upon conclusion of the research, and the plan for doing so
* An assurance that the PHI will not be reused or disclosed to any other person or entity, except as required or permitted by law.
1. **Genetic Research:** Does any part of this study involve genetic analysis of biological specimens?

[ ]  **No**

[ ]  **Yes,** the study is based on the premise that a link between a genotype or a biomarker and a specific disease or condition is clinically useful in predicting the development of that specific disease or condition. **Please complete the** [**Genetic Research Form**](http://www.dartmouth.edu/~cphs/docs/genetic_research_form.docx) **and upload it to the ‘Supporting Documents’ page in Rapport.**

***-OR -***

[ ]  **Yes,** the study is looking for an association between a genotype or a biomarker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve referral of participants to genetic counseling; however, participants will be informed of genetic testing in the consent form. **Please comment:**

1. **If your study does not have federal sponsorship, please check here** [ ]  **and respond to the following questions if you are interested in an interval of two years for continuing review for your study:**

a. Does any of the financial support for this study come from a Federal grant?

[ ]  **No** [ ]  **Yes**

b. Are the results of this investigation intended to be included in a Federal Grant Application?

[ ]  **No** [ ]  **Yes**

c. Are there anycontractual restrictions requiring adherence to federal regulations related to human subjects research of which you are aware for this study?

[ ]  **No** [ ]  **Yes**

**IMPORTANT NOTES:**

By submitting this application you are agreeing to:

* Use the data only for the purpose described here. If the intent of the request changes, you must re-apply with CPHS.
* Use appropriate safeguards to prevent inappropriate disclosure.
* Limit access to the data only to those who have been authorized to access the data.
* Ensure that storage of, and electronic transmission of research data (either via email or electronic file transfer (ftp)), utilizes encryption. Do not use the following to store research data: Personal computers, CDs, thumb-drives, mobile devices, removable hard drives, cloud storage.
* Use and access the minimum necessary data to complete research goal.
* Report inadvertent disclosure of PHI to CPHS within 5 calendar days.
* Not identify participants or contact participants (unless approved by the CPHS).

**DEFINITIONS OF TERMS USED IN THIS FORM**

**De-Identification** 45 CFR 164.514(b)(2)(i)

In order to be considered "de-identified," the health information collected must not contain the following information:

* Names
* Geographic subdivisions smaller than a state, except the initial three digits of a zip code as noted below
* All elements of dates (except year) for dates directly related to an individual
* Age, if over 89
* Telephone numbers
* Fax numbers
* E-mail addresses
* Social security numbers
* Medical record numbers
* Health plan beneficiary numbers
* Account numbers
* Certificate and license numbers
* Vehicle identification and serial numbers, including license plate numbers
* Device identifiers and serial numbers
* URLs
* Internet Protocol addresses
* Biometric identifiers, including finger and voice prints
* Full face and comparable images
* Any other unique identifier, characteristic, or code

\*The first 3 digits of a zip code can be retained if publicly available data from the Bureau of the Census indicates that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and the initial 3 digits of a zip code of all such geographic units containing 20,000 or fewer people is changed to 000.

**Limited Data Set** 45 CFR 164.514(e)

A limited data set permits the retention of some identifying information not found in the "de-identified" data.

|  |  |
| --- | --- |
| **Not Allowed**  | **Allowed** |
| * Names
 | * Dates
 |
| * Addresses, except for city, town, State, and zip code
 | * Age (including 90 or over)
 |
| * Telephone and fax numbers
 | * Zip codes
 |
| * e-Mail addresses
 |  |
| * Certificate or license numbers
 |  |
| * Vehicle ID and serial numbers, including license plate numbers
 |  |
| * URLs and IP addresses
 |  |
| * Full face photos and comparable images
 |  |
| * Social Security Numbers
 |  |
| * Medical record numbers
 |  |
| * Health plan beneficiary numbers
 |  |
| * Account numbers
 |  |
| * Device identifiers and serial numbers
 |  |
| * Biometric identifiers including finger and voice prints
 |  |
|  |  |

**Protected Health Information (PHI)**

Individually identifiable health information, which is created or received by D-H and is related to the past, present, or future

* Physical or mental health or condition of an individual,
* Provision of health care to an individual, or
* Payment for the provision of health care to an individual.