**Specimen or Data Collection Consent Template with Guidance 04/25/19**

**This template can be used whether the specimens or data obtained are for a single research protocol or multiple. Please customize each section in accordance with your protocol.**

**University of Vermont Consent Form for Repository Donations**

# Title of Research Project: title

**Lead Investigator:** name

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| --- | --- |
| **Affiliated Hospital Investigator:** | *(as applicable)*  If Central Vermont Medical Center (CVMC) is participating include local Investigator’s name here – no other affiliates are conducting research at this time |

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| **Sites Where Research is Being Conducted** | University of Vermont Medical Center  (*list Central Vermont Medical Center as applicable)* |

**Sponsor:** List all agencies or companies that are supporting this research. If internally sponsored, list the department. Do not list the sponsor here until you have obtained funding.

For studies involving children please add here - “Throughout this document “you” refers to “you or your child”.

**Introduction**

You are being given the opportunity to donate your specimen or data to a repository (bank) for research. This repository is located at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and is operated under the direction of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Principal Investigator, at the University of Vermont/ The University of Vermont Medical Center.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

**Key Information to Help You Decide Whether or Not This Study Is Right for You**

* All consent forms should provide a concise and focused presentation of key information that is most likely to assist in understanding the reasons why one might or might not want to participate in the research.
  + Use this section of the consent form to summarize the study using plain, non-technical language.
  + Highlight that the person has a choice to make. The consent form should be used as a decision making tool, not a sales pitch.
  + Include a brief description about why the study is being conducted and what is being asked of the participant (e.g. time commitment, procedures involved).
  + When deciding what risks or side effects to include in the summary, consider whether a potential participant would attach significance to the risk in deciding whether or not to participate. If applicable, state that “A complete list of the risks is given in the following pages.”
  + This summary should be limited to one page.
  + Consent forms are recommended to be at an 8th grade reading level to be appropriate for the general population. Microsoft Word has a readability program which can be found by:
    - Click the **File** tab, and then click **Options**.
    - Click **Proofing**.
    - Under “When correcting spelling and grammar in Word”, make sure the “Check grammar with spelling” check box is selected.
    - Select **Show readability statistics**.
    - After you enable this feature, open a file that you want to check, and [check the spelling](https://support.office.com/en-us/article/check-the-spelling-5cdeced7-d81d-47de-9096-efd0ee909227). When Word finishes checking the spelling and grammar, it displays information about the reading level of the document or just the highlighted section.



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| --- |
| **To improve subject comprehension the RPO office encourages researchers to use:** |
| * Headings * **Bolded type** * Pictures * Tables * Consider using bulleted points to highlight key information. * Keep sentences short and simple. * Do not use fractions or %. Instead, state “1 out of 10 people will…” * Use lay language – see plain [language dictionary](https://www.uvm.edu/rpo/human-subjects-research#Medical_Dictionary) |

Include the below statement at the end of the concise summary:

The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

Examples of model summary statements are available on the IRB website and may be found [Here.](https://www.uvm.edu/sites/default/files/media/concise_examples_for_the_web_2.6.19.docx)

What is the Purpose of this Repository?

Research repositories provide a continual supply of specimens or data that are used to understand human disease or conditions. The research conducted using these specimens or data may be used to develop new drugs, tests, treatments or products.

The types of research likely to be conducted from specimens or data taken from this repository are [be as specific as possible with the basic idea to determine if there is any type of research to which the subject might object].

[If not all research has been determined at time of consent, state so.]

State here if the research results are to be shared with the subject.

How Does the Repository Operate?

* Describe physical security measures of the repository.
* Describe if, how and to whom (potentially) the specimens or data will be released.

The following should be stated in the consent.

We will only release specimens or data to other investigators after they have had their research reviewed and approved by their local Research Ethics Committee.

What Is Involved?

* Provide details about the type of specimen and how it will be obtained from the person, whether as part of routine care, or specifically for research.
* Explain whether or not any private information will also be collected to be retained with the specimen.
* Indicate whether or not some studies using samples from the repository might involve concomitant review of the medical records of the subjects. Further explain what information you might need from their medical record.
* Indicate the length of time for which specimens and/or information will be retained in the repository. If the length of storage is indefinite, this should be stated.
* The degree to which ongoing access to medical records is being sought for correlative information, and the duration of such access needs to be listed here.\
* Whether they may be approached in the future for follow-up specimens or data.
* Research collecting identifiable private information and/or identifiable biospecimens must:
  + State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent, OR:
  + State that collected samples/data will not be used or distributed for future research, even if de-identified. If applicable, for studies that involve the collection of biospecimens, include a statement about whether the research will or might include whole genome or exome sequencing.
* If applicable, include a statement regarding whether clinically relevant research results will be given to the subject and under what conditions.

What Are The Benefits of Participating?

* Describe the benefits to the subject, if any, of participating in the repository. If there are no benefits to subjects, this should be stated.
* Describe the general benefits accruing to society from the creation of the repository and the availability of materials in it for research purposes.

What Are The Risks?

* Describe any risks involved in collecting the specimens which are not already associated with procedures being performed as part of the subject’s clinical care. If there are no additional risks, this should be stated.
* Describe the risks to insurability and employability that would result from unintended disclosure of data associated with the specimens or generated from analysis of them.
* Describe the possibility that, if results of studies using the specimens are relevant to their health, then disclosure of the information may have adverse psychological and social consequences to them.

*NOTE: If the study involves the collection, storage or analysis of genetic information, the following language is required.*

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder.

What Other Options Are There?

* Indicate that prospective subjects have the option of not contributing specimens to the repository.
* For repositories associated with a main treatment study, explain whether subjects may participate in the main study without participating in the repository.

include this section only when protected health information is used

What About Confidentiality of Your Health Information?

**What health information will be used and disclosed for this study?**

The health information we plan to collect for this study is listed below.

This list should be edited and revised to be accurate and study specific.

* Medical history and examinations
* Information that identifies you, such as your name, address, age, and sex
* Reports from hospital and clinic visits
* Laboratory and other test results
* X-ray and other images and reports
* Lists of medications you are taking
* Responses to health surveys and questionnaires
* Reports from mental health services and testing, if applicable
* Reports about drug and alcohol treatment if applicable
* Health related video and audio recordings, and photographs, if applicable
* Reports of testing for infectious diseases, including HIV, if applicable
* Genetic testing results if applicable

**Who is disclosing your health information for this research study?**

* The University of Vermont Medical Center
* Other doctors’ offices and hospitals where you may receive medical care while this study is active.

List other health care providers specifically by name if known

**Who will use your health information in this study?**

Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.

This list should be edited and revised to be accurate and study specific. The list should include, as applicable, a clinical research organization, an independent data and safety monitoring committee, a coordinating center, collaborators and their home institutions, and foreign regulatory agencies.

* The University of Vermont and its Committees on Human Research
* The University of Vermont Medical Center
* Other researchers and centers that are a part of this study, including individuals who oversee research at those sites
* Officials from agencies and organizations that provide accreditation and oversight of research
* The sponsor of this study **insert the name of the sponsor**, or others who fund the research, including the government
* Company(ies) that provide drugs or devices for this research project
* Federal and state agencies that oversee or review research information, such as the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
* Your health insurer, for portions of the research and related care that are considered billable

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

**How long will your health information be used for research?**

Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

**What if you decide not to give permission for research use of your health information?**

If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

**Who can answer your questions about the use and disclosure of your health information?**

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at insert phone number or the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

One of the following two sections must be included. Include this section when protected health information is used

Safeguarding Your Health Information

A record of your progress will be kept in a confidential form at the insert location. The security of your record will be maintained by name of person. The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

If you have any questions, you may contact the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

Or insert the section below when no protected health information used

What About Confidentiality

Your data and/or specimens will be kept in a confidential manner at the insert location. The security of data and/or specimen will be maintained by name of person. The data and/or specimens will be exchanged between investigators for future research, but confidentiality will be maintained by assigning a code number to your data and/or specimens. The code number will be kept by repository staff only.

The University of Vermont Committees on Human Research may review or receive information about you to check on the operation of the repository.

Right to Withdraw

If you decide later that you do not want your specimen and/or information to be used for future research, you can tell us, and we will destroy any remaining identifiable specimen and/or information. Contact the study doctor at his/her number below to do this.

What are the Financial Considerations?

You will not be charged for being in this research study. You will not be paid for being in this research.

Any specimens you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the investigators, UVM/UVM Medical Center or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Include a statement that biospecimens, even if de-identified, may be used for commercial profit, and whether/if that profit will be shared.

Financial Interest

If applicable include the following

You should also know that [investigator] has a significant financial interest (e.g. a separate relationship with the sponsor or a related company involving ownership or stock, payment for services or other significant financial payments) that could potentially compromise or influence the investigator’s professional judgment or actions in the performance of the study (e.g. the design, conduct, oversight, evaluation or reporting of the results of the study). The investigator has disclosed that personal financial interest to the IRB responsible for approving this study. The IRB reviewed the [investigator’s] financial interest and determined that any potential conflicts are being appropriately managed. However, negative impacts on subjects participating in this study, are always possible, and therefore the potential conflict is being disclosed to you. Please discuss with the Investigator any questions you may have about this.

Contact Information

You may contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_ , the Investigator in charge of this study, at \_\_\_\_\_\_\_\_\_for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Making Your Choice

You have the following choices to make regarding this invitation to participate. Circle either “yes” or “no” after reading each sentence.

1. My specimen/private information may be kept for future use in research to learn about, prevent or treat health problems (for example: cancer, diabetes, Alzheimer’s disease, or heart disease).

Yes No

1. (if applicable) Someone from the repository may contact me in the future to ask me to take part in new research.

Yes No

1. (if applicable) Do you wish to receive results from any research testing?

Yes No

Statement of Consent

You have been given and have read or have had read to you a summary of this research repository. Should you have any further questions about the repository, you may contact the person listed at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to donate your specimen and/or information and you understand that you will receive a signed copy of this form.

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Signature of Subject Date

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Name of Subject Printed

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Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number: