**Behavioral/Social Consent Template with Guidance – 3/24/2021**

**This template provides guidance and examples of text to be used within each section. Please customize each section in accordance with your protocol.**

**University of Vermont Consent to Participate in Research**

|  |  |
| --- | --- |
| **Title of Research Project:** | Title |
|  |  |
| **Lead Investigator:** | Name |
|  |  |
| **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 |
|  |  |
| **Sites Where Research is Being Conducted:** | University of Vermont  University of Vermont Medical Center  [list Central Vermont Medical Center as applicable] |
|  |  |
| **Faculty Sponsor:** | If you are a student, list your faculty sponsor here. Please refer to the Research Manual for the definition of a student. |
|  |  |
| **Sponsor:** | List all agencies, companies, or other Universities 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 invited to take part in this research study because[explain how/why the patient/subject qualifies or may qualify for the study]***.*** This study is being conducted by the University of Vermont [if any of the research is being conducted at UVMMC hospital or any of its campuses or include]at the UVM Medical Center.

Your participation in this research study is optional. 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.



|  |
| --- |
| **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)]

**Why is This Research Study Being Conducted?**

The purpose of this study is to [Give brief explanation of why study is being done, using one or two sentences written in clear language understandable to the target population].

**What Is Involved In The Study?**

Study participation will take a total of [insert length of time ex. approximately two hours].

[Explain in simple, non-scientific language, what will be happening to the participant or what s/he will be asked to do during the study, including the order in which they occur. Describe the participant's time commitment for each component. All procedures listed in the IRB application and funding proposal (as applicable) should be described here, and procedures (e.g., observations, interventions, manipulations, treatments) should be specifically noted. **If you plan to take photographs or make audio, video, or other types of recordings state so.**]

[For interview or survey procedures include some examples of the questions in order to provide a clear understanding.]

All study procedures will take place at [insert information]. [If different procedures will take place at different locations, specify accordingly]**.**

[If screening procedures have already been completed under an alteration include:]

If you decide to participate in this study, we will include the answers that we collected from your previous [phone call, survey] in your research record.

[Research collecting identifiable private information must include one of the two following statements. It is recommended that investigators choose the first bullet point to allow future additional research utilizing this consent form. If bullet two is chosen, future use will not be allowed.]

* + State that collected 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 data will not be used or distributed for future research, even if de-identified.

[If the study involves **deception or incomplete disclosure** which necessitates a debriefing process, a general statement may be added here or in the Benefits discussion that more information will be given to subjects at the conclusion of the study, e.g., "At the end of the study, we will explain in greater detail what we hope to learn from this research." If the investigator believes that such a statement would bias study results, he/she should discuss this in the protocol as part of the justification for use of deception or incomplete disclosure.]

**What Are The Risks and Discomforts Of The Study?**

[In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts that may occur as a result of participation:

* Include anticipated risks of discomfort or harm
* Address emotional and psychological risks, including risks of emotional discomfort from being asked about or discussing sensitive issues.
* Social or economic risks (e.g., accidental loss of confidentiality, violation of privacy; reputation, self-image, effects to financial standing, employability, or insurability)
* Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)
* Possible harm to individuals not directly involved in the research, but about whom the data are obtained indirectly (secondary subjects), or who belong to the class or group from which participants are selected
* Physical risks (e.g., nausea, muscle aches, rashes, infection, discomforts, etc.)
* Note, risks are not always immediate; anger, emotional upset, or stress may appear later. If this is a possibility, explain and provide an appropriate person’s name and contact information.]

[Describe support services that are available to the participant if necessary.]

[If participation does not introduce any risks, state so.] Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life.

[Many social-behavioral studies involve only minimal risk of harm to subjects. However, if the study involves greater than minimal risk, this statement is required:]

It is important that you promptly tell the researcher [insert investigator’s name], if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at [telephone number].

[Incarcerated individuals, parole status:]

Your participation in this research study will have no effect on your criminal case or future probation, furlough or parole status.

[Juvenile detention center:]

Your participation in this study will not affect your relationship with Department of Corrections/Vermont Department for Children and Family Services, or the Court.

**What Are The Benefits of Participating In The Study?**

[Describe the possible benefits of participation in the research. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., talking about/reflecting on an experience may lead to a better understanding of oneself).]

[If there are no direct benefits to the participant simply state,] There is no direct benefit to you anticipated from participating in this study. However, it is hoped that the information gained from the study will help… [e.g., educators or other professionals in this field to understand/learn more about \_\_\_\_\_\_\_\_\_\_\_.]

[Note: Compensation, financial incentives, learning about how a research study is conducted, receiving a gift, or earning extra credit for being a research participant are not benefits and should not be listed here.]

**What Other Options Are There?**

[If the research involves experimental treatment/therapy/intervention, describe any non-experimental alternatives that may be available. If there are no other options, then simply state.]

**Are There Any Costs?**

[Clearly state if there are any costs associated with study participation (and if so, specify what they are).]

**What Is the Compensation?**

[Compensation is only offered to cover expenses, time lost or inconveniences. If participants will not receive compensation, state so here. For those receiving compensation, specify what how much and what the compensation is for and whether the payment(s) are prorated based on completed tasks or visits. Explain how the payment will be made. Depending upon the total amount of compensation received, the income may be taxable.]

[If non-monetary compensation, e.g., course credit, will be offered for participation, explain how that will be done here.]

[If receiving monetary compensation include UVM procurement language:]

You will be required to provide your name and address each time you receive a payment. You will also be requested to provide your social security number if the amount of the payment is $100 or if the total payments from UVM are equal to or greater than $600. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be used for tax withholding and reporting purposes only and will allow the University to determine your US residency for federal income tax purposes.

**Can You Withdraw or Be Withdrawn From This Study?**

You may discontinue your participation in this study at any time. [Explain what will happen with any previously collected research information at the time of early withdrawal.]

and (if applicable)

The researcher may discontinue your participation in this study at any time. [The consequences of a subject's discontinuation from the study, and procedures of the orderly termination of participation should be stated here.]

**What About Confidentiality?**

[This section should explain how the researchers will minimize the risk of breach of confidentiality. Any regulatory/other agencies which may have access to the research records should also be noted, e.g.:]

To protect your confidentiality, we will... [Explain data security measures to be taken, e.g., storage, coding, encryption, limited access to study records, etc.]

[Retaining research records:]

When the research is completed, our research team may save the [samples/ tapes and notes/ study records] for use in future research done by myself or others. The same measures described above will be taken to protect confidentiality of this study data. [Or if different, give accurate information about retention and use of study data in future, e.g., "We will destroy the samples/ tapes and notes/ study records at the end of this study."]

If results of this study are published or presented, individual names and other personally identifiable information will not be used.

The sponsor(s) […..] or their appointed designees as well as the Institutional Review Board and regulatory authorities will be granted direct access to your original research records for verification of research procedures and/or data.

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 applicable, add statement that describes how photographs, audio and/or video recordings will be kept secure and stored and for how long. If recordings will not be destroyed, state so.]

[When research activities or communication with participants utilize electronic methods such as e-mail or social media, include the following statement:]

Any communications through email and social media are not considered private or secure. Though we are taking precautions to protect your privacy, you should be aware that information sent electronically through these methods could be read by a third party.

[If UVM (Luse Center) is the covered entity include the following]

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 Chief Privacy Officer at The University of Vermont at (802) 656-2003.

[Focus groups as applicable:]

We will ask that everyone in the group not repeat what they have heard others say, but there is always the chance that someone will repeat what you have said.  Everything you say will be kept confidential by the researchers.

Focus groups questions are directed to the group, not to individuals. You have the right to: (a) not answer a question, (b) terminate the interview, or (c) withdraw from the study at any time in the process.

[Sensitive/reportable research information:]

[If there is a reasonable expectation (from the topic under study and/or the subject population) that reportable information may be disclosed to the researcher during the study, an appropriate statement should be added, e.g.:]

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to harm yourself or others.

[Insert the following language if there is a Certificate of Confidentiality for the project.]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.  
   
There are some important things that you need to know.  The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.  
   
Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

[If the protocol meets the criteria for registration, include the following language:]

Clinical Trials Registration

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[If applicable, include this section:]

**Financial Conflicts of Interest**

You should 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). Please discuss with the Investigator any questions you may have about this.

**Contact Information**

You may contact Dr. [investigator’s name], the Investigator in charge of this study, at [investigator’s phone number], 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 harmed 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.

**Statement of Consent**

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study 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.

You agree to participate in this study, and you understand that you will receive a copy of this form.

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Signature of Subject Date

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Name of Subject Printed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator or Designee Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number:

Name of Faculty Sponsor:

Address:

Telephone Number: