**Medical Consent Template with Guidance – 5/16/18**

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

**Consent to Participate in Research**

# Title of Research Project: This should be the same as the protocol unless the IRB approves otherwise. In some cases the titles are very complicated thus the IRB will allow simplification.

**Principal Investigator:**

**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 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 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 the hospital or any of its campuses include]* at the UVM 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.
	+ Though not a regulatory requirement, consent forms are recommended 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_1-25-18-2.docx).

Why Is This Research Study Being Conducted?

[Subjects need to understand WHY this research is being conducted.]

* Include some background and specific aims.
* Do not include extensive biological, chemical or physiological information.
* Do not include animal data unless absolutely necessary.

What Is Involved In The Study?

* Briefly explain the study design.
* If this is a treatment study, discuss the study treatments and the probability for random assignment to each treatment including the use of placebo if any; explain the randomization process (if applicable).
* For treatment and non-treatment studies, describe all procedures. Indicate the time commitment involved for subjects, specifying number of visits, where the visits will occur (e.g., whether procedures are done on an inpatient or outpatient basis), etc. and the approximate time duration per visit. Include a schedule. Discuss anticipated duration of participation including treatment and follow-up.
* For treatment trials, clearly state which are experimental/research related procedures and which procedures are standard care.
* For investigational new drug or device studies, indicate that this drug/device has NOT been approved by the Food and Drug Administration (FDA).
* Describe procedures in lay terms e.g. blood drawing (not CBC), etc. Provide amount of blood or tissue to be taken. *If drawing over 450 cc of blood in an 8-week period provide special statements as provided below:*

 *For adults weighing at least 110 lbs:*

 *1. If more than 450cc will be drawn within an 8 week period then the treating investigator should perform a finger stick hematocrit prior to each drawing and the investigator should document that it is within the normal range. Add this additional procedure in lay terms to the consent.*

 *2. Both protocol and Consent Form should specify that volunteers will receive supplemental iron.*

 *3. Subjects should be advised against donating blood either 8 weeks prior to, or 8 weeks after, participation in the research project. Add this restriction to the consent form.*

*Note: When amounts drawn are close to, but still less than, 450 cc, it may be deemed appropriate to include some of the above elements.*

* If subject tissue or data that is collected as part of this protocol will be shared with others for different research purposes, this needs to be disclosed to the subjects. The reason for sharing and how their rights will be protected also needs to be explained.
* 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 Risks and Discomforts Of The Study?

[Subjects should be able to gain a realistic idea of the known and the unknown risks that they are taking and of discomforts or inconveniences they might experience as a result of participating in the study.]

* When necessary, include not only physical risks but also potential legal, economic or psychological risks that are relevant.
* List risks in order of likelihood of occurrence from common to uncommon and provide a measure of the likelihood of occurrence (such as 1 in 10, 1 in 100) when available.
* For all women of childbearing potential who are enrolled in a treatment trial, note potential risks to an embryo, fetus, or nursing infant. A contraception statement (if applicable) should be included for both males and females.
	+ CRC Recommended Language: Because the drugs/procedures in this study can affect a fetus, pregnant women may not participate in this study. If you are a female of child-bearing potential *[additional criteria may be included],* a urine *[or blood]* test will be done at the initial visit [or other time] to make sure that you are not pregnant. There is a period of time during which this test may not be accurate, as you may be too early in your pregnancy to test positive. If you think you might be pregnant, you should not participate in this study.
* When HIV testing is conducted as part of the research procedures, individuals whose test results are associated with personal identifiers must be informed and counseled in advance that an HIV test will be performed. The subject should be aware that both HIV and AIDS cases must, by law, be reported to the Vermont Department of Health and disclosure of a positive test may result in discrimination by friends, family, employers, insurance companies and others. If any test for HIV is positive, subjects should be provided these results in person. It is highly encouraged that disclosure of a positive HIV test result to any individual be done in consultation with the UVM Medical Center Infectious Disease clinic staff and social worker. The clinic can be reached at 847-4594. You should develop language for the consent form that explains the procedure you develop for your protocol.
* State that the particular treatment or procedure may involve risks that are currently unforeseeable.
* If there are no known risks, state so.
* If you are a mandated reporter, include the following:
	+ If the research intervention could result in the finding of a subject’s intent to harm himself or others, state in the consent that information regarding referrals for additional support will be provided and that this finding may be subject to mandatory reporting to the appropriate authorities.
	+ If child or elder abuse [include as appropriate] is revealed during the course of the intervention that fall under state statutes, mandatory reporting to the appropriate authorities is required.

If the protocol utilizes the UVM 3T magnet for neuroimaging studies, this section regarding incidental findings should be included:

Incidental Findings

There is a possibility that while reviewing your *(insert test)* we may see an abnormality that may have health implications that we did not expect to see. This is what is called an “incidental finding.”

If we see an incidental finding, a qualified person (usually a member of the research team) will communicate the information to you. If you wish, we will provide information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

This study is neither designed nor intended to detect health problems. The imaging that you will have as part of this research study does not substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should not rely on this study as a way to determine your health status. The information from this image will not be shared with you or your personal physician, unless (as mentioned above) there is an incidental finding.

An incidental finding may cause you to feel anxious. If you have further tests done, those results will then become part of your medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

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 Are The Benefits of Participating In The Study?

[An unbiased statement should be included.]

* If none, so state.
* Both personal and societal benefits should be stated.
* Note: money provided as compensation is not considered a benefit and should not be listed here.

What Other Options Are There?

[For treatment studies, describe options open to subjects if they do not participate.]

* Discuss appropriate treatment alternatives and their potential risks/benefit, this may include other research studies.
* Discuss that one alternative is to have no treatment or to have supportive care only if appropriate.
* Discuss if the same treatment is available outside of the research study.

Are There Any Costs?

[State all additional costs to subjects as a result of participating in the research.]

If drugs are provided free of charge, state that if the drug becomes commercially available subjects may have to pay for it. This typically would occur in a pharmaceutical sponsored study.

Clarify that standard testing/treatment will be billed to subjects or their insurance and not all expenses may be covered by their insurance, which would leave them responsible for payment.

What Is the Compensation?

[State the level of compensation and detail the point(s) at which compensation is given, e.g., only at the end of study or after each completed visit.]

* State the mechanism for proration.
* Avoid using the word "pay".
* Compensation is only offered to cover expenses, time lost or inconveniences. Specify what the compensation is for. Depending upon the total amount of compensation received, the income may be taxable.
* Payment is not made for inducing subjects to assume any risks.

If applicable, state “You will not receive payment for participation in this study.”

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

Can You Withdraw or Be Withdrawn From This Study?(if applicable)

Sample language for the subject.

“You may discontinue your participation in this study at any time.”

Example for treatment studies when the researcher withdraws subject.

“Should your disease become worse, should side effects become very severe, should new scientific developments occur that indicate the treatment is not in your best interest, or should your physician feel that this treatment is no longer in your best interest, the treatment will be stopped. In addition, the researcher may discontinue your participation in this study at any time.”

Example language when not a treatment study and the researcher withdraws subject.

“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.

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
* Reports about drug and alcohol treatment
* Health related video and audio recordings, and photographs
* Reports of testing for infectious diseases, including HIV
* Genetic testing results

**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.

**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
* Officials from agencies and organizations that provide accreditation and oversight of 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
* 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

**Future Research (**for protocols involving storage of data/specimens for repositories)

Your samples and data will be stored for future use if you have indicated that earlier in this consent form.

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?**

Include the following if UVMMC is the covered entity

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 the research team. 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 project includes videotaping, photography or voice recordings please include a special statement about disposition of materials.

[For studies that include reimbursement in any form include]

You may be requested to provide your name, social security number, and address. This information will be disclosed one time to either the University of Vermont’s Procurement Services Department or UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork for payment.

**OR**

this section when there is **no protected health information (HIPAA) used** (next 5 paragraphs)

**What About Confidentiality**

A record of your participation will be kept in a confidential form at the insert location. The security of your record will be maintained by the research team. The results of this study may eventually be published and information may be exchanged between investigators, but 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 project includes video recording, photography or voice recordings please include a special statement about disposition of materials.

The sponsor insert sponsor name or their appointed designees as well as the Institutional Review Board will be granted direct access to your original research records for verification of study procedures and/or data.

[For studies that include reimbursement in any form include]

You may be requested to provide your name, social security number, and address. This information will be disclosed one time to either the University of Vermont’s Procurement Services Department or UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork for payment.

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.

For research that is interventional and/or greater than minimal risk, include the following section:

What Happens If You Are Injured?

If you are injured or become ill as a result of being in this research, The UVM Medical Center, the hospital partner of the University of Vermont, will provide reasonable and usual medical care for that injury or illness. There will be no cost to you if the conditions listed below apply to your injury or illness. These conditions are:

1. The investigator determines that your injury or illness results from the research and not from your underlying condition or its usual treatment.
2. You let the investigator know about the injury or illness when you first notice it; and
3. You follow medical advice about proper treatment options for the injury or illness.

If the above conditions are not met, the UVM Medical Center may claim payments for your medical treatment from the study sponsor or your insurance company when these payments are allowed. ***If we bill your insurance for this care, you will be responsible for any associated co-payments or deductibles.***

For an injury or illness that results from being in this study, the University of Vermont and The UVM Medical Center will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, the UVM Medical Center and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the study.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

If applicable, include this section:

Financial Interest

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.

Statement of Consent

[example of language below]

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 to your present and/or future care.

You agree to participate in this study 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:

Name of Faculty Sponsor:

Address:

Telephone Number: