

**\*This template provides guidance on how to develop your consent. In many pharmaceutically - sponsored research studies a template is provided by the sponsor. You are not required to use our local template but you should make sure all the required elements are included in the consent that is submitted. Required sections or statements are in bold.**

## Informed Consent

**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:**

**Sponsor:** *You cannot 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”.

**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]. [If the study is being conducted under a grant/contract between the sponsor and the University of Vermont:]* **This study is being conducted by the University of Vermont** *[If the activities are occurring at Fletcher Allen add to that sentence the following]* **at Fletcher Allen Health Care, Inc., the hospital affiliated with the University of Vermont College of Medicine.** *[If the study is being conducted under a clinical trial agreement/contract between the sponsor and Fletcher Allen:]* **This study is being conducted by Fletcher Allen Health Care, Inc. [may add] ,the hospital affiliated with the University of Vermont College of Medicine.**

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

### 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.

### How Many People Will Take Part In The Study?

- Include national and local numbers.

### 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.

### 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.
  - GCRC 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 Fletcher Allen 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 T3 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.

*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. This law generally will protect you in the following ways:

Health insurance companies and group health plans may not request your genetic information that we get from this research. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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."

### 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.

## What About Confidentiality?

[Detail how confidentiality will be maintained. The greater the risk to the subject of a breach of confidentiality, the more detailed the discussion should be. If the study uses, creates or discloses protected health information you must have a separate HIPAA authorization form in addition to the consent. Below is an example.]

Complete and include the following: “A record of your progress will be kept in a confidential form at the [.....]. The security of your record will be maintained by [.....].The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

The sponsor(s) [.....] or their appointed designees as well as the Institutional Review Board and regulatory authorities [e.g., FDA, NCI, cooperative groups specify] will be granted direct access to your original medical and research records for verification of clinical trial 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] Please refer to the separate Authorization Form that explains more specifically how your personal health information will be used.”

[When videotapes, photography or voice recordings are used the consent should include a special statement about the disposition of the tapes/photographs.]

[For studies that include reimbursement to the subject:] Your name, social security number, and address will be disclosed one time to either the University of Vermont’s Procurement Services Department or Fletcher Allen’s Accounts Payable Department for purposes of reimbursing you for participation in this study. Your information will be coded and this code and the information will be kept under lock and key with only authorized personnel accessing the data.

*Note: 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.

## What Happens If You Are Injured?

## Fletcher Allen Health Care Policy

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

If you are injured or become ill as a direct result of participating in this research project, Fletcher Allen Health Care, the hospital affiliated with the University of Vermont, will provide reasonable and customary medical care for that injury or illness at no cost to you providing certain conditions are met. These conditions are:

- 1) It is the opinion of the investigator and/or sponsoring agency that the injury or illness is a result of the research;
- 2) For studies which provide treatment of a specific condition or disease, it is the opinion of the investigator and/or sponsoring agency that the injury is not associated with your disease/condition or with the expected complications of the usual therapies for the disease/condition;
- 3) You have followed all of the directions of the investigator;
- 4) You have notified the investigator of the injury or illness in a timely manner after onset; and
- 5) You have followed medical advice regarding the injury or illness.

Where applicable, reimbursement may be sought by Fletcher Allen Health Care directly from the Study Sponsor or your insurance company. The fact that Fletcher Allen Health Care provides free treatment or care to you as a result of a research-related injury or illness as just described is not an admission by Fletcher Allen Health Care or the University of Vermont that it is responsible for such injury or illness.

It is not the policy of the University of Vermont or Fletcher Allen Health Care to provide any further financial compensation in the event of an injury or illness. You should understand, however, that by acknowledging this you are not waiving or releasing any of your legal rights.

### Sponsor Policy

[In the case that a sponsor is willing to pick up some of the costs and medical care resulting from injury associated with the research study, this should be disclosed in this section.]

[For research that is non-interventional and not greater than minimal risk an abbreviated version of the language, as noted below under contact information, should be used.]

*If there is a significant financial interest the following section is required.*

### 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 Nancy Stalnaker, 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** \_\_\_\_\_

**This form is valid only if the Committees on Human Research's current stamp of approval is shown below.**

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**Name of Subject Printed** \_\_\_\_\_

The following highlighted signature lines can be deleted if not applicable to the research.

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*Minor Providing Assent* \_\_\_\_\_ *Date* \_\_\_\_\_  
*(applicable for children 11 years of age or older dependent upon their understanding)*

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*Name of Minor Providing Assent Printed* \_\_\_\_\_

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Signature of Legal Guardian or Legally Authorized Representative      Date  
*(applicable for children and subjects unable to provide consent)*

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Name of Legal Guardian or Legally Authorized Representative 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:**