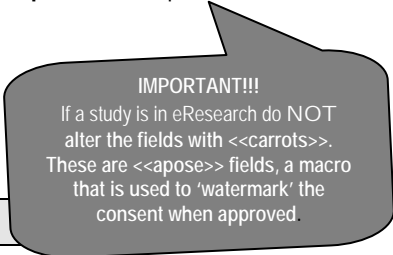


AVE
UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY TIPS HANDOUT



INFORMATION ABOUT THIS FORM

This IRB template contains a few tips for dealing with some sections. You should ALWAYS consult the comments, also known as instruction bubbles, before writing any section. Your IRB medical specialist can also help answer questions.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Informed Consent: an Interventional Study

1.2 Company or agency sponsoring the study: Center for the Advancement of Clinical Research
Brown Bag Series

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Kim Groner, NP, Chronic Pain and Fatigue Research Center, Div. of Rheumatology, University of Michigan.

Ana Austin, Research Associate and Regulatory Specialist, Center for the Advancement of Clinical Research, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Required?: Yes. 45 CFR 46.116 requires "an explanation of the purposes of the research"
Good sources: Protocol 'background and significance' sections, as well as 'specific aims'

Tips:

Do Not ...simply 'cut and paste' protocol sections, as these are rarely in lay language
...give elaborate details of the procedures of the protocol
...include highly scientific objectives or hypotheses that are of little relevance to the participants

Do ...Consider what the participant would want to know. Keep in mind that the participant's involvement may be limited, so a full explanation of all the research aims may be inappropriate.

Examples:

This study is being conducted to assess the impact of DFG-995 and/or therapeutic intervention on the "Informed Consent Anxiety" scale, to assess efficacy.

This multi-center study is a triple-stratified, double-blinded, intervention. Participants will begin by completing an EKG...

We believe that intensive therapeutic intervention will be most effective for highly anxious participants pre-disposed to neurosis and confusion.

Problems?

- 1) Use of scientific language (numbers instead of drug names; long, complex sentences). This first paragraph was probably cut and pasted directly from a protocol.
- 2) Detailed description of the study design and procedures: this topic should be covered in the procedures section, not here.
- 3) Use of scientific objectives, rather than a focus on objectives that are meaningful to the participant. For instance, even if a change on the "Informed Consent Anxiety" scale is the primary endpoint of the study, it is not the purpose of the research.
- 4) Note that revealing your hypothesis is not necessary, and can even cause problems in your research if you are trying to maintain a blind or avoid biasing participants' behavior.

One Possible Fix:

Many experienced study coordinators report that writing an informed consent is the most challenging part of their job. Several types of treatments may reduce the anxiety and frustration of writing an informed consent. This study is designed to test which treatments may be most effective for different people. The study will compare treatment with a drug, treatment with therapy and counseling, and no treatment, to see which approach helps reduce anxiety during informed consent writing.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

Required?: Yes. 45 CFR 46.116 requires this statement. You can expand upon it, but the basic elements must remain. One possibility is changing "you will not lose any benefits to which you are otherwise entitled" to "If you decide not to participate or you leave the study early, you would still get all the same health care benefits you have now."

3.1 Who can take part in this study?

Required?: This section is required by UM IRBMED, but it is NOT explicitly required by the code of federal regulations. This means that the level of detail you include in this section is up to you, the investigator, and the IRB.

Good sources: Use your protocol inclusion and exclusion criteria with caution!

Tips:

Do Not ...simply 'cut and paste' all inclusion exclusion criteria. Not only do they include scientific language, they often include complex criteria that are meaningless to participants. Thoroughness should be balanced with keeping your consent short enough to fit reading level guidelines.

Do ...Consider what the participant would want to know.
...Be selective. The IRB requests that this section include "important" criteria.
...Focus on those criteria that the participant can judge for him or herself.
...If you do not list all criteria, be sure to stress the importance of giving a FULL and COMPLETE medical history.

Example:

To participate, you must be:

Age >18

Persistent anxiety during informed consent writing that has not required hospitalization or emergency treatment.

No clinically significant medical condition or laboratory abnormality, which would, in the judgment of the investigator, interfere with the subject's ability to participate in the study or to be followed.

No use of antianxiety medications for 30 days prior to enrollment, unless dose is stable for 60 days prior to screening AND dose has been titrated to minimum tolerable levels as documented in medical record.

No atypical anxiety syndromes due to anticholinergic drugs, metabolic identified neurogenetic disorders, encephalitis, or other degenerative diseases (e.g., progressive supranuclear palsy).

Problems?

These are written from the point of view of the researcher, not the participant.

Participants cannot know if their medical conditions will be considered 'significant' by the investigator or not. Participants rarely know what exactly is 'documented' in their medical records. The last criteria are complex and use a lot of medical terminology. Again, it is unlikely that participants can tell whether their anxiety is 'typical' or 'atypical'.

The Fix:

To participate, you must be older than 18. You must have anxiety when writing an informed consent. You should not participate if you have ever been hospitalized or treated in the emergency room for your anxiety.

There are many reasons why you may not be able to participate in this research study. It is important that you discuss your full medical history and all your medications with the study doctor. We must also review your medical record. The study doctor will determine if you can participate and will answer any questions you have. You may not participate if the study doctor feels that you have health problems that may make it unsafe for you. If your anxiety is caused by medications or by a disease, you may not be able to participate. Again, be sure to tell the study doctor your full medical history and all your medications.

3.2 How many people (subjects) are expected to take part in this study?

Required?: Required by UM IRBMED; 45 CFR 46.116 states this information shall be provided "when appropriate".

Tip: Be realistic, but aim high. It is better to say 'No more than 10' than to say '6' and have to amend the consent half way through!

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

Required?: YES. 45 CFR 46.116 requires 'a description of the procedures to be followed, and identification of any procedures which are experimental.

Good sources: A study 'calendar' may be more useful than the 'procedures' section of your protocol. IRB application Section 7 will also include this information

Tips:

This is the most difficult section to write for many studies. It is also one where you can be the most creative!

Do Not

...Be repetitive. If some procedures happen at every visit, consider identifying them separately.

... Limit yourself to words. This is especially true for studies with a complex design (multiple groups or visits that may change depending on labs). Consider adding a diagram, table, flowchart, or picture **in addition** to your description.

...Get locked in to one format. Procedures are usually presented chronologically, but other formats may be more useful, especially for long studies with many similar visits.

For instance, instead of going visit by visit, you can say, "You will have 24 visits. At 12 of the visits, you will have a procedure called an EKG. To do an EKG, you will...At 6 of the visits; you will have an exercise test. During an exercise test, this is what will happen..."

Of course, be sure to explain what each procedure entails. This type of format should usually be accompanied by a table or study calendar for clarity.

Do ...Consider what the participant would want to know.

...Avoid unnecessary details. Some things that are important to the researcher may not be important to the subject (for instance, participants probably don't care whether urinalysis is done by dipstick or microscopy. If participants must fill out questionnaires, they probably want to know the general topic area and the length of time it will take: they usually do not care what the names of the different questionnaires are).

BUT

...Remember the necessary details. Things that are routine for researchers may be important to participants (some people might not want to participate if they knew they had to be weighed at each visit. Participants also usually want to know exactly how many needlesticks will be involved.)

...This is the place to explain randomization and blinding, if they will be used.

Examples

Examples of poor sections are difficult to include, as they are usually prohibitively long! Here is a much-shortened example:

At visit 1 you will have your blood pressure measured while lying down and standing up. You will answer the questionnaires "Anxiety while writing", "overall anxiety scale" and "Stress and

Anxiousness Global Measure". Your blood will be drawn for tests of iron levels, creatinine levels, hematocrit levels, liver function and other tests. You will be Randomized to group A, B, or C

At visit 2 if you are in group A, your visit will occur in 4 weeks and you will have your blood pressure measured while lying down and standing up. You will receive your first dose of study drug.....If you are in group B, your visit will occur in 6-12 weeks, after you have been assigned a counselor, and you will have your blood pressure measured while lying down and standing up...

Problems?:

Repetition, unnecessary detail, randomization poorly explained, confusion due to multiple groups.

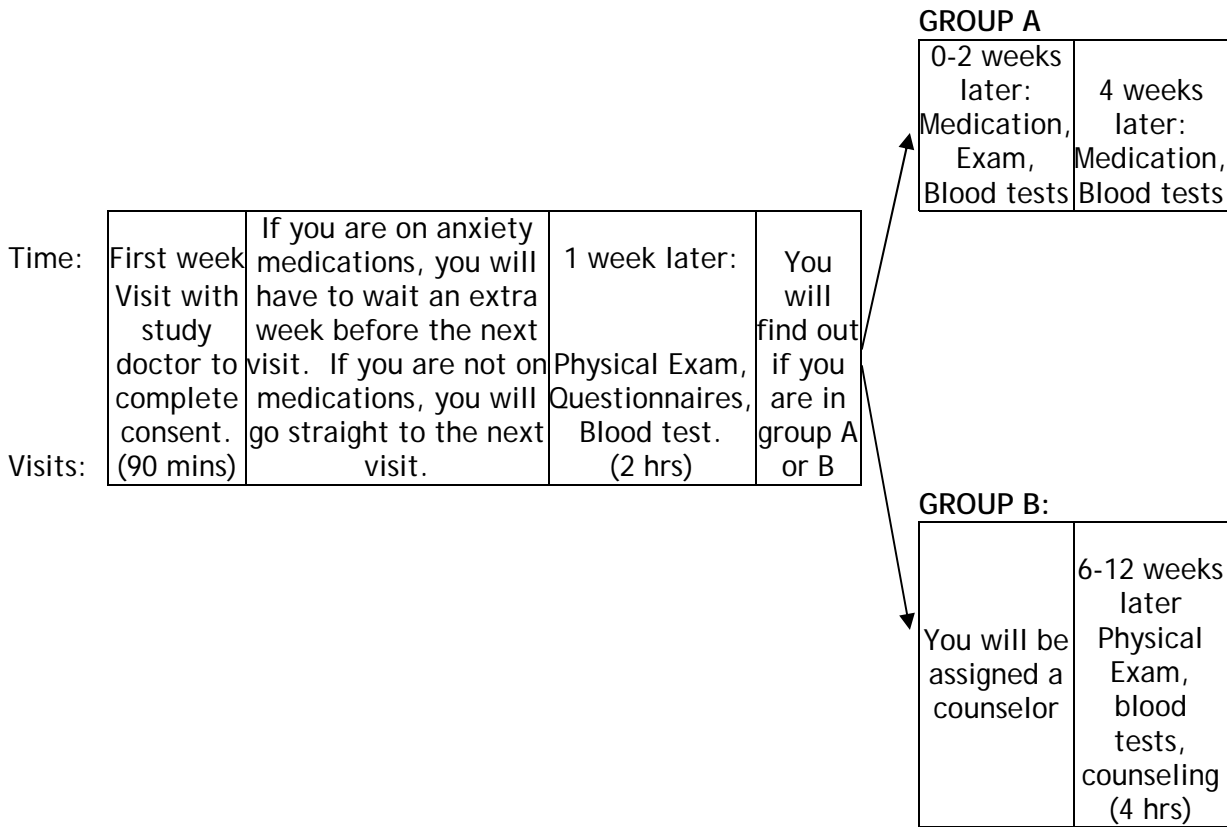
The Fix:

During the study, you will be randomized into one of three groups. Random means by chance, like flipping a coin. You have an equal chance of being in any of the three groups. Below is an explanation of what will happen at each visit, no matter what group you are in. Then there is a section explaining what extra things will happen depending on what group you are in. The diagram at the end of the section also shows what will happen in the study.

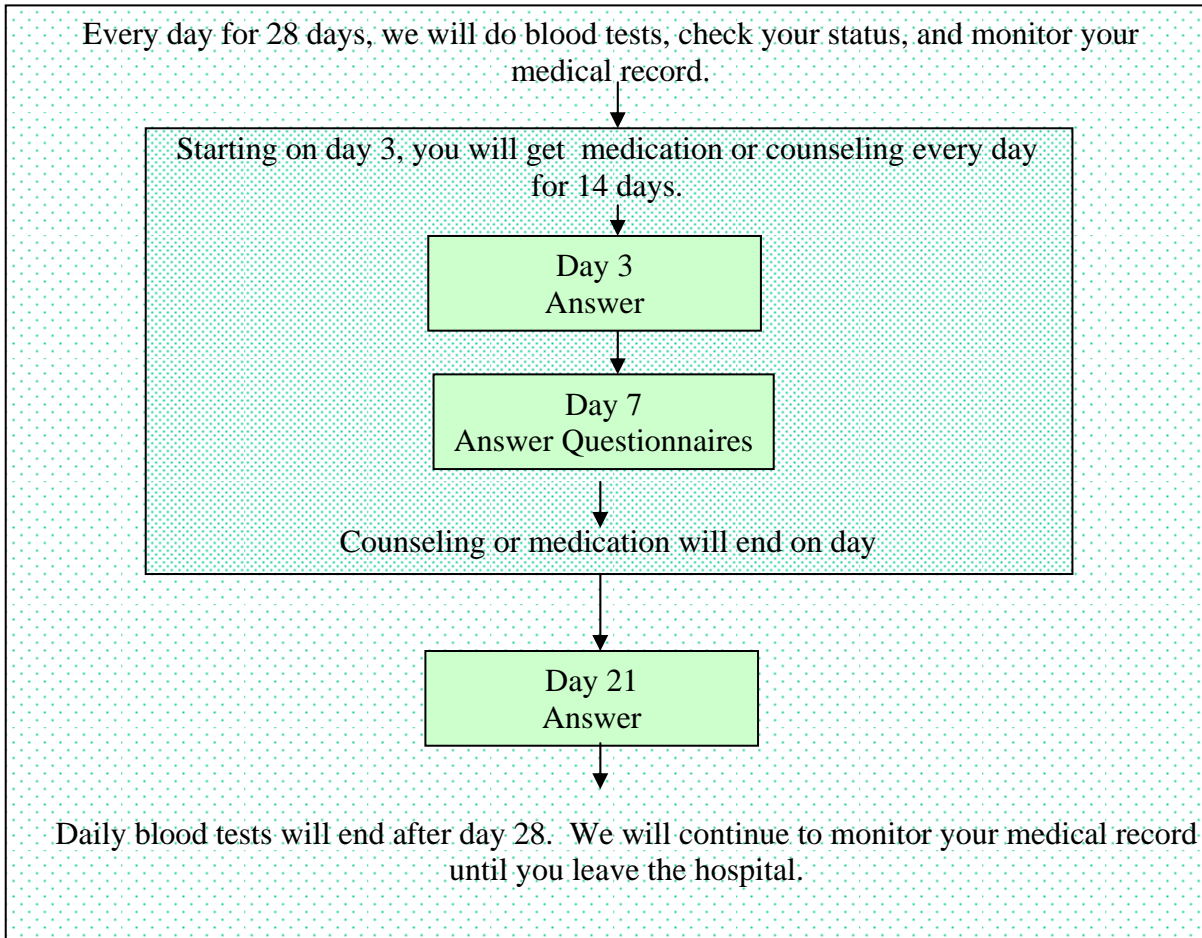
At every visit, you will have your blood pressure measured while standing up and lying down. You will have your blood drawn, using a needle, for standard tests of blood chemistry...etc.

Diagrams:

Diagrams can take many forms:



OR (for a different study design)



participation

in the study be over?

Required?: YES. 45 CFR 46.116 requires an explanation of the “expected duration of the subject’s participation”

Tip: Remember to include any follow-up periods. Researchers sometimes don’t consider follow-up visits part of the study, but participants do!

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Required?: YES. 45 CFR 46.116 (6) requires that for research involving more than minimal risk, the consent must give an explanation of whether there is any compensation and an explanation of medical treatments available if injury occurs. Explain these treatments and state where a subject may obtain further information.

Tips: Remember that most activities carry with them some degree of risk - even “just” filling out self-report forms. Do not overlook “soft” risks such as confidentiality and embarrassment.

Explain not only the risk but also the way the investigator is trying to reduce that risk.

Add the likelihood of occurrence (if possible). "The chance that you will get an infection is less than 1%." At the same time, be sure to explain numbers in lay language: "This means that usually, for every one hundred people who take the medicine, one will get an infection"

The IRB has some prepared language for certain tests, e.g., MRI.

Example:

No studies exist regarding the possible teratogenicity of study drug during pregnancy. However, it is not recommended during pregnancy due to androgenic effects.

You may be prescribed aspirin during the study. Aspirin may cause stroke, stomach upset, death, and allergic reaction.

With regard to adverse effects on the liver, there does not appear to be a relationship between changes in liver function (as reflected in clinical laboratory tests) and administration of study drug. The overall occurrence of adverse events in the liver and bile systems was low (0.5-0.6%).

Problems?

Use of scientific language.

No distinguishing between likely risks and extremely unlikely ones.

No information about what researchers may do to mitigate the risks.

The final example is a risk that is not a risk - it's not clear why it is included at all

Numbers are used but not explained in lay language.

One Possible Fix:

The possible effects of study drug during pregnancy on an unborn child or fetus are not known. It is not recommended during pregnancy because it may interfere with normal hormone levels during pregnancy.

You may be prescribed aspirin during the study. Aspirin frequently causes mild upset stomach. In extremely rare cases, it can cause stroke or severe allergic reaction leading to death. To reduce this risk, we will only prescribe aspirin if you do not have a medical history of any allergic reactions to aspirin or any bleeding problems, including stroke. You will be carefully monitored for side effects throughout the study.

Drugs are sometimes grouped into families. No two drugs in a family are exactly the same, but there are some similarities in their chemical structures. The study drug is part of a family of drugs that includes some medicines known to cause serious liver damage. However, patients receiving study drug have not shown increased risk of liver problems. It is considered very unlikely that patients in this study will develop liver problems due to study drug.

Additional Good Examples:

The known or expected risks are:

- 1) You may feel uncomfortable answering questions that contain personal information. You may elect not to answer those questions.
- 2) There is a small chance that you may experience a bruise, small amount of bleeding, pain, or infection at the site of the blood draw. To reduce this risk, only individuals educated in the proper and sterile technique of taking blood samples will draw your blood.
- 3) You may feel some dryness in your mouth and eyes from the medication. You can treat these symptoms with salt-water eye drops and by drinking lots of fluids or sucking on hard candies.

If applicable, also include: As with any research study, there may be additional risks that are unknown or unexpected (&/or 'to the embryo or fetus if the subject is or may become pregnant').

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

We do not address this section in detail in this talk. We recommend leaving this section as is or consulting your IRBMED specialist.

However, for sponsored studies, remember that no research participant can sign away their right to sue. The consent document is NOT intended to release the sponsor from liability, it is intended to protect and inform the subject. Be very careful not to include any language that may suggest to the participant that they are giving up their right to sue. It may even be helpful to add a sentence such as, "If you sign this form, you do not give up your right to seek additional compensation if you are harmed."

5.3 If I take part in this study, can I also participate in other studies?

Leave as is IF APPROPRIATE. If there is no risk to being in your study while being in another study (for instance a survey-only study), adjust this section as appropriate.

For instance: "You may still participate in this study, even if you are participating in other studies, and the risks to you will not change. However, you should always inform all the researchers of all the studies you are participating in."

5.4 How could I benefit if I take part in this study? How could others benefit?

REQUIRED?: YES. CFR 46.116 (3) requires a description of any benefits to the subject or to others which may reasonably be expected from the research.

TIPS: Include this as the first sentence:

You may not receive any personal benefits from being in this study.

"Society as a whole may benefit by knowledge gained in this study. The results of this study may help reduce anxiety for other study coordinators in the future."

Don't include: "You will receive \$100.00 for participating in this research project." This information is in section 8.2.

Be very cautious about including possible clinical benefits - if there is a chance the subject would be taking placebo, or if the drug is investigational, it is better not to mention clinical benefits at all.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

We do not address this section in this talk. We recommend leaving this section as is or consulting your IRBMED specialist.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Required?

Yes. 45 CFR 46.116 requires this section. However, there can be a wide variety in the level of detail you include.

Example:

There are many treatments for anxiety. Methotrexate is a medication commonly used to treat anxiety. Side effects include myelosuppression. Myelosuppression is a decrease in the ability of the blood cell-producing tissues of bone marrow to produce all types of blood cells. Other side effects include decrease in white blood cells that fight infection, decrease in platelets (may cause bleeding and/or bruising), fever, symptoms of infection, shortness of breath, nausea, vomiting, lymph node swelling, liver disease, including cirrhosis of the liver and lung inflammation or fibrosis. Methotrexate may also pose risks to the unborn child.

NSAIDs and aspirin are used to treat frustration headaches in patients with informed-consent-writing anxiety. Side effects include allergic reaction, stomach disorders, including gastrointestinal ulceration and bleeding, dark/black stools, upset stomach, nausea, vomiting, abdominal pain, swelling of the extremities and shortness of breath.

Problems:

This is probably overkill. Remember, it is your responsibility to keep the consent updated - are you going to be able to monitor emerging knowledge about these other medications and keep this section current? A shortened section would probably be better.

One Possible Fix:

You do not have to participate in this study to receive treatment for your anxiety. There are many treatments for anxiety. The most common treatments are methotrexate, drugs known as NSAIDs, and aspirin. Like all medications, these treatments have benefits and risks, including serious risks. If you are interested in other treatments, you should ask your doctor or the researchers.

Other Tips:

It is not required, but you may include referral to another study as one alternative.

For very simple studies, such as survey studies, a simple statement is all that is needed: Your participation is voluntary. If you decide not to participate, there will be no penalty to you. Ask the researchers about other options you may have.

If the medication used in your study is available by regular prescription, this section should make that clear - many participants assume that any medication used in a study is something they can't get from their doctor. One good sentence is, "You do not have to participate in this study to receive treatment for your anxiety, including treatment with the medication used in this study."

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

We do not address this section in this talk. We recommend leaving this section as is or consulting your IRBMED specialist.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

TIP:

Include: Information on side effects of withdrawing from medications or therapies too quickly.

Also include information on requirements related to termination visits or exit interviews.

Good Example: "If you are in the medication group, you could develop headaches if you stop the medication too quickly. The study is designed to give you smaller doses of the medicine as the study is finishing to avoid headaches.

If you are in the therapy group, there is no foreseeable harm to you if you stop the study quickly."

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Modify as appropriate, but do not delete.

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? If so, which costs? What happens if my insurance does not cover these costs?

TIP: Tell subjects if their insurance will cover any "usual and customary" care costs, or explain that all cost for the tests/therapy will be covered by the research study.

8.2 Will I be paid or given anything for taking part in this study?

Now you can tell them how much they will be paid!

TIPS: If an individual will be compensated for each visit, state it clearly. Remember that refusing appropriate compensation to those who leave the study early is not allowed.

"You will receive \$25.00 for each study visit. There are a total of 4 study visits so you may receive up to \$100.00. You do not have to complete all four visits receive payment. You will be paid \$25.00 each time you come in for a study visit."

8.3 Who could profit or financially benefit from the study results?

TIP: Delete this question and/or the subheadings if they do not apply.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

Section 9 may require minor modification as appropriate, but should be generally left unchanged for most studies. However, do read through it carefully - there are a number of bullet items that may need to be deleted because they do not apply to your study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Insert contact info.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Modify As appropriate.

12. SIGNATURES

Research Subject:

I understand (or - "I have been told") the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Just a quick final note: If you will not be using legal representatives for consent, or if your consent process does not include a witness, delete those signature boxes! It is pretty much guaranteed that sooner or later a subject (or a researcher) will sign in the wrong box if it is there!