INFORMED CONSENT:CONCISE PRESENTATION OF KEY INFORMATION

Emory IRB

2/14/2019

WHAT WILL BE COVERED IN THIS PRESENTATION?

- Common Rule's New Requirements- Key Summary
- SACHRP Recommendations
- New Templates
- Questions

REGULATION CHANGES:

Informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the **reasons why one might or might not want to participate** in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension, and provides sufficient **information that a "reasonable person" would want** to have. Informed consent as a whole must present information in sufficient detail relating to the research, and must be **organized and presented** in a way that **does not merely provide lists of isolated facts.**

WHAT IS "KEY INFORMATION"?

More Info In Preamble

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective subject or to others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

BUT NO OFFICIAL GUIDANCE YET

SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS (SACHRP)
Commentary on the New "Key Information" Informed Consent Requirements
October 17, 2018

The Secretary is responsible for regulatory oversight of the system for the protection of human subjects in biomedical and behavioral research supported or conducted by the Department of Health and Human Services (HHS).

SACHRP COMMENTARY

- Electronic consent, audio, or video presentations may best present key information
- Key information elements in preamble may not be sufficient: **Flexibility is key**
- May need to include other elements or information
- May exclude elements that won't help with subject understanding

SACHRP COMMENTARY: BENEFITS

- If applicable, include a statement that there are no direct benefits
- Otherwise include an ***accurate and specific*** description of potential benefit
  - For clinical research, keep in mind the potential for therapeutic misconception- study's primary goal is advancing knowledge and not delivering treatment
- Avoid unclear language
- Risks or potential benefits that would be used for decision on participation (in absence of more info) should be included

SACHRP COMMENTARY: RISKS

- Should refer to **the *most important risks*** with ***regard to frequency and magnitude***
  - Avoid exhaustive lists
- Clinical research: include how risks differ from standard of care
- Discomforts and inconveniences, rather than risks, might be key information (in SHB studies)

SACHRP QUESTIONS TO HELP IDENTIFY KEY INFORMATION

- What are the main reasons a subject will want to join this study?
- What are the main reasons a subject will not want to join this study?
- What is the research question the study is trying to answer? Why is it relevant to the subject?
- What aspects of research participation or this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject's expectations, or require special attention?

SACHRP QUESTIONS TO HELP IDENTIFY KEY INFORMATION

- What information about the subject is being collected as part of this research?
- What are the types of activities that subjects will do in the research?
- What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?
- How will the subjects' experience in this study differ from treatment outside of the study?
- In what ways is this research novel?

SACHRP COMMENTARY: LOGISTICS

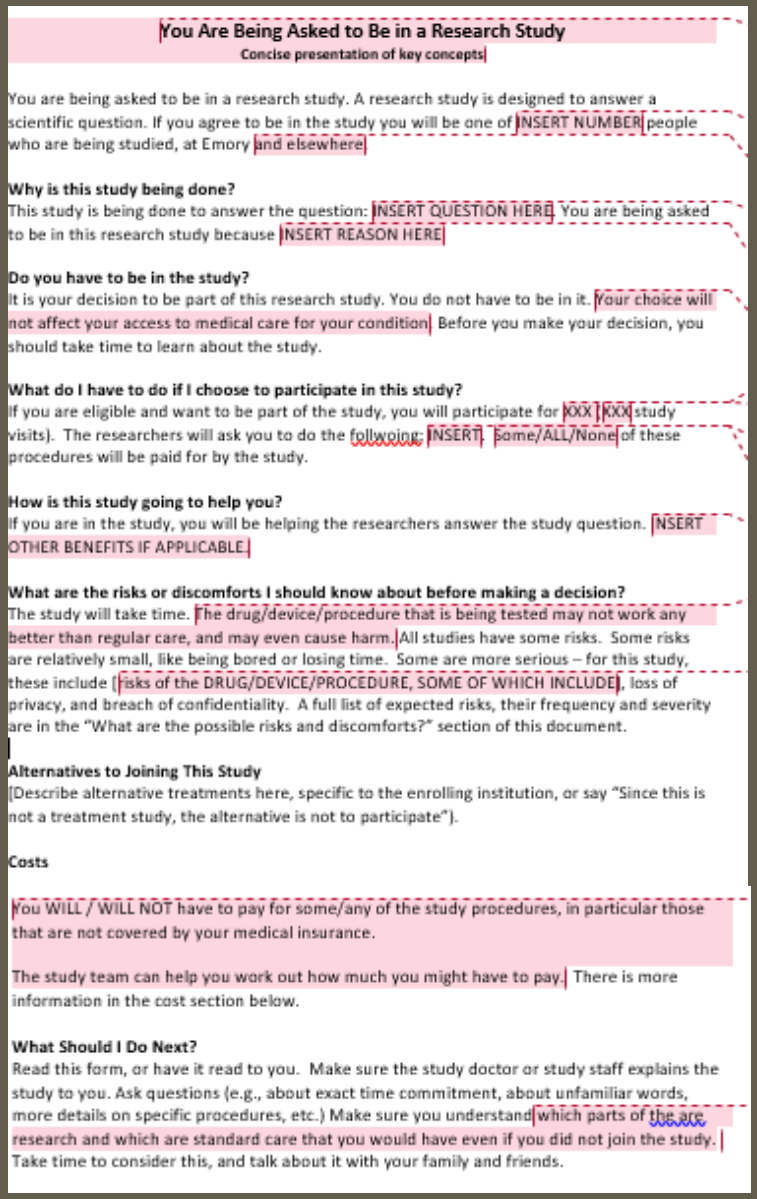
- Key information requirement will add to length of informed consent documents
  - No sections have been taken away
- Key information **does not need to be repeated** in body of document
  - Unless repetition facilitates understanding

SACHRP COMMENTARY: LOGISTICS

- Studies with simple design may have a concise enough informed consent document
  - For now, if your study **is federally funded**, you are **required to complete this section**
- For other studies not federally funded, the IRB will use discretion for documents that are only 1-2 pages
  - Document the highlights in summary: risks/benefits and reason for study

EMORY CONCISE SUMMARY TEMPLATE

Found in the website's consent toolkit



You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of [INSERT NUMBER] people who are being studied, at Emory [and elsewhere].

Why is this study being done?

This study is being done to answer the question: [INSERT QUESTION HERE]. You are being asked to be in this research study because [INSERT REASON HERE].

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. [Your choice will not affect your access to medical care for your condition.] Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for [XXX] [XXX] study visits). The researchers will ask you to do the following: [INSERT]. [Some/ALL/None] of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. [INSERT OTHER BENEFITS IF APPLICABLE.]

What are the risks or discomforts I should know about before making a decision?

The study will take time. [The drug/device/procedure that is being tested may not work any better than regular care, and may even cause harm.] All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include [risks of the DRUG/DEVICE/PROCEDURE, SOME OF WHICH INCLUDE], loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

[Describe alternative treatments here, specific to the enrolling institution, or say "Since this is not a treatment study, the alternative is not to participate").

Costs

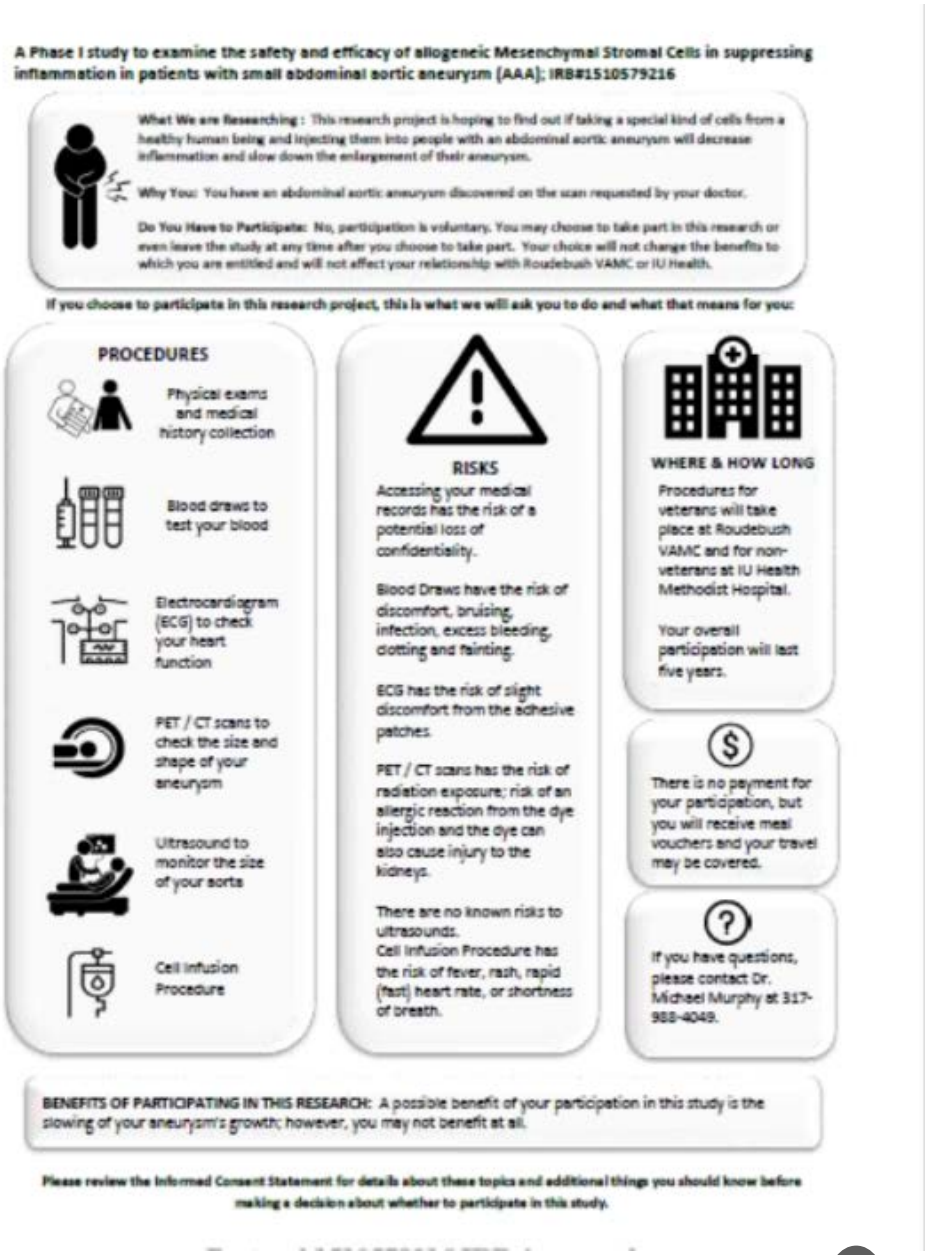
[You WILL / WILL NOT have to pay for some/any of the study procedures, in particular those that are not covered by your medical insurance.

The study team can help you work out how much you might have to pay.] There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand [which parts of the are research and which are standard care that you would have even if you did not join the study.] Take time to consider this, and talk about it with your family and friends.

OPTIONS TO ENHANCE READABILITY



A Phase I study to examine the safety and efficacy of allogeneic Mesenchymal Stromal Cells in suppressing inflammation in patients with small abdominal aortic aneurysm (AAA); IRB#1510579216

What We are Researching : This research project is hoping to find out if taking a special kind of cells from a healthy human being and injecting them into people with an abdominal aortic aneurysm will decrease inflammation and slow down the enlargement of their aneurysm.

Why You: You have an abdominal aortic aneurysm discovered on the scan requested by your doctor.

Do You Have to Participate: No, participation is voluntary. You may choose to take part in this research or even leave the study at any time after you choose to take part. Your choice will not change the benefits to which you are entitled and will not affect your relationship with Roudebush VAMC or IU Health.

If you choose to participate in this research project, this is what we will ask you to do and what that means for you:

PROCEDURES

- Physical exams and medical history collection
- Blood draws to test your blood
- Electrocardiogram (ECG) to check your heart function
- PET / CT scans to check the size and shape of your aneurysm
- Ultrasound to monitor the size of your aorta
- Cell infusion Procedure

RISKS

Accessing your medical records has the risk of a potential loss of confidentiality.

Blood Draws have the risk of discomfort, bruising, infection, excess bleeding, clotting and fainting.

ECG has the risk of slight discomfort from the adhesive patches.

PET / CT scans has the risk of radiation exposure; risk of an allergic reaction from the dye injection and the dye can also cause injury to the kidneys.

There are no known risks to ultrasounds.
Cell Infusion Procedure has the risk of fever, rash, rapid (fast) heart rate, or shortness of breath.

WHERE & HOW LONG

Procedures for veterans will take place at Roudebush VAMC and for non-veterans at IU Health Methodist Hospital.

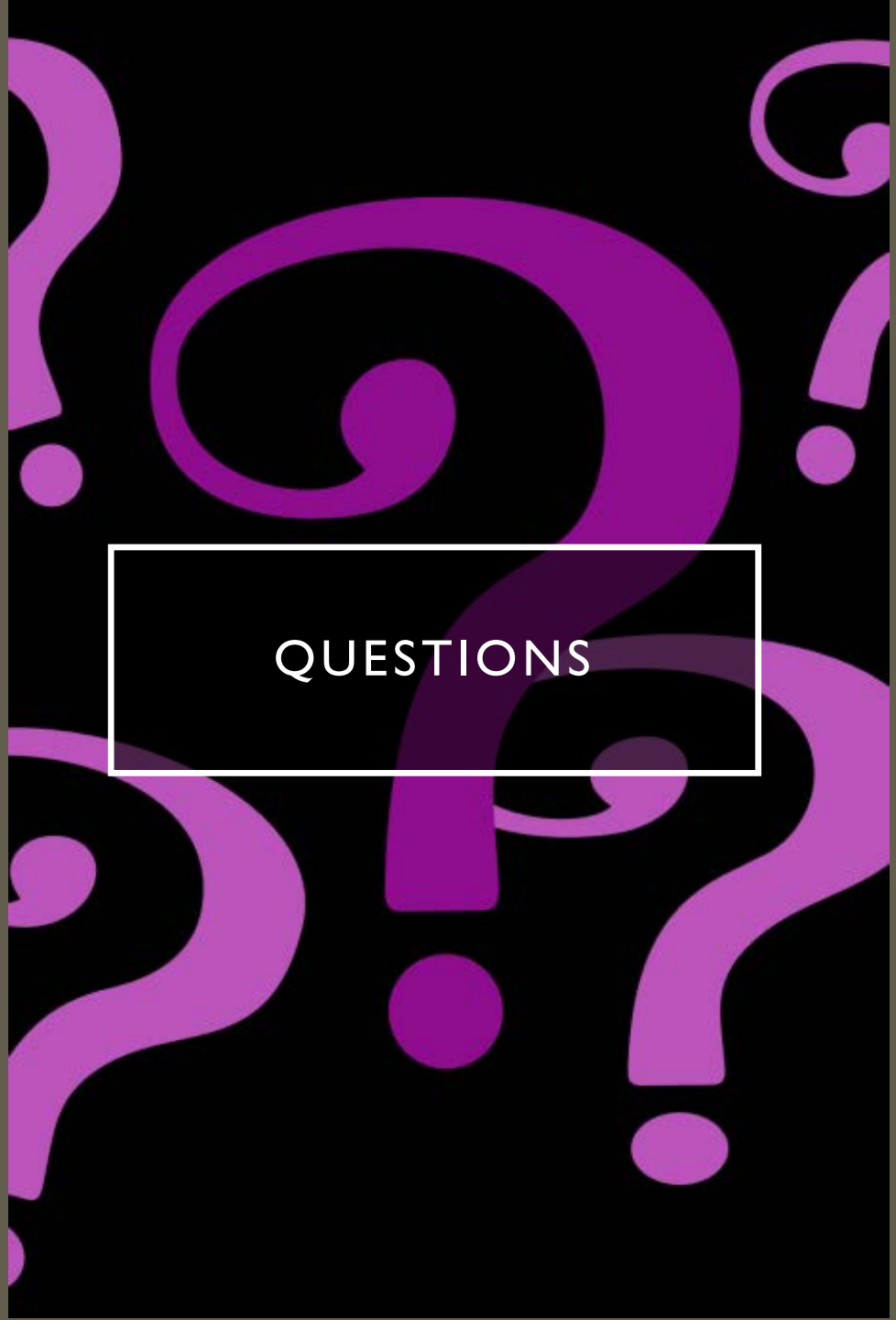
Your overall participation will last five years.

There is no payment for your participation, but you will receive meal vouchers and your travel may be covered.

If you have questions, please contact Dr. Michael Murphy at 317-988-4049.

BENEFITS OF PARTICIPATING IN THIS RESEARCH: A possible benefit of your participation in this study is the slowing of your aneurysm's growth; however, you may not benefit at all.

Please review the Informed Consent Statement for details about these topics and additional things you should know before making a decision about whether to participate in this study.


QUESTIONS

TEAM Q INFORMATION

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