AEREO Subcommittee on Key Information

Summary Report

March 2 2020

Subcommittee: Elisa Hurley, Susan Kornetsky, Megan Singleton, Holly Taylor

A. INTRODUCTION

This brief summary report is the product of an AEREO led effort to describe how HRPPs are addressing the new requirement that investigators include key information in their consent forms. What follows is a Background section noting the sources HRPPs have drawn Methods, Findings and Summary.

B. BACKGROUND

From CFR: "Except for broad consent obtained in accordance with paragraph (d) of this section: (i) 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." (Section 116. 5(i), FR p. Vol. 82, No. 12, p. 7265)

From preamble: "In general, we would expect that to satisfy §ll.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following: (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; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research, as required by § ll.116(a)(5)(i) and § ll.116(a)(4)." (FR p. Vol. 82, No. 12, p. 7214)

SACHRP Response to Question 2

"Examples of additional elements of consent or other information that might be key information in certain studies include:

- Essential study design elements such as randomization, the use of placebo, crossover design, or washout requirements from current effective treatments
- How the treatment in the trial is similar to or different from the clinical care the subject would receive if not in the trial
- Significant costs that could be incurred as a result of participation
- Compensation for injury
- How much time and/or how many research visits are required for participation
- Payments to subjects
- Impact on the subject's future clinical care. For example, whether use of an experimental intervention is likely to make a standard clinical intervention ineffective or unavailable after the study

• Potential impact on non-participants. Examples include caregivers, family members, children, partners and the public.
• Post-trial access to the experimental intervention"

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

C. METHODS

We requested that the 26 AEREO members leading or with easy access to the HRPP at their institution to provide templates, guidance and examples. 24 of the 26 responded with materials. We collected 21 Templates, 9 Guidance documents and 8 sets of examples. Two members of the sub-committee reviewed each set of documents. Findings are described below.

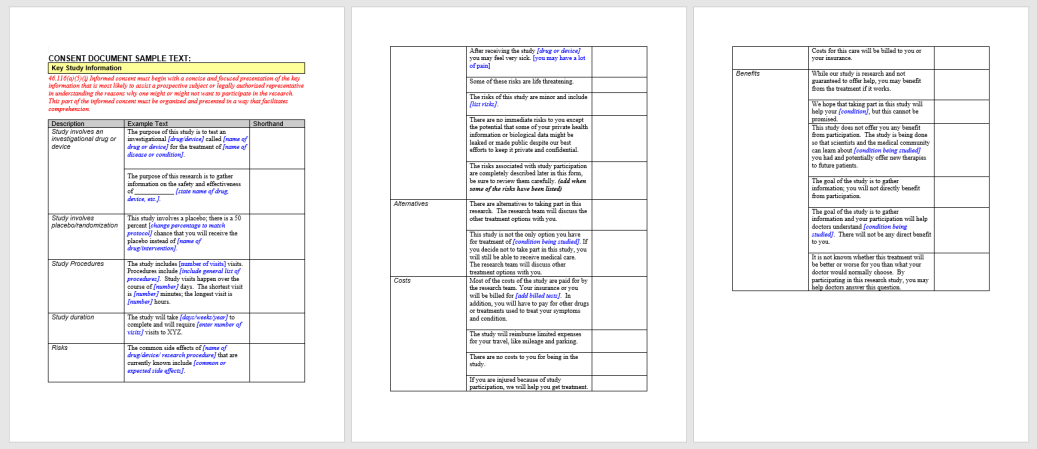
D. FINDINGS

1. TEMPLATES

- In absence of reference to specific categories of information considered key, some HRPPs have adopted the items listed in the Preamble to the new Common Rule and drawn from the list of what OHRP would expect to satisfy requirement for concise explanation:
    - (1) Voluntary; (2a) Purpose; (2b) Duration; (3) Risks; (4) Benefits; and (5) Alternatives
- Some have also drawn on SACHRP list of other elements.
- Some have included elements not on either list.
- Two additional recommendations (from regs):
    - Share information about why one might or might not want to participate
    - Present information in a way that facilitates understanding

Range of Formats:

1) Comprehensive, fill in the blanks with required language
2) Provide instructions rather than language
3) Non-directive, no suggested language (promote creativity)
4) Other



CONSENT DOCUMENT SAMPLE TEXT:

Key Study Information

46.116(a)(5)(i) 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.

Description	Example Text	Shorthand
Study involves an investigational drug or device	The purpose of this study is to test an investigational *[drug/device]* called *[name of drug or device]* for the treatment of *[name of disease or condition]*.	
	The purpose of this research is to gather information on the safety and effectiveness of _____ *[state name of drug, device, etc.]*.	
Study involves placebo/randomization	This study involves a placebo; there is a 50 percent *[change percentage to match protocol]* chance that you will receive the placebo instead of *[name of drug/intervention]*.	
Study Procedures	The study includes *[number of visits]* visits. Procedures include *[include general list of procedures]*. Study visits happen over the course of *[number]* days. The shortest visit is *[number]* minutes; the longest visit is *[number]* hours.	
Study duration	The study will take *[days/weeks/year]* to complete and will require *[enter number of visits]* visits to XYZ.	
Risks	The common side effects of *[name of drug/device/ research procedure]* that are currently known include *[common or expected side effects]*.	

	After receiving the study *[drug or device]* you may feel very sick. *[you may have a lot of pain]*	
	Some of these risks are life threatening.	
	The risks of this study are minor and include *[list risks]*.	
	There are no immediate risks to you except the potential that some of your private health information or biological data might be leaked or made public despite our best efforts to keep it private and confidential.	
	The risks associated with study participation are completely described later in this form, be sure to review them carefully. ***(add when some of the risks have been listed)***	
Alternatives	There are alternatives to taking part in this research. The research team will discuss the other treatment options with you.	
	This study is not the only option you have for treatment of *[condition being studied]*. If you decide not to take part in this study, you will still be able to receive medical care. The research team will discuss other treatment options with you.	
Costs	Most of the costs of the study are paid for by the research team. Your insurance or you will be billed for *[add billed here]*. In addition, you will have to pay for other drugs or treatments used to treat your symptoms and condition.	
	The study will reimburse limited expenses for your travel, like mileage and parking.	
	There are no costs to you for being in the study.	
	If you are injured because of study participation, we will help you get treatment.	

	Costs for this care will be billed to you or your insurance.	
Benefits	While our study is research and not guaranteed to offer help, you may benefit from the treatment if it works.	
	We hope that taking part in this study will help your *[condition]*, but this cannot be promised.	
	This study does not offer you any benefit from participation. The study is being done so that scientists and the medical community can learn about *[condition being studied]* you had and potentially offer new therapies to future patients.	
	The goal of the study is to gather information; you will not directly benefit from participation.	
	The goal of the study is to gather information and your participation will help doctors understand *[condition being studied]*. There will not be any direct benefit to you.	
	It is not known whether this treatment will be better or worse for you than what your doctor would normally choose. By participating in this research study, you may help doctors answer this question.	

2. GUIDANCE

Key messages included:

- Goal is to present information re: why subject may or may not want to participate
- Emphasis on creativity
- Need to tailor to study
- Focus on 5 domains
- Some note application to only Federally Funded/VA Sponsored vs. all consent forms

Length of guidance

Long

Medium

Brief

- No need to repeat in consent form, no need to provide key information is consent form itself is short.

3. EXAMPLES (*see pages to follow***)**

About 1/3 of our sample (n=10) include examples

In three cases, they use the same set of three, ABC-123 examples from Duke https://irb.duhs.duke.edu/forms/duhs-sample-consent

E. Summary

- Most AEREO participating institution are providing templates, but templates vary significantly in format and content.
- Wide variation in how directive the materials are regarding what do include (versus encouraging creativity)

S

Concise Summary

This is a research study to find out if a drug called ABC-123 is safe and to determine the safest, most effective dose of the drug.

Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via *i.v.* infusion in the clinic at Duke. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle. After two cycles, you will be evaluated and you may be able to continue receiving ABC-123 if you have had no bad reactions to the study drug or disease progression.

There are risks to this study drug that are described in this document. Some risks include: nausea, diarrhea, low white & red blood cell count, being tired & weak, fever, muscle pain and radiation risks from CT scans.

If you are interested in learning more about this study, please continue reading below.

Concise Summary

The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with ABC. Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to Duke's fitness center three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

Concise Summary

The purpose of this study is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and healthy children. The information we learn by doing this study may help us to develop some target treatments for GI complications in children with IBD.

Participants in this study will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from IBD and healthy children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire. Your child's participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There is a risk of bleeding after the tissue from the intestine is removed. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible.

If you are interested in learning more about this study, please continue to read below.

We are asking you to participate in the [redacted]

The [redacted] is a collection of samples (like blood, urine, and tissue) from individuals matched with their electronic medical record. The samples (without the names of the individuals) are shared with researchers who use them to find better treatments for diseases and health conditions.

Taking part in this study is voluntary

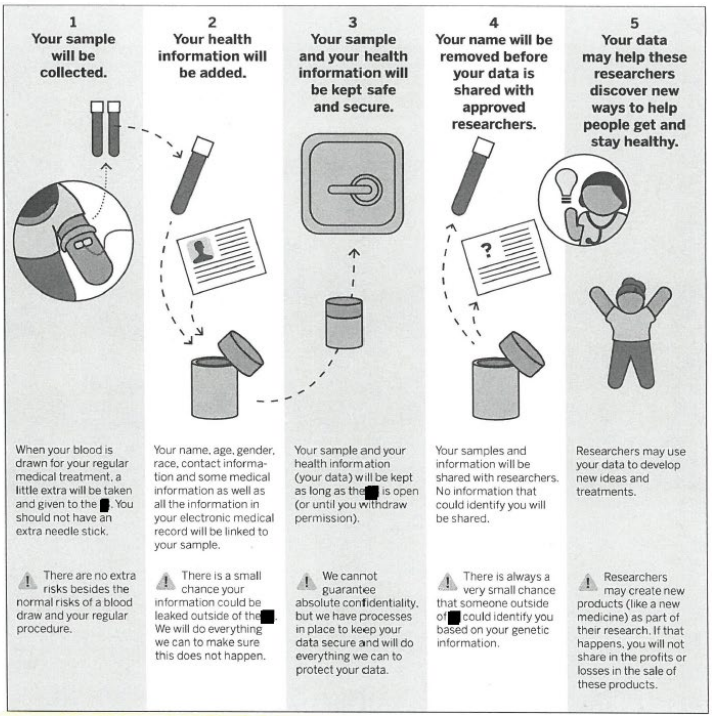
You will be asked to read this consent/authorization to use your samples and medical record information and decide whether you want to participate. You may choose not to take part in the study. You do not have to participate. Your choice will not affect your relationship with [redacted], and you do not have to sign this consent/authorization in order to receive treatments or benefits from [redacted] or [redacted]. If you do not sign this consent/authorization, you cannot participate. There is no cost to you for taking part. You will not receive any payment or benefit.

You can change your mind

You may leave the study and withdraw your permission to use your data at any time by writing to [redacted] If you do, your samples and the link to your health information will be destroyed. If your data has already been shared with researchers, they can keep using the information they have for research but the [redacted] will no longer have your information to share with anyone else.

You can ask questions

For questions about this study or to leave the study [redacted] about your rights as a research participant or discuss concerns, contact the [redacted] Human Subjects Office [redacted]



5a 2 of 2

What will happen in this study?

1. Your sample will be collected.

When your blood is drawn for your regular medical treatment, a little extra will be taken and given to the [redacted]. You should not have an extra needle stick for your donation.

2. Your health information will be added.

We will collect some personal health information about you such as your name, age, gender, race, contact information and some medical information. Your sample will be linked to your electronic medical record. [redacted] will give the [redacted] access to your medical record, including any mental health information, for this linking until the [redacted] is no longer open (or until you withdraw permission).

3. Your sample and your health information will be kept safe and secure.

Your sample and your medical record information together are your "data." The [redacted] gives each person a code number. The list of names and code numbers is kept at the [redacted] and only [redacted] staff can see it.

4. Your name will be removed before your data is shared wth approved researchers.

HOW YOUR INFORMATION WILL BE PROTECTED AND WHAT WILL BE SHARED

Researchers will see your data. The [redacted] will remove your name and other identifying information before sharing your data for research. Researchers who study your data will not know who you are because they will only see the code (no name or other identifying information). Those working on research projects will not have access to the list of names and codes.

One other kind of information about you that might be learned from your blood is DNA. DNA is what you inherit from your parents and pass on to your children. Every person's DNA is unique, so it could be used to identify you and unique things about you. However, there are rules on how people can use this information. This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law which generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and discriminate against you based on your genetic information. For more about GINA, visit: https://ghr.nlm.nih.gov/primer/testing/discrimination.

WHO YOUR DATA MAY BE SHARED WITH

Only researchers/research projects approved by the [redacted] steering committee may receive data for research.

Researchers may be from [redacted] other universities, government agencies (like the [redacted] State Department of Health), or private companies that work on developing new tests or treatments.

Any published results from research on your sample will not identify you.

OTHER ORGANIZATIONS THAT MIGHT ACCESS YOUR DATA

There are other organizations that may access [redacted] records and your information: the [redacted] Review Board (or its designees), and state or federal agencies with oversight responsibilities for this research, including the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH).

Some data may also be provided to a government health research database for broad sharing with researchers around the world, but the data will not contain any information which could identify you.

After your information is shared with the people and companies listed above, the law may not require them to protect your information.

You have the right to see and keep a copy of the personal health information collected during the study; however, to ensure the integrity of the study, you may not be given access until the study is complete.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the [redacted] NIH. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);

(2) if you consent to the disclosure, including for your medical treatment;

(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;

(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

5. Your data may help researchers discover new ways to help people get and stay healthy.

Your data could be used in many different ways such as:

- Study how genes (genes are part of your DNA) affect health or respond to treatment (this is why DNA is one of the things that might be shared).
- Better understand what keeps people healthy and what makes people sick.
- Create new medicines and/or vaccines.
- Create new ways to test for, treat, or cure illnesses.

You will not share in the profits or losses from any product or service created using your data.

The Indiana Biobank is not meant to support your clinical treatment. You will not receive any information based on researchers' use of your sample.

5c

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); [redacted]

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 [redacted]

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 [redacted]

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. [redacted]

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.