UT Health San Antonio
IRB Forum
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Informed Consent – Key Information
2018 Common Rule requirement for key information

• Consent must begin with a concise and focused presentation
  • At the beginning of the consent
• Key information most likely to assist the subject with an understanding of why one might or might not participate
• The information is organized in a way that will facilitate subject comprehension.
What are the elements of the key information?

- Statement that consent is being sought for research and participation is voluntary;
- Summary of:
  - The purpose of the research;
  - The expected duration of the prospective subject’s participation;
  - The procedures to be followed in the research;
- The reasonably foreseeable risks or discomforts;
- The benefits to the prospective subject;
- Appropriate alternatives procedures or course of treatment, if any that may be advantageous to the prospective subject.
Are all key information elements necessary?

• No
  • Brief
  • Content depends upon the research
  • Simple/minimal risk studies: 4 to 5 paragraphs
  • Complex studies: up to 2 pages
Is a concise summary containing key information required for a study with a simple design?

• No
  • If the consent form is only a few pages, it may meet the requirement of being clear and concise and also contain key information.
It is acceptable to omit or add key elements?

• Yes.
  • As long as the omission/addition **does not take away from subject understanding** or further **assists** a prospective subject or legally authorized representative **in understanding the reasons why one might or might not want to participate in the research**
Examples of additional key elements

• Research design
• Significant costs
• Impact on subject’s future clinical care
• Impact on non-subjects
• Post trial access to investigational intervention
Must all risks and benefits be included in the key information?

• No
  • Points to consider for including risk information
    • Risks information that will likely aid in decision-making
    • Risks with greatest impact (severity/frequency)
    • Discomforts and inconveniences
    • No direct benefits
    • Avoid using vague statements about receiving benefit
    • Listing risk/benefits in a pro:con format
Do key elements need to be repeated in the core sections of the consent?

• No.
  • Intent of the key information is to make consent more understandable and not to shorten or lengthen consent forms
  • If sections must be repeated, ensure that the repeated information assists with subject understanding
Does the Key Summary require a certain format?

• No
  • Consider using a bulleted outline format
  • Audio/Visual aids may be used
    • eConsent
    • Audio and Video presentations

Example: [https://youtu.be/AIzJDzOI9bc](https://youtu.be/AIzJDzOI9bc)
Title of Study: must match the title listed on the protocol EXACTLY

Concise Summary

[The informed consent process must begin with the Concise Summary. This section is intended to provide key information 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 Concise Summary is in addition to the requirement of reviewing the full informed consent document and obtaining signatures (if applicable).]

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

[Insert a short, 1-2 sentence summary of the purpose of the research. What do we know so far? What do we need to know? What is the study trying to accomplish?]

For more information, please see the Why is this Study being Done section below.

2. What will happen to me during the study and how is this different from continuing with usual care?

What are all my options for treatment, including the pros and cons?

[Insert a short, high-level summary of the main research activities. Include differences between the various therapies being tested, explain procedures that would not be part of typical care (i.e. study only procedures, questionnaires, data collection, randomization). Include appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Highlight the trade-offs (i.e. aggressive vs. less aggressive).

The Institutional Core Facilities are resources of the Office of the Vice President for Research.
Key Summary Example 1

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 IR. You should not have an extra needle stick.
   - There are no extra risks besides the normal risks of a blood draw and your regular procedure.
   - There is a small chance your information could be leaked outside of the IR. We will do everything we can to make sure this does not happen.

2. Your health information will be added.
   - Your name, age, gender, race, contact information and some medical information as well as all the information in your electronic medical record will be linked to your sample.

3. Your sample and your health information will be kept safe and secure.
   - Your sample and your health information (your data) will be kept as long as the IR is open (or until you withdraw permission).
   - We cannot guarantee absolute confidentiality, but we have processes in place to keep your data secure and do everything we can to protect your data.
   - There is always a very small chance that someone outside of IR could identify you based on your genetic information.

4. Your name will be removed before your data is shared with approved researchers.
   - Your samples and information will be shared with researchers. No information that could identify you will be shared.

5. Your data may help these researchers discover new ways to help people get and stay healthy.
   - Researchers may use your data to develop new ideas and treatments.

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Key Summary Example 2

**WHO**
- You are invited to take part in a voluntary research study being conducted by Dr. Teresa Zimmer and her research associates because either: 1) you are going to have surgery for pancreatic cancer or another condition (e.g., hernia repair), or 2) you have pancreatic cancer that cannot be treated by other means, such as chemotherapy.

**WHY**
- We want to learn more about why some people with pancreatic cancer experience cachexia (muscle wasting) while others do not, and with the hope of identifying markers (proteins or genes) in blood, fat, fluid, or tumor tissue that may provide information to control muscle wasting and help future patients.

**WHAT**
- **Study Procedures**: completion of a survey, medical record review, and specimen collection (blood, muscle, fat, fluid and/or tumor tissue) for analysis of certain characteristics.
- **Risks**: bleeding, discomfort, or infection which could occur as a result of blood draws and tissue collection.
- **Benefits**: You are not likely to receive direct benefit from participation.
- **Options**: You do not have to participate in the research to receive treatment.
- **Payment**: You will not receive payment for taking part in this study.
- **Cost**: Blood draws and tissue collection will be covered by the study.

**WHERE**
- Study procedures will be carried out at University Hospital, Sam Caner Center, or Eskenazi Health, depending on where you routinely receive care.

**WHEN**
- **Surgery participants**: Collection of specimens will be performed at the time of your surgery; blood sample collection and survey completion will be done at surgery follow-up visit at approximately 3 weeks, one month, and one year after your surgery.
- **Non-surgery participants**: Blood sample collection and completion of surveys will be done approximately once every 8-12 weeks during regularly scheduled clinic visits for as long as you are receiving treatment.

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UT Health San Antonio Research
Key Summary Example 3

**STUDY SUMMARY**
If you agree to participate in the study, you will attend up to three yearly visits with the study team that can be split over multiple days. The following things will happen during the study:

<table>
<thead>
<tr>
<th>Research procedures</th>
<th>Potential risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood draws</td>
<td>You might experience anxiety, pain and/or bruising from the needle stick.</td>
</tr>
<tr>
<td>Lumbar puncture (optional)</td>
<td>You might experience temporary back pain and a headache (lumbar puncture).</td>
</tr>
<tr>
<td>MRI scans</td>
<td>You might experience anxiety from being in a small space, or displeasure from hearing loud noises (MRI scans).</td>
</tr>
<tr>
<td>PET scans</td>
<td>You will be exposed to radiation (PET scans).</td>
</tr>
<tr>
<td>Experimental dye, used in the PET scan to help us see your brain</td>
<td>The most common, usually mild, side effects include diarrhea, headache, and a weird taste in your mouth.</td>
</tr>
<tr>
<td>Learn the result of your PET scan</td>
<td>Learning the results of your scan may be upsetting to you, whether it is positive or negative.</td>
</tr>
<tr>
<td>Questionnaires, cognitive testing and genetic testing</td>
<td>Anxiety, frustration, stress or boredom during testing. Learning your genetic result may upset you.</td>
</tr>
</tbody>
</table>
Scenario 1 – Minimal risk research
Scenario 1 – Minimal risk study

The purpose of the study is to examine relationships between and among measures of physical activity and health-related outcomes in an age 65 years and older. The study will include two study visits (2-hour each) where subjects will undergo physical and cognitive performance tests and self-reported assessments regarding pain, function, diet, and perceived quality of life. The first visit will include physical and cognitive test and the second visit will include the assessments. Risks are minimal to the subject; however, include temporary pain, discomfort over level of performance, anxiety prior to or after testing, and falling.
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Key Summary – Scenario 1

- **Statement of Research**
  - The purpose of the research study is examine relationships between and among measures of physical activity and health related outcomes in an ages 65 years and older.

- **Purpose**
  - If you agree, you will participate in two study visits (2 hour each) you will undergo physical and cognitive performance tests and self-reported assessments regarding pain, function, diet, and your perception of your quality of life.

- **Procedures**
  - Your participation is completely voluntary. You may choose not to answer a question or are free to withdraw consent and discontinue participation in the interview at any time for any reason without penalty or loss of benefits.

- **Duration**
  - Risks may include temporary pain, discomfort over level of performance, anxiety prior to or after testing, and falling.

- **Voluntary**
  - There are no direct benefits for taking part in this study.
Scenario 2 – Greater than minimal risk study
Scenario 2 – Greater than Minimal Risk Study

This is a Phase 2, randomized, double blind, double dummy study in which subjects with Condition A. This study will compare efficacy of Study Drug A versus Study Drug B as measured by the proportion of subjects demonstrating platelet and white blood cell (WBC) control. Group A will receive Study Drug A at a dose of 15 mg orally twice daily and Group B will receive Study Drug B at a dose of 10 mg orally twice daily. Subjects will be blinded during the 36 weeks of study treatment. After this treatment period, subjects will cross over to receive the opposite intervention for 36 weeks. Total subject participation will be 72 weeks. Procedures include bone marrow biopsies, blood draws, pharmacokinetic and biomarker blood draws, subject-diary completion, measurements of vital organs, and urinalysis.
We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary. This research study will compare efficacy of Study Drug A versus Study Drug B as measured by the proportion of subjects demonstrating platelet and white blood cell (WBC) control.

If you take part in this research study, you will be randomly selected to receive Study Drug A or Study Drug B. No matter which Study Drug you receive, you will be asked to take this medication twice per day at certain times during the day. After 36 weeks you will be allowed to receive the Study Drug that you did not receive in the first part of your study. Your total study participation will last 72 weeks and will include the following additional procedures: bone marrow biopsies, blood draws, at-home diary completion, measurements of vital organs, and urine tests. A schedule of when these procedures will occur will be provided to you in the information which follows this summary.

Your participation is completely voluntary.

There are some risks and discomforts associated with participating in this research study. The most severe risks are associated with the bone marrow biopsy which include pain, bleeding, bruising, dizziness, scarring and a small risk of infection. Additionally, there may be side effects from the numbing medication that is used during the procedure. Study drug A and B have similar risks. The most common side effects include: urinary tract infections, weight gain, flatulence (gas), constipation, high blood pressure, sore throat, constipation, cough, swelling in hands and feet, joint pain, weakness, and nausea. The more serious side effects include: the development of secondary cancer, inflammation of the heart, fast heart beat leading to heart damage, and increase hemorrhagic events. This may cause you to have unscheduled visits.

You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

You can get standard care for your condition even if you decide not to be in this study.
Summary

• Key information:
  • Is most likely to assist the subject with an understanding of why one might or might not participate
  • Meant to be brief
  • Elements depend upon the research study
  • Employ visual and audio aids that help facilitate subject understanding
References

- [2018 Requirements](#)
- SACHRP Commentary on the New “Key Information” Informed Consent Requirements - [Attachment C - New "Key Information" Informed Consent Requirements](#)
- Concise Presentations by Amy Waltz, Indiana University
- Stand Up to Cancer: Cancer Clinical Trials: Informed Consent [Youtube]