**EXAMPLES OF CONCISE SUMMARY/KEY INFORMATION FOR**

**SOCIAL BEHAVIORAL STUDIES**

**4 examples are provided on the following pages, you may pick one or create a combination of any of the below**

*The primary intent of the Concise Summary, or Key Information, is to provide potential subjects with a brief, but complete, summary of the study purpose, duration, procedures, risks and benefits in order to make an informed decision on whether or not to participate. Some people may be able to make a decision to not take part from the Concise Summary alone without spending the additional time to go over the entire consent document. However, the Concise Summary is not intended to take the place of a full consent or discussion of the study. Please note that relatively short consents may be considered as a Concise Summary in and of themselves and will be determined on a case by case basis. The examples below are examples only but contain the required elements necessary for a Concise Summary.*

*If you are unsure regarding requirements for your study, please contact the IRB Office for further guidance (**Irb@uthscsa.edu* *or 210-567-8250).*

**Example 1:**

|  |  |
| --- | --- |
| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of the study is to compare ABC therapy with 123 therapy for the treatment of XXX. |
| **Duration** | You will have one study visit twice a week for 12 weeks, for a total of 24 visits. |
| **Overview of Procedures** | You will come to a screening visit that includes obtaining your medical history and completion of cognitive-behavior and quality-of-life surveys. If you are eligible and enroll in the study, you will be randomized (like the flip of a coin) to one of two therapy programs. Both of these therapy programs are similar for treating your condition, but use different techniques during each therapy session.  |
| **Risks** | The most likely risk is that you may feel uncomfortable answering some of the questions on the surveys or in the therapy sessions. These risks are similar to what you would encounter if you were in therapy without being in this study. Another risk is a breach of confidentiality, but the researchers have taken steps to keep your information secure.  |
| **Benefits** | You may benefit if the physical therapy program helps treat ABC. |
| **Alternatives** | The therapies used this study are available to you without taking part in the study. Other therapy plans may also be available. You may discuss these options with your therapist.  |

**Example 2:**

|  |
| --- |
| * **Statement of Research** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is \_\_\_ [a brief description]
* **Duration.** It is expected that your participation will last \_\_\_ [the time commitment]
* **Procedures and Activities.** You will be asked to \_\_\_ [a brief description of what will occur]
* **Risks:** The risks or discomforts associated with this research include \_\_\_ [a brief description of the foreseeable risks – consider listing the primary risks of being in this study]
* **Benefits:** As a result of your participation, you can anticipate \_\_\_ [a brief description of what will occur], or: There is no expected direct benefit to you for taking part in this study.
* **Alternatives:** [only include if this is a therapeutic study and there are other alternatives – if the only other option is to not take part in the study, then omit]
 |

**Example 3:**

**Concise Summary**

**Participation is Voluntary**

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand.

**Study Purpose**

*[Include a brief statement (i.e. no more than 3 sentences) of the study purpose]*

The purpose of this research study is to *[Complete this sentence] Example: …see if mindfulness skills help decrease depression symptoms.*

**Study Procedures**

*[Include a brief yet complete summary (i.e., no more than 3 sentences) outlining study procedures. A detailed description will follow below in a subsequent section.]*

*Example: You will complete a series of questionnaires related to quality of life, a depression screening and a cognitive behavioral assessment. You will then be scheduled to attend 4 visits to practice mindfulness skills. At the end of each visit, you will complete the series of questionnaires again.*

**Expected Duration**

*[Include a brief statement (i.e. no more than 3 sentences) of the time commitment required]*

Your part in this study will last about XXX hours/ weeks/ months and will include XXX visits.

*Example: …1 hour for the first visit and 1½ hours for the remaining visits over 5 weeks. There will be 5 study visits.*

**Risks of Participation**

*[Include a brief summary of the* ***main risks*** *(i.e., no more than 3 sentences) for participants on this study. A detailed description will follow below in a subsequent section.]*

The main risks of participation include…XXX, XXX. *Example: …discomfort in answering some of the questions on the questionnaires or participating in the mindfulness activities. If you are uncomfortable answering some of the questions, you may discuss this with your study doctor or skip those questions. There is a small risk that your private information could be shared with others who are not part of your study team, but the research team will take precautions to keep your information secure.*

**Benefits**

*[Include a brief statement (i.e., no more than 3 sentences) of the benefits to the participant and/or possible benefits to science or society.]*

*[If direct benefit to the subject is anticipated]* The possible benefits you may experience from the procedures described in this study include *[Complete this sentence – the description of subject benefits should be clear and not overstated] Examples: increase reading comprehension; improved writing skills; learning about ways to improve your memory*

*[If no direct benefit to the subject is anticipated]* You will not directly benefit from participation in this study.

*[Include a brief statement (i.e., no more than 3 sentences) of the possible benefits to science or society] Examples: greater understanding of how stress influences memory*

**Alternatives**

*[Include a brief statement (i.e., no more than 3 sentences) of alternative procedures]*

The known alternative procedures include XXX, XXX, or XXX.

*[If no alternatives other than NOT taking part, omit this section]*

**Example 4:**

**Concise Summary**

You are being asked to take part in this research study because you have XXXX. *Briefly include the major reasons why the subject is being approached to participate. For example, “…you have been diagnosed mild cognitive impairment.”*

This is a research study to learn more about how XXXX effects/relates to/changes XXXX.

You will be asked to come for XXX study visit(s) that will (each) last about XX hours. If you take part, you will be asked to (*this listing of procedures should be limited to the most burdensome and/or main procedures that a reasonable person would want to know*):

* Complete cognitive function tests and questionnaires;
* Have a research blood draw;
* Perform computer tasks.

The main risks of this study are from the cognitive assessments. These include fatigue and embarrassment.

You will/not benefit directly from participating in this study *(if there are direct benefits, describe them)*.

Participation in this study is voluntary. If you do not choose to take part in this study, you can discuss other options with your doctor. You may also be eligible for a different research study *(only if applicable)*.

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