Permission to Take Part in a Human Research Study

Title of research study: Using the New Consent Form Template

IRB Protocol Number: 99-9999

Investigator: Jane Smith, PhD

Purpose of the Study

This is not the consent form template; do not use this document to create your consent form. The purpose of the document is to provide a visual frame of reference and supplemental instructions for using the consent form template. Do not let the size of the consent form template intimidate you. The template provides sample text and information for multiple research scenarios. It is likely that some of the information provided will not apply to your research. If that is the case, use what you need and simply delete the rest. This sample consent form uses some, but not all, of the language available.

We encourage you to download the consent form template from the IRB website every time you need to create a new consent form to ensure that the most up-to-date information is included. Also, it is not a good idea to “recycle” old consent forms into new ones as no two studies are exactly the same (important information may be left out) and cut/paste errors are likely to occur.

Finally, pay attention to grammar and formatting. The consent form is the public face of your research. Misspelled words and formatting issues look sloppy, suggest a lack of concern, and do not instill confidence in your work.

We invite you to take part in this research study because you are a researcher at CU Boulder.

We expect that you will be in this research study for two hours. We expect 500 people will be in the research study.

Explanation of Procedures

How your Explanation of Procedures section will look depends on the nature of your study. Studies with one visit of simple procedures may only need one paragraph to adequately describe the procedures. Studies that have multiple visits or a few visits with multiple components may need more description.
This section is where you describe what subjects can expect to “do” as a subject in your research study. Using non-technical, lay language is very important. If you give subjects a copy of this consent form to take home with them, they should be able to read it, without a researcher present, and understand what they are expected to do.

Visit 1
If you have multiple visits, it is a good idea to break them down visually so it is easy to understand.

Visit 2
Let subjects know how much time will elapse between each visit. For example: Visit 2 occurs 3 days after visit 1. During this visit you will…and proceed with describing what will happen. If you want to further break this down, you can: The following activities will occur during Visit 2:
  • Questionnaire – it asks basic demographic information like age, gender, and ethnicity.
  • Blood draw – we will prick the tip of one of your fingers and collect a couple of drops of blood.
This visit should take about 20 minutes to complete.

**Voluntary Participation and Withdrawal**

Whether or not you take part in this research is your choice. You can leave the research at any time and it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

If you are a CU Boulder student or employee, taking part in this research is not part of your class work or duties. You can refuse to enroll, or withdraw after enrolling at any time, with no effect on your class standing, grades, or job at CU Boulder. You will not be offered or receive any special consideration if you take part in this research.

**Risks and Discomforts**

If you only have one or two risks to describe, you may only need one paragraph. If there are several risks to address, you may want to describe each in its own paragraph, or you can display the risks in table format.

It is important that you tell the Principal Investigator, Jane Smith, if you think you have been injured as a result of taking part in this study. **You can call her at 999.999.9999.**

**Potential Benefits**

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include knowing your blood sugar level.

**Confidentiality**

Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the University of Colorado Boulder Institutional Review Board (IRB), Free Money Institute, and others who are
responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Office for Human Research Protections. The information from this research may be published for scientific purposes; however, your identity will not be given out.

There are some things that you might tell us that we CANNOT promise to keep confidential, as we are required to report information like:

- Child abuse or neglect
- A crime you or others plan to commit
- Harm that may come to you or others

**Payment for Participation**

If you agree to take part in this research study, we will pay you a total of $10.00 for your time and effort. You will receive $5.00 for completing the questionnaire and $5.00 for the blood draw. Payments will be made in cash at the end of the visit in which the procedures occur. If you leave the study early, you will be paid for the procedures you complete.

**Contact for Future Studies**

We would like to keep your contact information on file so we can notify you if we have future research studies we think you may be interested in. This information will be used by only the principal investigator of this study and only for this purpose. Please initial your choice below:

___ Yes, you may contact me for future research studies. The best way to contact me is: (enter preferred telephone number and/or email address)

_______________________________________________________________

___ No, you may not contact me for future research studies.

**Questions**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 999.000.1111 or email@address.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.
Signatures

Your signature documents your permission to take part in this research.

____________________________________          Date
Signature of subject

____________________________________
Printed name of subject

____________________________________          Date
Signature of person obtaining consent

____________________________________
Printed name of person obtaining consent