Information Sheet Template Instructions

(This template is for either clinical trials or clinical research)

Notes to Researchers:

1. Please note that this is a template modified to assist the Principal Investigator in the design of their Information Sheet for Participants. It is important that Principal Investigators adapt their own Information Sheet to the requirements of their particular study.

2. Delete the instruction page prior to IRB submission.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and **must not be included in your consent forms**.
   - examples are provided in blue italics.

5. When writing the consent form, remember the following:
   - The consent document is an invitation to participate in a research study that should be composed in second person with complete grammatically correct sentences. Additionally, scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
   - Language used throughout form should be at the level of a local student of class 6^{th}/8^{th}
   - Use reader-friendly formatting so that your document *looks* easy to read (i.e. wide margins and bullet points).
   - Make sure that a version number and/or date is used

TEMPLATE ON FOLLOWING PAGE

UNIVERSITY OF SOUTH ALABAMA
CONSENT FORM FOR RESEARCH

[Insert title of the study]

[Name of Principal Investigator]
[Name of Organization]
[Address of Organization]
[Contact information of PI]

INTRODUCTION

Briefly state who you are and explain that you are inviting them to participate in the research being conducted. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later. It as a federal regulation that you clearly state the study is research and that it is voluntary.

(Example: You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please ask if there is anything that is not clear or if you would like more information.)

WHAT IS THE STUDY ABOUT?

Explain the overall aim of the study. When describing the study take care to be as neutral as possible and avoid suggesting any bias about what you expect the outcomes from the research to be. If the research is being undertaken as part of a course of study state what qualification will result from the process.

(Example: Forces in Mind Trust (FiMT) has commissioned this piece of research to understand what more can be done to support the Armed Forces Community (ex-Services personnel, spouses and Reservists) in pursuing self-employment and thereby help to increase their chances of a successful and maintainable transition from the military. This research seeks to fill the current gap in knowledge and contribute to policy-making and service delivery.)

DO I HAVE TO TAKE PART?

Explain that participation is completely voluntary and that the person has the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever.

(Example: It is entirely up to you to decide to participate. You will be free to withdraw from the study at any time, without giving a reason.)

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Explain what taking part in the research will involve including a list of topics that you will discuss and the expected location and duration of participation. If you plan to use audio-recording discuss that also.

(Example: If you are happy to take part after reading this information sheet, please fill in the questions on the webpage and then send the form to us. Your answers will be anonymous and cannot be linked back to you.)

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?
Give a frank and realistic assessment of the possible benefits of the research – do not oversell what the research will achieve. Consider any possible physical or psychological harm that may come to a participant as a result of participating in the research and what you will do should such a situation arise.

(Example: There are no anticipated risks to you as a research participant. In terms of benefits, it is anticipated that the final report will be made available to all participants: this will provide anonymised data on all participants' experiences of self-employment, highlighting the successes and failures, and so give current and future self-employed ex-Service personnel the opportunity to learn from others.)

WILL I GET ANYTHING TO DO THE STUDY?
Describe any payment or incentives for participating in the research study that will be offered to all participants. This may be as compensation for time and effort or as an incentive to participate. Incentives must be minor and may not constitute undue influence to participate. If the incentive involves entering a drawing for a prize, describe the drawing, prizes, and approximate likelihood of winning. The contact information of the participant must be separate from the project. If there is no payment, provide a statement that they will not be compensated or offered any incentives for their participation.

(Example: You will not be compensated for being a part of this study)

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?
Outline fully and realistically your plans for the dissemination of the final research product including conferences, publications and teaching use. If your plans for the research only consist in submitting your dissertation then simply state this.

(Example: The results of the study will be published in a final report and also a peer-reviewed article will be prepared for publication in an academic journal. FiMT is responsible for the publication of the final report but we would anticipate that all participants will be sent a copy, if they wish.)

WILL TAKING PART IN THIS STUDY BE CONFIDENTIAL?
Explain what steps you will take to ensure the confidentiality and anonymity of the participant and any individuals they talk about.

(Example:We will follow strict ethical and legal practice and all information about you will be handled in confidence. All data and summarised notes will be anonymised and will be stored securely in a password-protected folder at IER. All participants will be given a pseudonym or sequence number for the purposes of reporting, and any identifiers removed to ensure confidentiality. All contact details and consent forms will be safely stored and then destroyed securely. Only the researchers will have access to the data.)

WHO SHOULD I CONTACT FOR MORE INFORMATION?
Provide the name, affiliation and contact details of all researchers involved as well as supervisor details where relevant.

(Example: If you have any questions about any aspect of the study, or your participation in it, not answered by this participant information sheet, please contact: xxx@southalabama.edu)

Additional Information

You can withdraw at any time without consequence. Please contact me at _____ or the Institutional Review Board at the University of South Alabama at (251) 460-6308 if you have questions about your rights as a research subject.