NOTE: IRB strongly encourages the use of this template for consent documents. Research has shown that the Q and A format is more understandable to participants. It also assists investigators to determine they have covered all the elements of informed consent in an orderly fashion. NOTE that all questions may not be relevant to every study, and additional questions or issues may be appropriate for some topics. Investigators must use their judgment to select, adapt, or add elements. The order of questions may vary. That they are answered is relevant is more important than exactly where they are asked.

Study Title:

Investigator(s) (Name, Position, Faculty or Student, Institution if other than UA :)

Funding Source:

You (and your child, spouse, partner, caregiver, etc.) are being asked to take part in a research study.

IF consent is being obtained from a legally authorized representative, parent, or guardian who is not also a participant, say, “You are being asked to give permission for your child/adult relative/person for whom you are a guardian/legal representative (as appropriate) to take part in a research study.

This study is called (Title). The study is being done by (NAME [S]) who is a professor (or a master’s or doctoral /student) at the University. (IF STUDENT, identify supervising professor: Ms. Jones is being supervised by Dr. _____, who is a professor of X / licensed clinical psychologist/registered nurse, etc.)

(For funded research) This study is being paid for (partially paid for) by a grant from (external or internal funder).

[Next, please address conflicts of interest and testing of future marketable products, if any, that may be of concern to participants]. For example,
Is the researcher being paid for this study?

This question is relevant if prospects are likely to be concerned about researchers profiting from research. Some minority groups or people of lower SES often believe researchers “get rich” from research and are reassured to know the researcher is not receiving payment beyond the usual salary.

Examples: “The study grant covers supplies, equipment, and mileage only. The researcher is not receiving extra pay for this study.”
OR
“Because the researcher does not ordinarily work during the summer, s/he is receiving additional summer salary to do this study.”
OR
“The physician/medical practice is being paid for the cost of the extra care given to you while in this study by the sponsor.

NOTE: The University of Alabama does not routinely allow investigators to accept recruitment or finders’ fees. However, if the sponsor’s protocol allows them, IRB will consider their use and determine whether the consent document should disclose them.

Is this research developing a product that will be sold, and if so, will the researcher profit from it?

In studies of drugs or devices participants usually understand a product may be marketed. However, disclose any financial interest in the product. (The next question may suffice for this issue.)

Does the researcher have any conflict of interest in this study?

Answer this question IF a COI exists and explain if and how it might affect the study.

Example: The researcher owns stock [or has some other financial interest] in the company sponsoring this study which creates a conflict of interest. This conflict of interest has been reviewed by the University of Alabama IRB and the University of Alabama Conflict of Interest Review Board. A Conflict of Interest Management Plan has been put in place to ensure that the financial interest of the researcher does not create additional risk to participants or have any other adverse impact on this study.

What is this study about (or What are we trying to learn)?
This study is being done to find out (what). (Explain purpose in clear language, understandable to the target group. Bullets may make the purposes of multiple-aim studies clearer to participants. Avoid lengthy seriated statements and excessive technical language or jargon. Define words that may be unfamiliar—what is a clinical trial, a Phase 2 study, or a focus group? Err on the side of simplicity.)

Clearly explain what is experimental/new about this study.

This knowledge is important/useful because (Both the purpose sentence—what—and the significance sentence—why-- must be used. Explain significance in clear language.)

Why have I been asked to take part in this study?

You have been asked to be in this study because you are (describe selection criteria in understandable language).

How many people will be in this study?

About (N) other people will be in this study. (Give an estimated sample size).

What will I be asked to do in this study?

(Explain the study procedures as simply as possible in chronological order or by phase. This may involve describing screening procedures; if these are extensive, separate consents for screening and enrollment of prospective participants may be desirable.)

(If screening is needed, describe screening activities first. State that if you do not meet the criteria, you cannot take part in the study and will be removed from it by the investigator.)

If you meet the criteria and you agree to take part in this study you will be asked to do these things:

(Activities/steps may be presented using bullets, numbers, or in paragraphs describing such phases of the study as “Home visit 1” or “interview 1”.)

If participants will be randomized (by chance, like the flip of a coin) to different treatment conditions, explain those conditions, the chances (probability) of being in any group, and that the participants may not choose which group they wish to be in.
Provide an estimate of the total time needed to participate and, if the study has multiple activities, psychological instruments, or phases, provide estimates for the various study parts. “It should take you about one hour to complete the questions”. “Each home visit should take about 90 minutes. It will take you about 30 minutes a week to complete your records between home visits. In all, being in this study will take about 20 hours of your time over the next three months.”

For some studies it may be useful to use “How much time will I spend being in this study” as another question.

Verification or renewal of consent: Consider whether verification of ongoing consent or renewal of consent is appropriate for multi-session studies. This is especially important for studies of physical performance, studies of sensitive issues, and studies where people’s health or other circumstances may have declined. If so, include a statement that informs prospects that they will be asked at the start of each session whether they wish to proceed/continue with the planned activities and whether they will be asked to sign their name or mark a checklist to document their wish to continue. If the prospect does not wish to continue, the PI may try to reschedule or the participant may stop all participation.

Reconsenting is required if a participant who is a minor at the beginning of the study becomes an adult (becomes 19 years old) by year two.

Leave identification of risks and benefits until those sections of the consent form.

*Compensation is NOT considered a benefit. Compensation can be described at the point in the procedure section where it is relevant, in a summary paragraph at the end of the procedure, or under costs. Regardless of where compensation is described, cover the amount, the timing, and the conditions under which full compensation will or will not be given. Compensation may include giftcards and things (books, toys, glucometers, etc.) as well as money.

*Current consent preference is to avoid use of the words “paid” and “payment” which suggest an employer/employee relationship and downplay the voluntary nature of research participation. Instead, money or other incentives are given “in appreciation of your time” or “to thank you for your time”.

Examples: “After screening and regardless of whether you are found to be eligible for the study, you will be given $25.” OR “When you finish the first three office visits, you will be given $50.” OR, “You will be given $10 for each interview (3) completed, and $25 each for the 3-month follow-up and
the 6-month follow-up. This means that you could receive as little as $10 or as much as $80.” OR “If you do not finish the study, you may keep the toys you have earned but you will not receive the $20 for finishing.”

*Incentives/compensation should not be so large as to be an undue influence on the prospect.

How much time will I spend being in this study?

Provide estimates of time for each study activity and an estimate for the total time for all study activities. Please take some step to ensure the provided estimates are realistic.

Will being in this study cost me anything?

Include all costs. Costs may include participants’ time, time missed from work, costs of drugs or materials not supplied by the sponsor or investigator, and costs of travel to research sites.

Explain which costs are covered by insurance and what costs are additional for research purposes. If these are not covered by a funding agency, identify “having medical insurance” or “the ability to pay for “X additional laboratory tests” as sample criteria.

Will I be paid for being in this study?

Describe the amount and frequency of any compensation, both for completion of individual study parts or for the total study.

Can the researcher take me out of this study?

The researcher may take you out of this study if s/he feels that (the treatment is not helping you/the treatment appears to be upsetting you/something happens that means you no longer meet the study requirements.)

Describe any special measures to be taken to ensure a safe and orderly removal of the participant, such as referral to a specialist, psychologist, counselor, etc.

What are the benefits (good things) that may happen to me if I am in this study?

Remember that benefits cannot be promised in research. Investigators need not “reach” to identify benefits.
In many cases, the most accurate description of benefits is simply to state, “There are no direct benefits to you from being in this study.”

In other cases the study may offer benefits: “Although benefits cannot be promised in research, it is possible that you will (learn new ways to help your sick relative, learn new ways to manage your stress, have better control of your high blood pressure, be able to sleep better. “

All participants may not regard more self-knowledge as a benefit. Acknowledge this possibility by using indefinite wording: “You may or may not regard information about your risk of diabetes/your physical fitness as a benefit.”

It is permissible to identify altruistic feelings as a benefit if that is likely or reasonable: “Although you will not benefit from being in this study, you may feel good about knowing that you have helped future caregivers of stroke victims manage their stress.”

What are the benefits to scientists or society?

This study will help psychologists/nurses/physicians/social workers, dietitians, etc. learn how to help people with (STUDY CONDITION) better/provide better treatments/services to people with (STUDY CONDITION).

Society will benefit if we can reduce the number of obese children who are likely to experience diabetes and cardiac problems as adults.

What are the risks (dangers or harm) to me if I am in this study?

Describe the CHIEF or MOST LIKELY risks first. If the risk is a technical term, please explain it in simpler language. (“Anemia” is a condition in which you do not have enough red blood cells. It can cause tiredness and shortness of breath.)

If information is available about how common these risks are, please provide it. “There is one chance in 100 that this will happen to you” or “In earlier/similar research, 3 people out of 250 complained of this.” If the probability of a risk is unknown, state this.

If there are many risks, group them by type or severity: The most common (or serious) risks are A, B, and C. The less common risks are D, E, F.

Remember that risks are not only physical. They may be economic, psychological or involve threats to one’s privacy or reputation.
If risks involve loss of privacy or confidentiality, there will be some overlap between the Risk section and the Privacy and Confidentiality sections of the informed consent document.

Provide information about how risks will be minimized or handled, should they occur. “You will be interviewed in a private room so others cannot overhear us.” “If we think you are depressed/upset, we will refer you to a psychologist/social worker for counseling.”

Provide information about who to contact in case of a research-related injury to the participant.

Describe what medical treatments are available, if any, and where if injury occurs. “A person trained in CPR will be available during the exercise sessions, and we are only 5 minutes away from a hospital emergency room.”

Explain who is responsible for the cost of any research-related injury or complication. For example, “If you are injured because of being in this study, we will take you to the hospital immediately but you will need to pay for the care received.” If compensation is available, explain what it consists of and where further information can be obtained.

Veterans Administration hospitals have a mandatory statement about emergency medical care that should be inserted here.

Other information to be provided when appropriate:

In medical studies it may not be possible to predict all risks. State that participation in research may involve unknown risks.

A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable. Here and/or in the procedure section, explain such steps as pregnancy testing at each session, ineligibility for the study if pregnant at screening, removal from the study if pregnant.

A statement that the participant will be informed if significant new findings arise that might affect his/her willingness to continue in the study.

If withdrawal from the study involves some risk or need for ongoing supervision or gradual withdrawal, explain those circumstances.
How will my privacy be protected?

Privacy refers to people and how they and the investigator can control other people’s access to them. Privacy can be protected by such means as interviewing participants in a private room or a site of their choosing and telling them in advance what they will be asked about. Strike a balance between listing every variable or question and saying “we will ask about your feelings” which is too vague.

Telling participants that they do not have to answer any questions they do not want to answer is protection of privacy.

Notifying people that the investigator must report signs of spouse, child, or elder abuse or certain diseases is a privacy issue, as it may force the participant to be in contact with the police or other protective services.

If a Certificate of Confidentiality has been requested, explain its protections and limitations within “Privacy” section.

How will my confidentiality be protected?

Confidentiality refers to data and how it will be safeguarded. Confidentiality is protected by such things as separating signed consents from other data before analysis, using ID numbers for records, providing locked drop boxes in safe sites, using software that removes addresses from e-mail or internet responses, encrypting data bases, storing data in locked files in locked offices, restricting the number of people who may access data to selected study personnel, and destroying raw data or name-number lists after data have been entered.

Requesting a waiver of consent or signed consent also protects confidentiality by avoid a link between data and participant identity.

Use language prospects can understand—all may not know what an “encrypted data base” is.

Although HIPAA is called the privacy act, it actually deals with confidentiality. If you need access to Protected Health Information (PHI), tell prospects exactly what information you will need and how you will protect it. If participating institutions require certain PHI forms, use them in addition to the consent form.

If studies are funded by NIH, FDA, or another sponsor who requires data sharing, or if the investigator intends to make the data available to other investigators, the consent document must describe this possibility, any known intended use, and whether or not the data will be de-identified.
What are the alternatives to being in this study? Do I have other choices?

“The alternative or other choice is not to participate” fits many studies

In medical studies, explain other courses of treatment: You can be treated with other drugs, with surgery, etc.—or choose not to be treated at all.

What are my rights as a participant in this study?

Taking part in this study is voluntary—it is your free choice. You can refuse to be in the study. If you start the study, you can stop at any time. There will be no effects on your care or your relations with the University of Alabama.

The University of Alabama Institutional Review Board (IRB) is the committee that protects the rights of people in research studies. The IRB may review study records from time to time to be sure that people in research studies are being treated fairly and that the study is being carried out as planned.

In some studies the federal government or the study sponsor may review study documents. Please inform participants if this is the case.

Who do I call if I have questions or problems?

If you have questions, concerns, or complaints about the study right now, please ask them. If you have questions, concerns, or complaints about the study later on, please call the investigator (NAME) at (TELEPHONE NUMBER). If you have questions about your rights as a person taking part in a research study, you may call Ms. Tanta Myles, the Research Compliance Officer of the University at (205)-348-8461 or toll-free at 1-877-820-3066.

You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://osp.ua.edu/site/PRCO_Welcome.html. You may e-mail the Research Compliance Office at participantoutreach@bama.ua.edu.

After you participate, you are encouraged to complete the survey for research participants that is online at the outreach website or you may ask the investigator for a copy of it. Mail it back to the University of Alabama Office for Research Compliance, Box 870127, 358 Rose Administration Building, Tuscaloosa, AL 35487-0127.

I have read this consent form. I have had a chance to ask questions. I understand what I will be asked to do. I freely agree to take part in it. I will receive a copy of this consent form to keep.
FOR RESEARCH INVOLVING LARS ONLY, ADD: I understand that I am serving as the legally authorized representative for (NAME) and give permission for him/her to participate in this research study. My decision is based on what I believe that person would choose and what I believe is best for that person, based on the information I have been given.

_____________________________  __________________    _________
Signature of Research Participant OR LAR        Date

_____________________________  _________
Investigator        Date

Notes: As of March 7, 2012, the FDA requires the following language in all consent forms for drug or device clinical trials that are initiated on or after that date: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

It is desirable but not required by regulations that all signatures on consent forms be witnessed by someone other than the investigator. If the study involves multiple sessions, sensitive topics, demanding performance, or more than minimal risk, obtaining a witnessed signature is highly recommended.

IRB and Investigators have the option of asking prospects to initial each page of the consent form as well as the terminal signature.

UA does require that all consent documents, whether for FDA-regulated research or not, be signed, unless the PI is requesting a waiver for written documentation of consent. This applies to long and short forms. Either a signature or initials will suffice for studies where participants reaffirm their willingness to continue. These reaffirmations must be dated.

Some studies allow prospects to choose among options for participation. If this is the case, list the options as a checklist that makes clear exactly what the consent covers. Example: I agree to participate and you may ask my child to participate; I agree to participate but you may not ask my child; I do not agree to participate but you may ask my child; I do not agree to participate and you may not ask my child.
See policies for special elements for consents for vulnerable populations. For example, consent forms for prisoners must always state that participation will not affect the length of your sentence.

Additional separate consent forms will be needed for:
1. Asking prospects if they would be interested in being contacted about future studies
2. Asking permission for use of images, audiotapes, or videotapes if they will be used outside of the data analysis process or shown to non-research audiences.

The UA IRB goal for consent forms is that they be written at no more than an eighth grade reading level. Please check and report the reading level of the consent form when submitting the application. Two common formulas are the Flesch Reading Ease Formula and the Flesch-Kincaid Grade Level Formula. These are calculated on Microsoft WORD.