NOTE: IRB strongly encourages the use of this template format for consent documents. Research has shown the Q and A approach to be more understandable to participants. It also assists investigators to be sure they have covered all the elements of consent in an orderly fashion. NOTE that all elements may not be relevant to every study, and additional questions or issues may need to be addressed for some topics. Investigators must use their judgment to select, adapt, or add elements. The order of questions may vary. That they are asked and answered is more important than exactly where this occurs. Bold face elements are the essential questions to ask. Material in black non-boldface is suggested wording and organization. Material in *italics* is commentary or suggestion.

Study title:

Investigator’s Name, Position, Faculty or Student Status

Institution if other than or collaborating with UA:

You (and your child, spouse, partner, 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/undergraduate student/graduate student at the University of Alabama. *If investigator is a student,* say “Ms./Mr. X is being supervised by Professor (Name) who is a professor of X at the University of Alabama.

*Is the researcher being paid for this study?* *Applicable to funded studies only. This question is relevant to many prospects because it affects their trust in research and*
many believe that researchers “get rich” from studies. They may be reassured to learn that the researcher is not receiving payment beyond the usual salary.

This study is supported by a grant from the XYZ Company/funding agency.

Examples of explanations: The grant covers supplies, equipment, and mileage only. The investigator is not receiving extra pay for this study. OR because the investigator does not ordinarily work during the summer, the grant pays the investigator a summer salary to do the study.

Is this research developing a product that will be sold, and if so, will the investigator profit from it? This is sometimes relevant to non-medical studies. For example: This research is testing a new questionnaire that will be sold to psychologists if it is found to be effective. The investigator is being paid to conduct the research but will not profit from any future sales. OR The investigator has developed the survey being tested and hopes to market it to schools and student counselors if future research shows that it is an improvement over other surveys.

Does the investigator have any conflict of interest in this study? Relevant only if a conflict exists. Explain the conflict and if and how it might affect the study. Example: The investigator is part owner of the company sponsoring this research, which creates a conflict of interest. The conflict has been reviewed by the 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.

NOTE: Stock in retirement plans does not pose a conflict of interest as long as the investigator does not control the actions of the company in any way.

What is this study about? What is the investigator trying to learn? This study is being done to find out (WHAT). Explain purpose in clear language that will be understandable to the target group. Bullets may make the purposes of multiple-aim studies clearer to the participants. Avoid lengthy seriated statements and excessive technical language or jargon. For instance, the exact names of psychological tests are rarely of interest to participants; they would prefer to know that you are testing intelligence, anxiety, and mood. Define words that may be unfamiliar—what is a focus group or a Delphi Survey? Err on the side of simplicity.

Be very clear about what is experimental or innovative.
Why is this study important or useful?
This knowledge is important/useful because (Both the purpose sentence—what-- and the significance sentence—why-- must be used. Explain significance in clear language.)

The results of this study will help (WHO) understand better ways to help (WHO).

Why have I been asked to be in this study?
You have been asked to be in this study because (describe selection criteria and process in understandable language: Your name was randomly sampled from the voter registration list of Tuscaloosa County; You responded to our advertisement and expressed interest in this study, You have stated in a telephone screening that you are a person over age 45 who is caring for an aged parent at home.

How many people will be in this study?
About (NUMBER) other people will be in this study. (Give an estimated sample size.)

What will I be asked to do in this study?
If you meet the criteria and agree to be in this study, you will be asked to do these things:
This may be as simple as stating that you will complete a short survey or interview or come to a laboratory and play computer games that test (STUDY VARIABLE)

For more complex studies, explain the study procedures as simply as possible in chronological order or by study phase, if that is relevant. Clearly identify what is new or experimental about the study.

If screening is involved, describe that activity first and state that if you do not meet the criteria, you cannot take part in the study—the investigator will remove you from consideration. If screening procedures are extensive, separate consents for screening and enrollment in the study may be desirable. A numbered or bulleted format for multiple activities is more understandable to prospects than a long paragraph or a paragraph with many steps listed in the narrative.

If breaks will be a feature of the design, include that fact.

Leave details of privacy, confidentiality, risks, benefits, and any compensation for later portions of the informed consent.

How much time will I spend being this study?
Provide an estimate of the total time needed to participate. Please verify that this is a realistic estimate before preparing the consent form. If multiple activities are involved, state the time required for each component activity and the total time for participation.
EXAMPLE: Each interview should take about 30 minutes, 90 minutes for all three interviews. It will also take you about 30 minutes per week to complete your study diary. The entire study will take about 7 hours of your time over ten weeks.

NOTE for multi-session studies: Consider whether the nature of the study makes it appropriate to provide the participant with the opportunity to renew his consent or
willingness to continue. This is called “reconsenting”. It is appropriate when studies are dealing with sensitive personal issues such as bereavement or family conflict, when study activities are physically or mentally rigorous, or when people’s health or other circumstances may have changed enough to affect their desire to continue. Reconsenting does not mean that the entire study must be presented again. Rather, it involves a statement that at the start of each session the task to be completed will be reviewed and the participants asked if they wish to continue with the planned activities that day. (EXAMPLE: Today we are to discuss how your family situation has changed over the last month. Is it OK with us to go ahead with that?). Ask them to sign their name on a sheet that contains signature lines and dates for each session, or mark a checklist to demonstrate willingness to continue. It is possible that participants will simply wish to reschedule or that they will wish to discontinue participation in the study completely.

Reconsenting is required if a participant who is a minor at the beginning of the study becomes 19 years of age during the data collection period.

Will being in this study cost me anything?
The only cost to you from this study is (your time, your mileage to the University campus, time missed from work, etc.)

Will I be compensated for being in this study?
You will not be compensated for being in this study. OR In appreciation of your time, you will receive X dollars (WHEN), free parking, a gift certificate to a local discount store, etc.

Compensation is not considered a study benefit so do not describe it there. Avoid references to “paid/payment” as this language undermines the voluntary nature of research. Better language is to say “in appreciation of your time, you will be given $X. Compensation may include money, gift cards, and things (books, toys, etc.) Describe the amount of compensation, its timing, and the conditions under which full compensation will or will not be given. Examples: If you start the study but do not finish, you will still receive the ten dollars. OR You will be given $10 for each completed interview (3), and $25 each for the three-month and six-month follow-up interviews. 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 the study.”

Can the investigator take me out of this study? (If appropriate for the topic)
The investigator may take you out of the study if s/he feels that (the study is upsetting you, something happens that means you no longer meet the study requirements, etc.)

What are the risks (dangers or harms) to me if I am in this study?
The answer may be that little or no risk is foreseen as when nonsensitive surveys or interviews are used.
Remember that risks may be physical, economic, psychological, legal, or social. The nonphysical risks are fairly common in nonmedical research, such as the danger to one’s reputation if risky or illegal behaviors are described. EXAMPLES: The chief risk is that you may get tired from the interview, bored by the study activities, upset by thinking about your family relationships, etc. Describe how you will minimize or avoid these risks—through breaks, rescheduling the interview, recommending a counselor, or removing the person from the study, etc.

Risks to privacy and confidentiality can be identified and managed here or they may be identified here and their management described in the privacy and confidentiality sections of the consent form. Sometimes there is some unavoidable repetition between these sections.

**What are the benefits (good things) that may happen if I am in this study?**
Remember that benefits cannot be promised (guaranteed) in research and that investigators should not “reach” to identify personal benefits to participants. Desirable wording is that “You may (NOT “WILL”) experience some relief from talking about your grief with an outside person.” Often the right thing to say is “There are no direct benefits to you.”

It is permissible to identify altruistic feelings as a benefit if that is reasonable within the study context. “Although you will not benefit personally from being in the study, you may feel good about knowing that you have helped other teens avoid trouble with the law.”

**What are the benefits to science or society?**
This study will help (WHO--high school counselors, probation officers, etc.) to be more helpful to (WHAT KIND OF PERSONS). Society will benefit from a lower crime rate if we can do a better job of predicting which criminals released from prison will not commit more crimes.

**How will my privacy be protected?**
Privacy and confidentiality are two different things. Please address them separately in the consent form.
Privacy refers to people and other people’s access to them. It includes such means as interviewing participants in a private room or a site of their own 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 you about your feelings” which is too vague.

Other ways to protect privacy are telling people they do not have to answer any questions they do not want to and that the investigator must report signs of spouse, child, or elder abuse if s/he observes them. This would force the participant to be in contact with police or other protective services.
If a Certificate of Confidentiality has been obtained, explain its protections and limitations within the Privacy section. This is because it is actually safeguarding access to the person.

How will my confidentiality be protected?
Confidentiality refers to data and how it will be safeguarded. Confidentiality is protected by such actions as separating signed consents from datasheets, using ID numbers for records, locked drawers and doors, using software that removes IP addresses, encrypting data bases, restricting the number of people who can access data, and destroying raw data or identifiers after data have been entered.

Remember that it is not possible to promise confidentiality when using focus groups. You can state that you will request people to keep the discussion confidential but you cannot guarantee this will happen.

See Note 10 if you need access to Protected Health Information.

What are the alternatives to being in this study? Do I have other choices?
“The alternative to being in this study is not to participate” fits most nonmedical studies. Students in the University subject pools may choose the designated alternative assignment for course credit.

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 it at all. If you start the study, you can stop at any time. There will be no effect on your relations with the University of Alabama.

The University of Alabama Institutional Review Board (“the 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 (NIH, NSF) may review study documents. Please tell participants about this if it is the case.

If appropriate: If new information becomes available that might affect your willingness to continue participating in this study, we will tell you.

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 (PHONE).
If you have questions about your rights as a person in a research study, 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 or email 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 and mail it to the University 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 agree to take part in it.
I will receive a copy of this consent form to keep.

_________________________________________________________________   _______________
Signature of Research Participant                                      Date

_________________________________________________________________  _______________
Signature of Investigator                                              Date

NOTES:

1. **UA requires that all consent documents, including long and short forms, be signed, unless a waiver for written documentation of consent has been approved. 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.**

2. **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.**
3. If your study involves deception or concealment, please see the UA policies and forms for that topic. Your application must explain the rationale for this practice and provide for debriefing of participants. You must also request an alteration in consent on the FORM Request for Waiver/Alteration of Informed Consent.

4. Under Alabama law the age of consent for research, unless the person is otherwise emancipated, is 19. If using persons younger than this, permission must usually be sought from parents or guardians. It is also possible to request waiver of parental consent. See POLICY Waivers and Alterations of Informed Consent.

5. If your study involves audiotaping or videotaping, you must inform the prospect about this plan and either allow the option of participating without being audio- or videotaped or state that agreement to taping is necessary to participate. A checklist of what taping options the participant will consent to may also be possible. Describe the protection of confidentiality and the storage and destruction of the tapes in both your application and the consent document.

6. If your study involves participants whose understanding or capacity to give informed consent may be questionable (age, mental status, language fluency, etc.), you may need to assess their understanding or obtain permission from a parent or Legally Authorized Representative (LAR). Strategies for assessing participants’ understanding of the study are described in the POLICY Investigator Assurance of Participant Comprehension. This may be done through questioning, asking prospects to describe the purpose or risks of the study to you in their own words, with standardized instruments such as a mental state exam, or with a form provided by IRB (Decision Making Capacity Assessment Tool). Reassessing comprehension in multi-session studies involving such persons may also be desirable if mental status/capacity may fluctuate.

7. Strive for consent forms with reading levels of Grade 8 or less and state the reading level in your application. Reading level formulas are not perfect but they are very helpful. Two formulas commonly found in word processing packages like Microsoft WORD are the Flesch Reading Ease formula and the Flesch-Kincaid Grade Level formula.

8. If the research involves prisoners, please emphasize the voluntary nature of participation and state that participation in the study will have no effect on the person’s sentence. If incentives are used, please check with prison officials to be sure they are acceptable. The most common acceptable incentive is for small amounts of money to be deposited to the prisoners’ accounts.

9. Remember that in addition to the vulnerable populations identified in federal regulations (children; pregnant women, neonates, fetuses; cognitively impaired
persons; and prisoners) other populations may be considered vulnerable for specific studies. For example, employees may need to be assured that their employers will not know whether they participated or what they said. Students are also considered a vulnerable population if studied by their professors.

10. Occasionally non-medical studies need access to participants’ Protected Health Information (PHI). If so, please review IRB policies and forms on Privacy and PHI. Although the relevant act (HIPAA) is called the Privacy Act, it actually deals with confidentiality. Tell participants exactly what information you will need and how you will protect it. Agencies that have the PHI usually have a special form to complete for access to that data. Append it to the consent form and obtain separate signatures for this document.

11. If research prospects cannot give their own consent, consent must be obtained from their Legally Authorized Representatives (LARs). See UA IRB POLICY Investigator Responsibilities for Informed Consent Process and Documentation and the GUIDANCE Investigators and Legally Authorized Representatives. **NOTE THAT additional language is added to the consent form when LARs are used.**

12. Additional separate consent forms will be needed for:

   a. Asking prospects if they would be interested in being contacted about future studies (names and contact information being placed on a database of potential subjects)

   b. 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.