INFORMED CONSENT FORM

The below template for developing an informed consent document to use in your research study is meant to provide structure and guidance to the process, not to serve as your exact informed consent document. Please remember to consult your institution and IRB for specific consent requirements, instructions and templates.

For the purposes of this document, guidelines within the template will be provided in italics. If this document is used to develop your informed consent form, please remember to delete the italicized instructions and insert your specific information.

Informed Consent Document Template and Guidelines

Informed Consent Form

Arkansas Tech University

Title of Project: *(complete title of the project as it appears on the protocol and abstract)*

Principal Investigator: (o*nly one person may be named as principal investigator)*

Other Investigators:

Participant's Printed Name: _____

The Introductory Paragraph

Example Introductory Paragraph:

We invite you to take part in a research study *(title*) at *(location/institution*), which seeks to (purpose of study). Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

Section 1. Purpose of the Research

This section is required in all consent forms. It focuses on explaining to the participant why they were asked to participate in the study and the purpose of the research study.

Example Section 1: Purpose of the Research

You are being offered the opportunity to take part in this research study because *(state why the individual was selected, e.g., condition, age, or healthy volunteer).*

This research study is being done to find out……..

OR

The purpose of this research is to……

OR

The purpose of this research study is to obtain information on the safety and effectiveness of *(name of drug, device, etc.).*

Approximately *(number)* people will take part in this research *(nationwide or worldwide)* and about *(number)* people are expected to take part at *(your institution)*.

Section 2. Procedures

This section is required in all consent forms. It outlines the procedures of the study and explains exactly what will happen to the individual should they choose to take part in the study. It should clearly identify what parts of the procedure, if any, are experimental.

Section 3. Time Duration of the Procedures and Study

This section is required in all informed consent forms. The purpose of this section is to clearly outline the time commitment a participant is committing to in choosing to take part in the study.

Example of a Time Duration Section:

If you agree to take part in this study, your involvement will last approximately (*give length of time of participation)*.

Section 4. Discomforts and Risks

This section is required in all informed consent forms. For certain research studies, it may suffice to say that there are no know risks associated with the research. However, in most studies, this section will outline in lay terms what risks or discomforts may be associated with each procedures or drug administered. List by regimen the physical and nonphysical risks of participating in the study in percentages and numbers whenever possible. Nonphysical risks may include such things as the inability to work, potential anxiety related to the sensitive nature of the questions asked, etc. List the known human experiences related to the treatment and procedures involved, including bruising or discomfort from blood draws, as well as any relevant animal data. Highlight or otherwise identify side effects that may be irreversible, long-term or life threatening. The use of lists or a table format is recommended.

Example of a Discomforts and Risk Section for a Drug Study:

While on the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person. Drugs will be given to make some of the side effects less serious and uncomfortable. Many side effects go away after the drug is stopped but, in some cases, the side effects may be serious and/or lasting.

Drug XYZ side effects.

More likely:

- Decreased appetite
- Difficulty sleeping
- Headache, dizziness

Less likely:

- Hallucinations or delusions
- Nausea and/or vomiting

(The following text should be added for trials with a placebo arm)

If you are in the treatment group that receives placebo (inactive substance) your symptoms or condition may worsen or not improve.

Other Possible Risks Associated With Participating In This Study

Venipuncture: The risks of drawing blood include temporary discomfort from the needle stick, bruising, bleeding, and rarely, infection.

Subcutaneous Injections: Injections to the skin may be less convenient than some other forms of treatment, such as oral medications. In addition, injections may cause momentary discomfort and other local symptoms, such as bleeding, bruising, and, rarely, infection.

(Also, if applicable, the following should be added)

There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. Your doctor will discuss this with you. You should not breast-feed a baby while on this study.

Section 5. Potential Benefits

This section must be in all informed consent forms. However, the way it is included may vary depending on the type of research. The purpose of this section is to describe the benefits of participating for the participant and for others. The following should be included in this section;

- *This section should address two parts: 1) potential benefits to the participant; and 2) potential benefits to others. The two ideas can be integrated, but for the purposes of the example below, they have been separated into separate paragraphs.*
- *NOTE: Payment given to the participant for participation in the study is not a benefit, it is a compensation for participant's time and any expenses that s/he could incur as a result of participation in the study, and should not be included in this section.*

Example of Possible Benefits Section:

Possible benefits to the participant:

(For clinical research studies where direct benefit is possible) The possible benefit you may experience from the (research drug/device/procedure) described in this research includes (list any benefits that may be reasonably expected). However, there is no guarantee that you will benefit from being in this research.

(For research with no direct benefit) You will not benefit from taking part in this research study.

Possible benefits to others:

(Address potential benefits to others) *The results of this research may guide the future treatment of…*

or

Medical science may gain further understanding of….

Section 6. Statement of Confidentiality

This section is required in all informed consent forms. This section must outline how all confidential information and or materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section.

6a. Privacy and confidentiality measures

Example Statement of Confidentiality:

Your research records that are reviewed, stored, and analyzed at *(your institution)* will be kept in a secured area in (*list where records are stored*). (*Include the following if specimens are collected for research purposes*)Your samples collected for research purposes will be labeled with (*list all that apply: a code number, your initials, etc*.) and will be stored *(list where the samples will be stored and how they are secured).*

(For research records/samples that are sent outside of your institution, describe methods that will be used to ensure confidentiality. If records and specimens are sent to different entities or labeled differently, describe their confidentiality measures separately) For research records *(and specimens)* sent to *(outside entity)*, you will not be identified by name, social security number, address or phone number. The records *(and specimens)* may include (*list all that apply: a code*

number, your initials, date of birth, etc.). The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.

OR

For research records *(and specimens)* sent to *(outside entity)*, you will be identified by *(list all that apply: name, social security number, address, phone number, date of birth, any other direct personal identifier, code number)*. The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.
(Remember to include separate descriptions for records and specimens if they are labeled differently or stored differently or sent to separate entities.)

The following statement is considered mandatory for all research studies:

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

The following statement is for those studies that do not include section 6b.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services *(for drug/device studies, add the U.S. Food and Drug Administration)*
- The (*your institution)* Institutional Review Board *(a committee that reviews and approves research studies)* and
- The *(your institution)* IRB Office
- The National Institutes of Health, the study sponsor

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

6b. The use of private health information:

- *Section 6b is mandatory if the research creates, obtains, uses, and/or discloses <u>identifiable</u> health information about the research participants. The 18 identifiers are listed under HIPAA regulations.*
- *Do not include any part of Section 8b unless the research fits the above criteria.*

Example Statement of Use of Private Health Information:

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the *(your institution)* Privacy Notice. If you have not received this notice, please request a copy from the investigator. At *(your institution)* your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study. *(When specific therapy is only available through the research, include these sentences:* The research-related therapy is investigational; therefore, it is not available unless you allow the use of your health information that is collected during this research study.*)*

(For blinded studies) People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will (*Describe the date or event that will trigger the expiration of this authorization e.g., "expire upon completion of the research study" or "expire when FDA approval of the study drug is obtained" or "will continue for the period of time necessary for the preparation of a related follow-up research study" or "continue indefinitely" or "will continue until the NIA notifies the investigator that the information is no longer needed.").* At that time the research information not already in your medical record will be destroyed (*or "will be retained until ___ in order to ___" or "information identifying you will be removed from such research results at (your institution)").* Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information *(if applicable, add:* and your samples*)* at any time. You must do this in writing. Write to Dr. *(PI)* and let *(him/her)* know that you are withdrawing from the research study. *(His / Her)* mailing address is *(address)*.

If you withdraw your permission:

- We will no longer use or share medical information about you *(if applicable, add the following:* or your samples) for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

- *(List any and all medical information collected from or about the participant in connection with this research study, e.g. blood and other tissue samples and related tests, your medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc.)*
- *Indicate the span of time from which the records are pulled, e.g., "since your diabetes was diagnosed", "the last five years", "only during the time span of the research study".)*

Representatives of the following people/groups within *(your institution)* may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, ___(*name*)___
- The *(your institution)* Institutional Review Board
- The *(your institution)* Institutional Review Board
- *(If using the Investigational Drug Pharmacy)* The *(your institution)* Pharmacy
- *(If applicable)* The *(your institution)* Financial Analyst for Clinical Research
- *(List every other class of persons or group <u>affiliated with</u> (your institution) (e.g., the research team, the study coordinators, etc.) who might need to use and/or disclose the participant's information in connection with this study.)*

The above people/groups may share your health information with the following people/groups outside *(your institution)* for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original *(your institution)* records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *(List every other class of persons or group <u>NOT affiliated with</u> your institution (e.g. fellow researchers in this study at (list other institutions), outside data analysts appointed for this study, the Data Safety Monitoring Board appointed for this study, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant's information might be disclosed.)*
- *(If the study is international)*Representatives from regulatory agencies in other countries may also review your research record, including research-related medical reports and information, along with the NIA and/or the FDA.

Section 7. Costs for Participation

a. Costs:

- *If there are costs to the participant that may result from participation in the research, include a statement describing any additional costs associated with study participation.*

b. Treatment and compensation for injury:

- *Include your institution's mandatory wording for treatment for injury (see below).*

Example Cost for Participation Section:
(If there is no risk of physical injury to the participant, do not include this section.) Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Add, as a separate paragraph, one of the following statements regarding payment for direct costs of treating research-related injuries.

(If the institution will cover all costs of research-related injuries but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *institution (include the names)* will reimburse the standard charges for the treatment of these complications or injuries. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the investigator institution will cover costs of research-related injuries not covered by the participant's insurance carrier but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *investigator*, *(include the name of institution if appropriate)* will reimburse the standard charges for the treatment of these complications or injuries, provided these charges have not been reimbursed by your non-governmental medical insurance or other third party. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the investigator institution has not agreed to cover costs of research-related injuries, include this statement as a separate paragraph) Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance,

they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay.

(End this section with the following statement) You will not lose any legal rights by signing this form.

Section 8. Compensation for Participation

This section is required in all research studies. It should clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.).

Example of Compensation for Participation Section:

You will be given $__ on each visit to compensate you for time and expenses for participating in this study.

(If participants do not receive any reimbursement for participation) You will not receive any compensation for being in this research study.

Section 9. Research Funding

- *Funding disclosure: Disclose what grantors, institution(s) (e.g., NIA) or companies are involved in the research through funding or grants. If none, say so.*
- *Conflict of Interest: Include information about any consultative or financial relationships the investigators may have with the NIA.*

Example Research Funding Section:

The institution and investigators are receiving a grant from *NIA (list any other grantors)* to support this research.

(For funding disclosure) The institution will be reimbursed by the NIA for use of this site's facilities and for the work the research staff does for this research.

Section 10. Voluntary Participation

Example Voluntary Participation Section:

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include (*Briefly list major responsibilities. NOTE: Do not include this sentence if there are no major responsibilities for the participant).* You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

(Optional, if appropriate) Your investigator may take you out of the research study without your permission. Some possible reasons for this are: *(list possible reasons, for example: you did not follow the study instructions, etc.).* Also, the NIA may end the research study early. If

your participation in the research ends early, you may be asked to visit the investigator for a final visit.

*(Optional, if appropriate) (For clinical studies)*If you will be participating in another clinical trial at [Institution] or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.

(Optional, if appropriate) During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 11. Contact Information for Questions or Concerns

- *Clarify the participant's right to have questions answered.*
- *Indicate whom to contact in case of further questions about the research or to report a research-related injury.*
- *Indicate contact information for questions about participant rights and privacy issues.*

Example Contact Information for Questions or Concerns Section:

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact *(Principal Investigator)* at *(phone number)*. *(If clinical protocol, add the next phrase)* or the *(study)* doctor on 24-hour call at *(phone number).*

(All informed consent forms should include this paragraph). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research *(add the next phrase if using identifiable health information:* or about your privacy and the use of your personal health information*)*, contact the research participants protection advocate in the *(your institution's)* IRB Office at *(phone number)*. You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about the Institutional Review Board (IRB), a group of people who review the research to protect your rights, please visit Arkansas Tech University's *IRB* web site at *(website)*. Included on this web site, under the heading "Participant Info", you can access federal regulations and information about the protection of human research participants. If you do not have access to the internet, copies of these federal regulations are available by calling the *(your institution)* at *(phone number)*.

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

_____	_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

_____

Description of the Legally Authorized Representative's Authority to Act for Participant

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Only approved investigators for this research may explain the research and obtain informed consent.

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.

INSTRUCTIONS: The following applies to optional parts of the research only, e.g., storage of leftover tissue for future research, optional sub-studies, etc.

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part.

(For research involving optional storage of tissue for future research) Optional Tissue Storage for Future Use

As part of this study, we are obtaining (*tissue and/or blood and/or cells)* from you. If you agree, the (*researchers)* would like to store leftover sample(*s)* of your (*tissue and/or blood and/or cells)* so that your (*tissue and/or blood and/or cells)* can be studied in the future after this study is over. *(Add the following statement if storage is optional)* These future studies may provide additional information that will be helpful in understanding [disease/condition], but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither the investigator nor you will receive results of these future research tests, nor will the results be put in your health record. Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(*s)* (*is / are)* used for this kind of research, the results will not be put in your health records. It is possible that your (*tissue and / or blood and/or cells)* might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact (*PI name)* at (*phone number)*.

(For linked samples) Your leftover samples will be labeled with (*list all that apply: "a code number", "your initials", etc.)*. These samples will be stored (*describe how the samples will be secured: "Dr. (PI's name)'s locked laboratory)* at _____. If you consent to the collection of samples of your ___ (*e.g., blood, tissue, bone marrow)* for future research, the period for the use of the samples is unknown. If you agree to allow your (*tissue and/or blood and/or cells)* to be kept for future research, you will be free to change your mind at any time. You should contact (*PI name)* at (*phone number)* and let (*him/her)* know you wish to withdraw your permission for your (*tissue and/or blood and/or cells)* to be used for future research. Any unused (*tissue and/or blood and/or cells)* will be destroyed and not used for future research studies.

(For unlinked samples) Your samples will not be labeled with any of your personal information, such as your name or a code number. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

(Add the following tissue options or variations if storage is optional) You should initial below to indicate your preferences regarding the optional storage of your leftover (*tissue and/or blood and/or cells)* for future research studies.

a. Your sample*(s)* may be stored and used for future research studies to learn about, prevent, treat or cure *(disease/condition)*.

_____ Yes _____ No

b. Your sample[s] may be stored and used for research about other health problems.

_____ Yes _____ No

c. Your sample*(s)* may be shared with other investigator/groups without any identifying information.

_____ Yes _____ No

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

_____	_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

_____

Description of the Legally Authorized Representative's Authority to Act for Participant

Person Explaining the Research: Your signature below means that you have explained the optional part of the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

This document was created using the following resources:
CTN Best Practices ctnbestpractices.org
http://www.fullerseminary.net/sop/travis/humsubj/ic_template.doc

http://www.cancer.gov/clinicaltrials/understanding/NCI-IC-Template-May-2006

Checklist for application submission:

- ☐ IRB/IRB application (include grant proposal if funded project)
- ☐ Informed consent/assent forms
- ☐ Outline or script to be provided prior to participants' agreement to participate
- ☐ Instrument(s) [questionnaire, survey, testing]

Submit one complete hard copy with signatures to the
Arkansas Tech University,
Jason E. Warnick, Ph.D., IRB Chair
Witherspoon Building, Room 350
Russellville, AR 72801

Email application as an attachment to: jwarnick@atu.edu

ANY CHANGES IN THE PROJECT AFTER APPROVAL BY THE IRB/IRB MUST BE RESUBMITTED AS A MODIFICATION FOR REVIEW BY THE IRB BEFORE APPROVAL IS GRANTED. MODIFICATIONS DO NOT CHANGE THE PERIOD OF INITIAL APPROVAL.

APPROVAL IS GRANTED FOR ONE-YEAR MAXIMUM AND MAY BE SUBJECT TO REVIEW AT ANY TIME THROUGHOUT THIS PERIOD. ANNUAL REQUESTS MUST BE MADE TO THE IRB FOR CONTINUATION, AS LONG AS THE RESEARCH CONTINUES.

REFERENCES TO 45CFR46 (Code of Federal Regulations) may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html