Informed Consent Guide and Template

Parker University Institutional Review Board (PU-IRB)

# General Comments

Informed Consent for research should be considered a process, not a form to be signed. The intent of Informed Consent is to provide a potential research participant with sufficient information with which they can make an intelligent decision regarding participation. They should be provided all the information they might reasonably want to know about the research. Once entered into a research project, the participant must never feel surprised about anything that they are asked to do or have done to them.

Please consider these aspects of the Informed Consent process.

* Provide a comfortable, private setting.
* Provide adequate time to present the project.
* Provide adequate time for questions.
* Evaluate the person’s understanding of the research.
* Avoid anything that can be interpreted as coercive or undue influence.
* Continue to informally confirm consent with the participant throughout the project.
* Once approved, if changes are necessary in the Informed Consent document, you must submit an amendment to the IRB and receive approval prior to implementing the change.

# The Elements of Informed Consent Documents

The necessary elements required for an Informed Consent document are determined by the FDA or OHRP (Office for Human Research Protection) and delineated in 21 CFR 50. The FDA also publishes “A Guide to Informed Consent” and other helpful documents. These documents can be found at [www.fda.gov/oc/ohrt/irbs](http://www.fda.gov/oc/ohrt/irbs).

With the attached template, the PU-IRB is providing guidelines for meeting the necessary elements of informed consent. The template will also suggest language that the PU-IRB considers appropriate and may favor. Alternative language and formats may also be acceptable.

At the end of this document, the PU-IRB provides a template for a cover letter appropriate for informed consent in survey research studies.

**The Privacy Act**

The Privacy Act (45 CFR parts 160 & 164; also known as HIPAA) establishes rules for using individual health information for research purposes. Under the Privacy Act, Protected Health Information (PHI) can only be used (created or reviewed or collected) or disclosed (shared with others) with the authorization of the patient. Please consult one of the documents below for more information and a list of what is considered PHI.

The HIPAA authorization must be signed by the research participant. This authorization can be included within the Informed Consent document or can be a stand-alone document. The GHS-IRB prefers the authorization be part of the Informed Consent document.

The Privacy Act specifies the required elements of the Authorization. These are outlined in the Informed Consent template. In limited circumstances, an IRB can approve a waiver or alteration of authorization to use PHI. To request a waiver or alteration of the HIPAA authorization, please complete the appropriate waiver forms found on IRBNet.

* <http://privacyruleandresearch.nih.gov/pr_02.asp>
* <http://privacyruleandresearch.nih.gov/authorization.asp#samplelang>

# Readability

The information in the consent form *must be in language understandable to the study participant*.

Please refer to the FDA document, *A Guide to Informed Consent*, for guidance on consenting participants who do not speak or understand English or are unable to read. This document can be found on the FDA website, [www.fda.gov/oc/ohrt/irbs](http://www.fda.gov/oc/ohrt/irbs).

The PU-IRB does not mandate a particular reading level for all consents. In general, we recommend the consent be in a language understandable to a junior high student. On our application form, we will ask you to provide us a Flesch-Kincaid Grade Level reading score. This can be determined by using the Spell/Grammar tool in Microsoft Word. If your initial consent is intended for a general audience and has a reading level greater than 9, please make changes to reduce the reading level. It may also be helpful to ask a non-medical person to read the consent and provide feedback.

The following are suggestions to improve readability:

* Include only 1 thought per sentence. Avoid run-on sentences.
* Use short, simple, and direct sentences.
* Use simpler words.
* Avoid medical jargon and abbreviations.
* Paragraphs should be short and convey a single message. Avoid long paragraphs.
* Terminology used (drug names, procedures) should be consistent throughout the document
* Provide clarifying tables or diagrams for complex information.
* Use bulleted lists. This is especially helpful for list of tests to be done or drug side effects.
* Use Headers to begin new sections.

**These resources may be of assistance in improving readability.**

1. Paasche-Orlow MK, et al. Readability standards for informed-consent forms as compared with actual readability. *New Engl J Med* 2003;348:721-6 (Feb 20).

2. National Cancer Institute document, “Simplication of Informed Consent Documents”.

* <http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/allpages>

3. University of Michigan IRB, “Simplication Guide to Medical Terms”

* <http://www.med.umich.edu/IRBMED/guidance/guide.htm>

# Using the Parker University Institutional Review Board Template

The following Template is provided to assist in the preparation of a consent form for your research project. It follows a question and answer format. All elements of informed consent, as indicated by 21 CFR 50, must be included. The IRB can waive the requirement for particular elements of the informed consent. To apply for such a waiver, please complete the Waiver of Informed Consent document available on IRBNet.

A variety of formats might be acceptable. Following the PU-IRB template will enhance the review process and minimize changes that might be necessary. If you are submitting a consent form prepared by a sponsor, please make as many necessary modifications prior to submission to the PU-IRB.

# Formatting Requirements: Please use the following format

* 12 point font size or larger
* **Bold** those items that are **bold** in the template.
* Add the page number(s) in the bottom right corner of the footer using the “Page *X* of Y” format (see below)
* Add “Pt. Initials: ­­­­\_\_\_\_\_\_” above or in front of “Page X of Y” in the bottom right corner of the footer. *To do this, place cursor in front of the word “Page” and type “Pt. Initials:­­­­­ \_\_\_\_\_\_\_\_*”

**Example 1**

Pt. Initials: \_\_\_\_\_\_\_\_

Page 3 of 9

**Example 2**

Pt. Initials: \_\_\_\_\_\_\_\_ Page 1 of 9

When submitting the Informed Consent Document to the IRB **please insert line numbers**. Microsoft Word can do this for you (TAB: Page Layout: Line Numbers: Continuous).

Please remove the current footer if you cut and paste this template for your own use.

**Informed Consent Document for Research Study Participation**

**Project Title:** [Insert Official Project Title here]

**For research to be conducted at** [Insert all local sites at which the research will be conducted]

**Principal Investigator:** [List Principal Investigator and Business location]

**Research Team**: [List any individual & title that might be obtaining informed consent. Listing other research team members is optional.]

**Why is this study being done?**

***Content***: Include a brief statement of the rationale for this study. Do not include the “purpose statement.” That follows in the next section.

***Suggested wording***: Possible statements include:

* “Our usual treatments for \_\_\_\_ are not very effective (or have lots of side effects).”
* “Early studies with \_\_\_\_\_ show it might work better than our usual treatment.”
* “\_\_\_ and \_\_\_ are both used to treat \_\_\_\_. We don’t know if one is better than the other.”

**What is this form?**

***Content***: Please provide the following information either with the suggested or similar wording.

***Suggested wording***: You are being asked to participate in a research study. The purpose of this consent form is to give you the information you need about the study. It will tell you about why the study is being done. The risks and benefits will be explained. You may ask any questions you have. You may want to talk it over with other people before deciding.

You are being asked to participate in this study because [insert what qualifies this person to be considered for this trial; possible statements include “...you have pneumonia” or “...you have trouble swallowing” or “...you have lung cancer that has come back.”]

You are free to choose if you want to be in the research study. You should not feel pressured to participate.

If you decide to participate in this research study, you will be asked to sign this form. You will be given a copy to keep.

**What is the purpose of this study?**

***Content***: Please state the purpose(s) of the study as outlined in the protocol. Modify the language to be appropriate for the participant. Following the purpose statement please indicate what part(s) of the study interventions are considered investigational and what interventions would be considered standard care.

***Suggested wording***: The purpose of this research is [state the purpose as clearly as possible].

The use of [insert drug name or other intervention] is standard therapy for [disease]. The use of [insert drug name or intervention] is considered investigational.

**How many people will be in this study?**

***Content***: Indicate the total number of participants in the study. If multicenter, you may also indicate how many will likely participate in your center.

***Suggested language***: This study will include [insert number] of participants. We anticipate about [insert number] will participate at [Genesis Medical Center].

**How long will I be in the study?**

***Content***: Please indicate the total duration of the participant’s involvement with the study. You may qualify the statement if the duration depends on group assignment or other factors. If post-study follow-up is planned, please indicate that duration, also.

***Suggested language***: Potential statements may include, “We expect you to receive treatment in our study for 4 months. After the study is over, we would like to follow you for an additional 5 years to see how you do.”

**What will happen during the study?**

***Content:*** Describe the study protocol including any of the following that apply:

* baseline evaluations
* interventions
* tests and procedures
* clinic or hospital visits
* questionnaires
* any additional activities the participant will be asked to do

Also include the following:

* Indicate what is standard care versus what is being done only because of the study.
* Be specific on when and how often interventions, tests or procedures might be done.
* Indicate the number of follow-up visits required, where they will occur, what will be done at each visit and about how long the visit will take.
* Indicate whether hospitalization might be required for any part of the study.

For more complex protocols, diagrams or tables can be included. Subheadings can be used to make this section easier to understand. Break-up long paragraphs.

***Suggested language for randomization***: “Randomization assigns participants to a particular group by chance – like flipping a coin. Neither you nor your doctor will be able to pick your treatment group. You will have an equal chance of being assigned to any particular study group.”

***For questionnaires*** include a statement such as this: “You are free to skip any question that you do not want to answer.”

**What are the risks of this study?**

***Content***: Describe the foreseeable risks of interventions, procedures, testing or medications. Risks may be physical, psychological or emotional. Risks may relate to privacy issues or time commitments.

Information about frequency, severity and reversibility of treatment side effects, if known, can be included. It can be useful to organize the risks into categories such as “likely,” “less likely,” “uncommon, but serious.”

You may explain safeguards to minimize these risks or treatments that may reduce side effects.

Large number of risks may best be presented in bulleted lists.

When appropriate, include a statement regarding pregnancy. Please include information about any required contraception methods specified by the protocol.

***Suggested language*** regarding pregnancy.

“The drugs used in this study may be harmful to a fetus. You should not be pregnant (or father a child) during the study. We will do a pregnancy test before beginning the study. You should use birth control while on these medicines. If you think you might be pregnant (or fathered a child) during the study, inform your doctor immediately.”

**Are there benefits to taking part in this study?**

***Content***: This section should describe reasonable benefits the participant may expect. Do not overstate benefits. If the participant should expect no direct benefit from the study, this should be stated clearly. Potential benefit to future patients or society can be mentioned.

For all but minimal risk studies, include a statement that participation (treatments) may actually be harmful.

Compensation (money, free medical care, free drugs) cannot be listed as a benefit to the study. This information should be provided to the patient in the section on “costs and compensation.”

***Suggested language may include one or more of the following:***

* “You will not directly benefit from this study. However, we hope that, in the future, other people will benefit from what we learn from this study.”
* “Benefits of participation in this study may include [insert reasonable benefits].”
* “You may not benefit from participation in this study. Some treatments may even be harmful*.*”

**What other choices do I have if I do not take part in this study?**

***Content***: List reasonable alternatives to study participation. This may include the same treatment, but not on protocol. It may include standard medical care or the decision not to have further treatment. If no alternatives other than not participating exist, please state this. You do not need to discuss the options in detail. You may state that “Your study doctor can discuss these options with you.”

**Will my medical information be kept confidential?**

 ***Content:*** Briefly indicate any steps you will use to keep the research records confidential (for example, secure storage of records, passworded computer files, use of code numbers, etc.). Indicate who might have access to the research records. This may include the FDA and research trial sponsors. Please include the Genesis Health System Institutional Review Board in the list of those who have access to their research records.

 This is the not the same information as required by the Privacy Act for use of Protected Health Information (HIPAA) for protected health information (PHI).

 ***Suggested language*** may include one of more of the following:

* “We will keep your participation in this research as confidential as possible.”
* “Your research information will be kept [in a locked office or safe or other secure location]”
* “Your research data will be entered into a computer file. The computer files are pass-worded.”
* “A code number will be used on your research records when they are sent into the sponsor. Your name will not be used.”
* “If the results of this research are shared with others or published, you will not be identified by name.”

 **Required language**

* “If you agree to participate in this research study, the following groups will have permission to review your research information. They may also review your personal medical record. This information may identify you by name. [list these groups in bullet format]”
* “A copy of your signed consent may be included in your office or hospital medical record.”

**Authorization to use or disclose (release) health information that identifies you (HIPAA)**

**Suggested language for introduction to Authorization:** Many people have concerns about who can see and use information about them. This is true about health information. This includes information that can identify who you are. Health care providers and hospitals are allowed to use your health information while taking care of you. However, your health information cannot be used for research without you giving your specific permission. Your signature at the end of this document will give your permission.

You are being asked to take part in research. During this research, the research team will want to use your health information in one or more of the following ways:

* Review existing information about you from hospital records or clinic charts.
* Create new health information about you related to the research activity. This new information may include results of examinations, laboratory tests, or medical procedures.
* Share your health information with other people involved in the research.

**What health information of mine will be used in the study?**

[Note to investigator: Select any of the following that apply. Add others that apply.

* The research team will want to collect information from your [entire] medical records at Parker University. This may include information such as the dates you were in the clinic, your medical history, medications used, laboratory tests, x-rays and scans, and doctors’ notes. This includes past hospital records and future hospital records.
* The research team will want to collect information from your [entire] chiropractic records at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (chiropractic office). This may include information such as the dates you were seen in the office, your medical history, medications used, laboratory tests, x-rays and scans, and doctors’ notes.
* The research team will create new information obtained during the research study. This may include dates your were in the office or hospital, treatments received, results of procedures performed, results of laboratory tests, x-rays and scans, doctors’ notes, and side effects to medication.
* The research team will use information that may be used to personally identify you. This may include your name, address, telephone number, medical records number, birth date, and social security number.
* [other – for example, school records, records from other institutions]

# Who will use my personal health information and for what purpose?

[Notes: please add the specific persons or groups that will receive subject information]

* The research team will use your protected health information and create new information while performing the research study.
* The research team will share your protected health information with the following people or groups also for the purpose of performing the research study and analyzing the results.
	+ The study sponsor, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
	+ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* The research team will share your personal health information with the following people or groups who are responsible for watching over the safety and quality of the research study.
	+ The study sponsor, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	+ The Parker University Institutional Review Board
	+ The FDA (Food and Drug Administration)
	+ Other federal agencies that may ask to see the information.

The research team is required by law to protect your health information. When your health information is shared with the people and groups listed above, the same law may not apply to them. However, you should expect that they would want to keep your information confidential.

# How long will my permission to use my personal health information last? Can I change my mind?

[Note: Be as specific as you can without limiting your ability to complete the research. Include dates, if they are known. You can also say, "at the end of the study," or "3 years after the study is completed." It is also acceptable to say "the authorization does not expire," or "we want to use your information indefinitely."

* When the study is completely done, your health information will no longer be used.

Or

* We are asking to use your protected health information indefinitely. However, you can change your mind and take back your permission at any time.
* You can take back your permission to use your health information at any time. To take back your permission you must tell your research team in writing. Send your letter to: [Insert: Name and address to whom the letter should be addressed.]
* If you take back your permission, the research team may still use or share any information that has already been collected.

**Must I give permission to let my personal health information be used?**

* Giving your permission allowing the research team to use and share your personal health information is your choice. However, if you do not allow the use of your protected health information, you will not be able to participate in the research study. You can say no and still receive your health care here.

**What are the costs of being part of this study?**

***Content:*** Clearly indicate what costs will be charged to the participant (or their insurance company). Indicate what happens if the insurance company does not cover all charges. Indicate specifically what costs will be covered by the research sponsor.

***Suggested language*** may include one or more of the following:

* “All chiropractic care for this study will be charged in the usual manner to you or your insurance company. You will be responsible for any costs not paid for by your insurance company. Before you agree to be a participant, you might want to ask your insurance company about what they will pay.”
* “The research sponsor will provide the following at no cost to you: [list drugs or procedures or office visits provided free].”

**Will I be paid for participating in this study?**

***Content***: Indicate whether or not a participant will be paid. If the participant will receive payments, you must specify how much and when the payments will be made. Remember, payments must be appropriate for the level of participation. They should not be coercive in encouraging someone to enlist in the trial or remain in the trial beyond their comfort.

***Suggested language*** may include one of the following:

* “You will not be paid for participation in this study.”
* “You will receive [$25 for each of the four study visit you complete]. Payment will be [mailed to you within 30 days after your last study visit] or [after each visit has been completed].”

**Who is funding this study?**

 ***Content:*** Please provide disclosure about the study sponsor.

 ***Suggested language*** may include:

* “[Name of sponsor] is paying to do this study. This sponsor is providing payments to the research team to conduct this study. This may include salary support for some research team members.”

**What happens if I am injured because I took part in this study?**

***Content***: This section should be included in all protocols exceeding minimal risk.

Indicate when treatment is offered for injuries or illnesses related to the study. Indicate who is responsible for paying the costs of this treatment. Indicate under what circumstances, if any, that treatment for injuries or illnesses might be paid by the study sponsor.

***Suggested language***: “It is important that you tell your study doctor, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[investigator's name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[telephone number]*.”

“You will receive medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for this medical treatment.”

**What are my rights if I take part in this study?**

***Content:*** Persons being recruited for this study must understand participation is voluntary, they can change their mind at any time and their choice will not influence access to care.

***Suggested language***: “Taking part in this study is your choice. You may choose either to take part or not to take part in the study. You may leave the study at any time.

No matter what decision you make, there will be no penalty to you. You will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.”

**What if I have questions?**

***Content***: Please encourage potential participants to ask questions. Provide them your contact information for questions. Also, provide them the contact information for the Parker University IRB for questions about their rights as a research participant.

***Suggested Language***: “Please ask any question you have about this research study. You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[name(s)]* at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[telephone number]*.”

“For questions about your rights as a research participant while taking part in this study, call the Parker University Institutional Review Board (IRB) at xxx-xxx-xxxx. The IRB is a group interested in the safety and rights of research participants.”

**Getting more information about this study.**

***Content*:** The FDA requires the language shown below be placed in the informed consent for all applicable trials initiated after September 27, 2007. Applicable trials include all Phase II-IV clinical trials for a drug, biological product, or medical device subject to FDA regulation and conducted under an IND or IDE.

***Required Language, if applicable***: “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 any information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.”

**Signatures**

***Content***: Four signature boilerplates are provided below.

* #1: For use when adult participants are consenting for themselves.
* #2: For use with minors as study participants, including older minor children that might be asked to provide assent to participation.
* #3: For use with adults unable to consent for themselves with consent provided by a Legally Authorized Representative.
* #4: For use with adult participants unable to read the informed consent, yet able to understand and provide consent for themselves.

Select the signature boilerplate most appropriate for your study.

***# 1: For use when adults are consenting for themselves: Required language*:**

**Participant: I would like to participate in this research. I know this is voluntary.**

Participant’s Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Statement of person who obtained consent**

I have discussed this research study to the person indicated above and have answered all questions. It is my opinion that the participant understands the risks, benefits and procedures involved with this research study.

Person Obtaining Consent (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_

**#2:** ***For use when parents or guardians are consenting for minor children***: Note: The IRB may determine that both parents must agree and sign the consent. In this case, extra signature lines can be added.

**Required language:**

As a parent or legal guardian, I agree to have this child participant in this research project. I understand that this is voluntary.

Participant’s Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent or Guardian name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent or Guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: \_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_

If the IRB determines that assent from the minor participant is required, the following signature lines will be added:

I have been told about what will happen during the research study. I understand my parents (or guardians) think that I should participate in this study. I agree with my parents.

Signature of the minor participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Statement of person who obtained consent**

I have discussed this research study to the person indicated above and have answered all questions. It is my opinion that the participant understands the risks, benefits and procedures involved with this research study.

Person Obtaining Consent (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_

**#3: For use with adult participants unable to consent for themselves**

I have been told about this research study and have had all of my questions answered. As the Legally Authorized Representative for the person named below, I agree they should participate in this research study. I understand that this is voluntary.

Participant’s Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative’s Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: \_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_

**Statement of person who obtained consent**

I have discussed this research study to the Legally Authorized Representative of the person indicated above and have answered all questions. It is my opinion that the legal representative understands the risks, benefits and procedures involved with this research study.

Person Obtaining Consent (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_

**#4: For use with adult participants unable to read the informed consent, yet able to understand and provide consent for themselves.**

Under these circumstances, the informed consent document must be read to the research participant in the presence of a witness of the participants choosing. The witness should be impartial (or partial in favor of the participant). The witness cannot be associated with the investigator. The witness must sign as indicated below. It is encouraged that the informed consent process be audiotape or videotaped.

I have been told about this research study and have had all of my questions answered. I agree to participate. I know that my participation is voluntary.

Participant’s Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s signature or mark (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness:

With my signature I confirm that I was present during the entire presentation of the research study to the person listed above. I confirm the information in the consent form and any other written information was explained accurately. I believe the participant understands what was presented. The participant has freely chosen to be a research study participant.

Witness Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: \_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_

**Statement of person who obtained consent**

I have discussed this research study with the person indicated above and have answered all questions. This was done in the presence of the witness listed above. It is my opinion that the participant understands the risks, benefits and procedures involved with this research study.

Person Obtaining Consent (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_

The following template is provided to assist in developing a cover letter that should accompany a research questionnaire or survey. The items that should be covered are in [***bold and brackets]***. The language you use may be adapted to your particular study.

Date \_\_\_\_\_\_\_\_\_\_ *(if letter form)*

Dear \_\_\_\_\_\_\_\_\_\_\_\_: (Including an individual salutation is optional)

We are writing to invite you to participate in a **[research]** study. The purpose of the study is to determine ***[Study Objective]*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

We are inviting you to be in this study because ***[Inclusion Criteria]*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Approximately ***[No. of participants]*** \_\_\_\_\_\_\_ participants will be invited to take part in this study.

If you agree to participate, we would like you to complete the following enclosed questionnaire(s).

***[Method of Participation]*** We would appreciate your returning the completed questionnaires in the enclosed envelope (or alternative language appropriate to your study). ***[Method of Non-Participation]*** If you do not wish to participate, you may return the blank questionnaire in the enclosed envelope. You are welcome to skip any questions that you prefer not to answer.

***[Confidentiality Statement]*** We will keep the information you provide confidential, however federal regulatory agencies and the Parker University IRB may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

The only potential risk to this study is the small chance that others may see the responses to your questionnaire and ***[Potential Risks]*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

***[Costs]*** You will not have any costs for being in this research study.

***[Reimbursement]*** You will not be paid for being in this research study.

***[Voluntary Statement]*** Taking part in this research study is completely voluntary. If you decide not to be in the study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you have questions about the research study itself, please contact ***[PI Contact Information]***.

If you have questions about the rights of research subjects, please contact the ***[IRB Contact Information]*** Parker University Institutional Review Board at xxx-xxx-xxxx or dlawrence@parker.edu.

Thank you very much for your consideration. Returning the completed questionnaire will indicate your willingness to participate in the study.

Sincerely,