Federal guidelines (§46.116; <http://www.hhs.gov/ohrp/policy/consentckls.html>) require that the following items be included in each informed consent document:

* A statement that the study involves research
* An explanation of the purposes of the research
* The expected duration of the participant’s involvement in the research
* A description of the procedures to be followed
* Identification of any procedures which are experimental
* A description of any reasonably foreseeable risks or discomforts to the participant
* A description of any benefits to the participant or to others which may reasonably be expected from the research
* A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
* A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
* For research involving more than minimal risk, an explanation as to whether any compensation will be provided, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
* An explanation of whom to contact for answers to pertinent questions about the research and participants’ rights, and whom to contact in the event of a research-related injury to the participant
* A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled

The following additional elements are prescribed, as appropriate:

* The approximate number of participants involved in the study
* Any additional costs to the participant that may result from participation in the research
* A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
* Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent
* The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant
* A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant

This **checklist** is provided as a tool for the researcher. It does not need to be included with the informed consent that is provided to participants.

An informed consent document **template** can be found on the next page. Researchers may make formatting changes to the informed consent document (e.g., font, font size) as appropriate to their research study. However, no sections should be deleted or rearranged.

Notes: It is up to the IRB to determine in a particular instance whether some or all of the above additional elements must be included as part of the informed consent process for a particular study. The IRB will make this determination based on the nature of the research and its knowledge of the local research context. If the IRB determines that additional elements are appropriate to the research study, this additional information should be considered just as essential as the eight basic elements of informed consent described in the HHS regulations at 45 CFR 46.116(a). Furthermore, an IRB may require that additional information beyond the basic and additional elements be given to subjects during the informed consent process, when in the IRB’s judgment the additional information would meaningfully add to the protection of the rights and welfare of the subjects (45 CFR 46.109(b)).

For additional guidance, researchers are encouraged to consult the set of FAQs available at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>. These provide detailed answers to a variety of questions that commonly arise in relation to the informed consent process, including but not limited to the following:

* What is informed consent and when, why, and how must it be obtained?
* What does it mean to minimize the possibility of coercion or undue influence?
* When does compensating participants undermine informed consent?
* Can non-financial incentives constitute undue influence?
* What constitutes coercion or undue influence when students are involved in research in a college or university setting?
* What constitutes coercion or undue influence when employees are the subjects of research?
* How can the consent and parental permission processes be designed to facilitate understanding?
* Can an electronic signature be used to document consent or parental permission?
* What are the requirements for assent and parental permission in research with children?
* Is child assent always required when research involves children?
* How should child assent be documented?
* Can consent or parental permission ever be “passive” or “implied”?
* May the requirement for obtaining informed consent or parental permission be altered or waived?
* Who can be a legally authorized representative for the purpose of providing consent on behalf of a prospective participant?

*(Red italicized text indicates where you may add information about your proposed research. Do not delete, rearrange, or otherwise modify the black non-italicized text in this template. Once you have replaced the red text with information about your study, please delete these instructions and change your additions to black non-italicized text.)*

**Title of Study:** *(Type the title of the study here)*

**Principal Investigator’s Name:** *(Type the principal investigator’s name here)*

**Affiliation:** *(Type the name of your department or school here)*, Fairfax University of America

**Introduction:**

You are invited to be a part of a research study that examines *(provide a general statement about the purpose of the study here)*. The study is being conducted by *(name the member(s) of the research team here, along with information about their roles and institutional affiliations)*. You were selected as a possible participant because *(provide the reason(s) for the potential participants’ selection here, including how they meet the inclusion criteria).* The study is expected to last for *(indicate the duration of the study here)*.

Please read this form and ask any questions that you might have prior to agreeing to participate in this study.

**Procedures:**

If you agree to participate in this study, you will be asked to do the following:

*(Step by step, describe the procedures that participants will be asked to take part in here. Be as specific and as detailed as possible. As relevant, include information on assignment to groups, types and frequencies of procedures, video and audio recording, and so on. Be sure to identify any procedures which are experimental.)*

**Risks and Benefits:**

This study involves the following risks:

*(Describe any known and potential risks here, including the likelihood of these risks. No research is without risks. However, if the risks are minimal, please be clear in stating this. Minimal risks are defined as those that do not exceed the risks that a participant would encounter in everyday life. If participation in the study might reveal information that entails mandatory reporting requirements (such as for child neglect, child abuse, elder abuse, intent to harm others, or intent to harm self), this must be disclosed to study participants and included as a risk)*.

The benefits of participating in the study are:

*(Describe the benefits of the study here, clearly identifying which are likely to constitute direct benefits to the participants themselves and which may benefit society more generally)*.

**Injury or Illness:**

*(As relevant, describe whether any medical treatments are available if injury or illness occurs as a result of participation in this study. Describe what these treatments consist of and/or where further information may be obtained. If this study does not involve more than minimal risk, repeat that fact here.)*

Fairfax University of America will neither be held responsible nor provide medical treatment or financial compensation if you are injured or become ill as a result of participation in this research. However, this does not waive any of your legal rights or release any claim that you might have based on negligence.

**Compensation:**

*(As relevant, describe how participants will be compensated for their participation. If no compensation will be provided, state that fact here)*.

**Confidentiality:**

*(Describe what steps will be taken to protect participants’ privacy and confidentiality. Include information on who will have access to the participants’ data, where the data will be stored, how it will be protected, how it will be reported, and how and when it will be disposed of. If there are any limits to confidentiality (e.g., among participants in focus groups), describe them here.)*

*(Here is some wording you may be able to use in this section, but please note that it should be elaborated with additional details: The data and records for this study will be kept private and confidential. [Explain how.] They will be stored securely [explain how], and only the researcher will have access to them. In any report of this research, all efforts will be made to ensure that the identification of participants is impossible. [Explain how.])*

**Voluntary Participation and Withdrawal:**

Participation in this study is completely voluntary. Your decision regarding whether or not to participate will not affect your current or future relations with the researcher or anyone else at Fairfax University of America *(additionally include other relevant parties here, such as professors or supervisors)*. If you decide to participate, you may choose to withdraw from the study at any time for any reason with no penalty. *(Describe the procedures for voluntary withdrawal here, including when it will be possible to withdraw and what will be done with the data of participants who decide to withdraw.)*

**Contacts and Questions:**

The study is being conducted by *(repeat the researcher’s name, university affiliation, and department here)*. You may ask any questions you have now. If you have questions later, you are encouraged to contact *(add the researcher’s name)* at *(provide contact information here)*.

If you have any questions or concerns regarding this study and would like to talk with someone other than the researcher, you are encouraged to contact *(if the researcher is a student, additionally include the faculty advisor’s name and contact information here)* Fairfax University of America’s Institutional Review Board (4401 Village Drive, Fairfax, Virginia, 22030) at [irb@fxua.edu](mailto:irb@fxua.edu).

**You will be given a copy of this information to keep for your records.**

**Statement of Consent:**

*(For research that qualifies for a waiver of signed consent, please remove the signature lines from the bottom of this document. Information on when the documentation of informed consent may be waived is available here:* [*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html)*. Please note that, even when participants are not required to sign an informed consent form, the information must still be provided to them for their records.)*

I have read and understood the above information. I have been given the opportunity to ask questions and have received answers to any questions that I had. I voluntarily consent to participate in the study.

**Participant signature:** Date:

**Parent or guardian signature** *(if minors are involved)***:** Date:

**Investigator signature:** Date: