{*Place on departmental or applicable institutional letterhead}*

**This template is for use in survey research that is NOT distributed over the internet.**

**For surveys distributed via Qualtrics or similar services, please use the Cover Letter for Internet Research template.**

**Eliminate any wording in RED. Provide information prompted by the BLUE statements, if applicable. Return all text to black when you have completed the consent form and before you upload the consent to the IRB application.**

**Consent forms should be written at an 8th grade reading level, avoiding technical language, defining all acronyms and abbreviations when they first appear in text. Participants should receive a copy of the consent form for their records.**

**Student Researchers are only permitted to provide their email addresses and NOT their contact numbers.**

**If your consent form is longer than 3 pages you must begin the form with a concise and focus presentation of key information that is likely to assist potential subjects in understanding whether they want to participate. Include a concise description of the elements of the study. This is crucial to the subject’s decision to be in the study.**

**The highlighted information are key points to incorporate into the consent form.**

**Begin your consent form with the title of the research.**

**Purpose of the Study**: Give a brief description of the background and purpose of the study. Include an estimate of the number of subjects expected to participate.

**Major Requirements of Study**: This is the Procedures section of the consent form. What procedures will you be asked to follow? Describe the procedures in lay terms.

**Significant Risks:** Describe any risks or discomforts that subjects may experience, as well as the probability of said risks and/or discomforts, as a result of the study.

**Potential Benefits**: Briefly describe any direct personal benefits there may be to the subject, also how this study may benefit the scientific field/society.

**Duration of Participation**: Briefly state that the subject is not required to participate in the study and any alternative procedures or courses of treatment, if applicable.

**Informed Consent**

**Title of Research:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher(s): *{List Faculty and Students* – *do not include student phone numbers}*

You are asked to be a volunteer in a research study designed to: *{insert purpose of study}*. [The word RESEARCH is required] You were selected as a possible participant because [describe inclusion criteria]. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Participation is completely voluntary.

**Purpose:**

[This section is required] Give a brief description of the background and purpose of the study. Include an estimate of the number of subjects expected to participate.

**Procedures:**

[This section is required] If you decide to be in the study, you will be asked to *{insert a description of the procedures you are asking participants to follow and the expected duration of their participation. All methods included in the IRB application should be included here in simple language. Include description of data to be gathered that is not received directly from the participant. Include a statement telling participants if there will be audio/video recording}*. *Approximately {# of people}* people from *{the population group} will be asked to participate in the study.*

**Risks or Discomforts:**

[This section is required and must disclose any reasonably foreseeable risks and discomforts that a participant may experience] Describe any risks or discomforts that subjects may experience, as well as the probability of said risks and/or discomforts, as a result of the study.

This study has {*more risk than/no more risk than*} you may find in daily life. *{If there are risks, then state them. Any risks you have described in the IRB application should be included here. Please include how those risks will be minimalized.*

Example statements:

“There is no more risk than what is encountered in everyday life with this study.”

“We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.”

 “Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time”.*}*

**Compensation to You:**

[This section is required, even if there is no compensation.] There *{is/is no}* compensation for you to be in this research. *{If compensation is provided, disclose the type and amount of compensation, clarifying the level of participation required for compensation and any prorating of compensation for partial participation}*.

**Benefits:**

[This section is required and must include a description of any benefits expected for the participants or for society] Briefly describe any direct personal benefits there may be to the subject, also how this study may benefit the scientific field/society. *{omit previous sentence, state possible benefits to the participant or society. Do not include compensation for participants here.}*

You can choose not to be in this study. If you decide to be in this study, you may choose not to answer certain questions or not to be in certain parts of this study.

***{If applicable}***This research study is funded by *{insert name}*.

If you decide to be in this study, what you tell us will be kept private unless required by law to tell. {*If applicable, disclose possible times when information may not be kept confidential*}. If we present or publish the results of this study, your name will not be linked in any way to what we present.

**Confidentiality:**

[This section is required] *{Listed below are various privacy/confidentiality examples for different types of data.* ***Include only the information relevant to your study and delete the rest.*** *Please feel free to modify accordingly.}*

*If collected data will be anonymous:*The data collected in this study are anonymous. This means that not even the research team can match you to your data.

*If collected data will be confidential:*The data collected in this research study will be kept confidential. Participation in research may involve some loss of privacy. We will do our best to make sure that the information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in the research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law, such as pursuant to a court order.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

We will collect your information through *[recordings, interviews, Qualtrics survey, etc.].* This information will be stored *[in a restricted access folder, an encrypted cloud-based system, locked office cabinet, etc. If identifiers will be separated from data, describe storage plan for the identifiers and how long they will be retained.]*

*[Indicate what steps you will take to keep data confidential / secure (e.g. use of a coding system, secure storage, using summary data from a whole group, use of pseudonyms for direct quotes).]*

*If data collected has the potential to trigger mandatory reporting responsibilities:*There are two circumstances where we would be required to break confidentiality and share your information with local authorities. The first is if we become aware or have a reason to believe that a child, an elder, or a disabled individual is being abused or neglected. The second is if you make a serious threat to harm yourself or others.

*If data is collected using an online survey or data collection tool (even if anonymous):*The research team will work to protect your data to the extent permitted by technology. It is possible, although unlikely, that an unauthorized individual could gain access to your responses because you are responding online. This risk is similar to your everyday use of the internet.

*If data is collected in a focus group:*

We will request that all participants respect the confidentiality of the group and do not share any other participant’s responses outside of the group. However, we cannot guarantee your privacy or confidentiality because there is always the possibility that another member of the group could share what was said. Pseudonyms will be assigned to each participant, and during the course of the interview and in all notes, you will only be referred to by your pseudonym.

*If photographs/audio/visual recordings will be collected:*

*[Photographs/Audio/visual recordings]* will be collected during this study and used to *[describe purpose].* The recordings will be *[kept indefinitely, destroyed after transcription, destroyed after X years, etc.].* The recordings [will/will not] be shared *with [the general public or other researchers].* You *[do or do not]* have to agree to be recorded in order to participate in the main part of this study.

*If direct quotes may be used in dissemination:*

If you give the research team permission to quote you directly, the researchers will give you a pseudonym and will generalize your quote to remove any information that could be personally identifying.

*If collecting identifiable information or biospecimens one of the following statements is required:*

Identifiers might be removed from your *[information/biospecimen]* and the de-identified *[information/biospecimen]* might be used or distributed to other researchers for future research without your additional consent.

Identifiable *[information/biospecimens]* might be used or distributed to other researchers for future research without obtaining additional consent from you.

Your *[information/biospecimens]* will not be used or distributed for future research studies.

*If collecting biospecimens this statement is required:*

Biospecimens collected for this study will become property of Western Carolina University. You will not share in any commercial value or receive compensation if any commercial products are developed using the biospecimens.

*If this project is funded by NIH and collects identifiable information, all of the following is required:*

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services. This means that we cannot disclose or provide any identifiable information about you to any federal, state, local, civil, criminal, administrative, or legal proceeding. For example, your identifiable information may not be subpoenaed pursuant to a court order.

This certificate does not limit the ability of personnel from the federal or state government agency sponsoring this research to request information needed for auditing or program evaluation purposes or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

The information protected by this certificate may not be disclosed to anyone outside the research team except in the following situations: if there is a federal, state, or local law that requires disclosure (such as mandatory reporting of child abuse or communicable disease); if you have consented to disclosure, including for medical treatment; or if your information is used for other scientific research as allowed by federal regulations governing research involving human participants.

This certificate does not prevent you from voluntarily releasing information about yourself or your involvement in the research. If you would like the research team to release your information to an insurer, medical care provider, or other individual not connected to the research, you must provide additional consent to the allow the researchers to release it.

**Costs to You:**

[This section is required] *and must disclose the cost, if any, that participants will bear as a result of being in this study. If there are no costs, this information should also be specified.*

There *{are no costs to you / are expenses you will incur}* for being in this study *{disclose, if applicable}*.

*{If applicable, elaborate as appropriate}* You should not be in the study if you have any physical or mental illness or weakness that would increase your risk of harm from the study.

**Questions about Your Rights as a Research Participant:**

[This section is required] If at any time you want to stop being in this study, you may stop being in the study without penalty or loss of benefits by contacting: *{list person and contact information - make sure phone number formats matches throughout document.}* If you choose not to participate or decide to withdraw, there will be no impact on your *{grades/academic standing, employment, access to medical care][If applicable, describe how individuals may withdraw from the study}*

*{If the research involves experimental treatments/interventions, describe any non-experimental alternatives that may be available. For students receiving course credit, alternatives to research participation should be mentioned here.}*

If you have questions now about this study, ask before you sign this form.

If you have any questions later, you may talk with *{list person and contact information. This is usually the PI}.*

If this study raised some issues that you would like to discuss with a professional, you may contact *{list contact person and contact information. This is usually the PI}*.

This study was approved by the Radford University Committee for the Review of Human Subjects Research. If you have questions or concerns about your rights as a research subject or have complaints about this study, you should contact Dr. Jeanne Mekolichick, Institutional Official and Associate Provost for Research, Faculty Success, and Strategic Initiatives, jmekolic@radford.edu, 540.831.5114.*[Make sure that this and any other phone numbers in this document all have the same numbering format.]*

It is your choice whether or not to be in this study. What you choose will not affect any current or future relationship with Radford University *{add any other organization as appropriate}*.

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

*{If applicable: If the consent document would be the only record linking the subject and the research and breach of confidentiality would be the principal risk for potential harm in a minimal risk study that involves no procedures for which written consent is normally required outside the research context, documentation of informed consent may be waived under 45 CFR 46.117(c).*

*NOTE – YOU MUST INCLUDE A REQUEST FOR THE APPROPRIATE WAIVER regarding Consent IN YOUR APPLICATION IF YOU ARE GOING TO INCLUDE THE STATEMENT BELOW}:*

According to Federal Regulations, this study is eligible for waiver of signed consent. If you do not wish to sign this consent, please remove it, keep it for your records and return the survey in the self-addressed stamped envelope *{or use whatever is applicable for your study}.*

*{If waiver of signed consent is not used, insert the following}*:

If all of your questions have been answered and you would like to take part in this study, then please sign below.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature Printed Name(s) Date

I/We have explained the study to the person signing above, have allowed an opportunity for questions, and have answered all of his/her questions. I/We believe that the subject understands this information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher(s) Printed Name(s) Date

*[Note – you may add extra lines appropriate for the number of researchers expected to sign this document. Make sure that all spacing is properly aligned and professional looking.]*

Note: A signed copy of this form will be provided for your records.

*[Example: Use when direct quotes or audio/video may be used]*

I do □ or do not □ give my permission to the investigators to quote me directly in their research.

The investigators may □ or may not □ digitally record this interview.

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

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