**Cover Letter Template Instructions – Exempt or Flex Protocols**

Delete this text box (click on the border and press Delete) and page before submission

**Regulatory and WVU Policy Requirements for Cover Letters:**

1. All Exempt and FLEX Protocols using questionnaires, surveys, focus groups or interviews must be accompanied by a cover letter. Cover Letters are recommended for Not Human Subjects Research (NHSR).
2. The cover letter must be distributed to all participants before beginning research.
3. If you are conducting a telephone survey, the cover letter should be read to the participant.
4. Cover letters, telephone scripts, surveys and questionnaires must be included in the attachments section of the protocol submission.
5. Outlines must be included as attachments for focus groups and interviews
6. Combining the cover letter as part of survey or questionnaire in one document is permissible.
7. For focus groups: The cover letter must include a statement that confidentiality cannot be guaranteed from the other persons in the focus group.
8. A cover letter should be one page and language should be written at the 8th grade level.
9. Use the guidance on the next page to create your cover letter.

**Using the Template to Customize Your Cover Letter:**

1. Replace red text with project specific information and change the text to black before submission.
2. The **black text** in the letter template CANNOT be modified as it is approved by the WVU IRB and General Counsel’s office.
3. Remove all instructional purple text.
4. Modify and submit this template with the protocol application as follows:
   * **Initial Submission**: Submit the letter as both a Word document and a PDF.
   * **Revisions**: Turn on **Track Changes**, make the suggested revisions and submit the tracked change version of the ICF along with a PDF **with** the changes accepted.
   * **Final Submission After Approval:** Remove all older versions of the Word document and save and upload the final version as a PDF document after revisions are complete.
5. **WVU IRB Approval:** Upon approval, the system will insert a WATERMARK on the letter with the approval date and the expiration date, along with the protocol number.
6. The letter containing the WATERMARK **must** be used in the consent materials, **including e-consent materials created using REDCap or Qualtrics.**
7. **Delete this page and the next page before submitting to the WVU IRB.**

**REMOVE THIS PAGE!**

**Guidance - Create a Custom Cover Letter**

**Introduction and Purpose**

Introduce yourself and explain your affiliation with WVU. Explain that you are inviting them to participate in a research study. Include any inclusion criteria for the project or why they are being asked to participate. If you are a professor, please state your department. Describe the purpose of the study. If you are a student completing this project as a part of your degree, include information about the degree you are working on, under the PI's supervision, including their position and Department name.

**Description of Study Procedures**

Describe the research procedures so that the participant is aware of what her/his participation will involve. Include a description of the topics that will be asked (especially if there are any sensitive topics), the length of time required to complete the activities, and whether the participant will be contacted again in the future. If sensitive questions will be included, disclose this and provide counseling services as applicable at the end of the cover letter or as an attachment to the cover letter or questionnaire

**Confidentiality**

Describe how the participant's privacy will be protected. **Do not** interchange the terms "confidential" (i.e., maintained in a way that prevents inadvertent or inappropriate disclosure of participants' identifiable information) and "anonymous" (i.e., identifiers are not collected or known). Information is either confidential or anonymous, not both. If you are audio/video recording, inform the participant and provide the option to decline. Describe how and when the recordings will be destroyed at the earliest opportunity.

**Financial Considerations or Extra Credit (Students)**

Clearly explain the compensation, the amount, and intervals of payment. Explain compensation for participants who do not complete the study. Refer to the WVU Procurement and Contracting webpage for information on the WVU prepaid card system, Vincent, and other payment options. Example: You will be paid with a $10.00 gift card after each focus group. You can receive up to $30.00 in gift cards for completion of the three focus group sessions.

**Voluntary Participation**

Explain that participation is voluntary, and there will not be negative consequences if a participant opts not to participate or withdraw from participation. Include the statement that participants can end their participation at any time and can skip any questions they do not want to answer.

**Contact Persons for Questions**

Provide your contact information, your faculty advisor's contact information (if applicable).

**WVU IRB Acknowledgement**

Always include the following statement: The West Virginia University Institutional Review Board's acknowledgment (if this is an Exempt protocol) or approval (if this is a FLEX protocol) of this project is on file with the WVU Office of Human Research Protections.

Dear Prospective Participant,

This letter is a request for you to participate in a research project [insert purpose of the project here]. This project is being conducted by [Jane Doe, BA] in the [Insert Department Name] at WVU (if applicable) [under the supervision of Dr. John Smith], an [Insert position at WVU] in the [Insert Department Name], to fulfill requirements for a Master's Degree in Research.

If you decide to participate, you will be asked to [describe activities or procedures the participant will need to complete]. Your participation in this project will take approximately [insert the time commitment to participate in the research activities]. (Include Inclusion Criteria as applicable.) You must be 18 years of age or older to participate. (If applicable) You will receive [Describe the compensation provided for participation. Explain the method, amount, and frequency of payment. (Refer to the WVU Procurement and Contracting website for payment options).

Your participation in this project will be kept as confidential as legally possible – or – Your involvement is anonymous. All data will be reported in the aggregate. You will not be asked any questions that could lead back to your identity as a participant. Your participation is entirely voluntary. You may skip any question that you do not wish to answer, and you may stop participating at any time. If enrolling students: Your class standing will not be affected if you decide not to participate or withdraw. If enrolling employees: Your employment status will not be affected if you decide not to participate or withdraw. The West Virginia University Institutional Review Board's acknowledgment (if Exempt) – or approval (if FLEX) of this project is on file with the WVU Office of Human Research Protections.

If you have any questions about this research project, please feel free to contact me at [phone number] or by email at [email address] or (if applicable) [enter supervising faculty member's contact information]. Additionally, you can contact the WVU Office of Human Research Protections at 304-293-7073.

I hope that you will participate in this research project, as it could help us better understand [describe the research goals]. Thank you for your time and consideration.

Sincerely,

[Enter Name of the PI]