**Cover Letter Template Instructions – Expedited Protocols**

Delete this page before submission

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

1. All Expedited Protocols using questionnaires, surveys, focus groups or interviews with a waiver of documentation must be accompanied by a cover letter.
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 separate 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.
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 PRIOR TO IRB SUBMISSION
Guidance - Create a Custom Cover Letter**

**Introduction and Purpose**

Introduce yourself and explain your affiliation with WVU. If you are a professor, include your department. If you are a student, completing this project as part of your degree, include information about the degree and that you are working under the PIs supervision. Include the PIs name, position, and department. Explain that this letter is an invitation to participate in a research project. Include the inclusion criteria or why they are being asked to participate. Briefly describe the purpose of the research**.**

**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, 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 service information as applicable at the end of the cover letter or as an attachment to the cover letter.

**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. Note: Information should be destroyed as soon as possible. State that even if personal identifiers are removed, the subjects’ data may be used for future research purposes. Additionally, if funded by the NIH and subject to data sharing policy, list the specific variables/information that will be shared with the database as well as the database name, location, and who manages it (should be congruent with grant).

**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 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. Additionally, if you are targeting WVU employees or WVU study employees, notify them that they must report the total amount of compensation received for participation in a research study to the WVU Tax Services Office upon receipt of payment.

**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. If students will be enrolled, include a statement that the class standing, grades, student work status, or status on an athletic team, if applicable, will not be affected if they decide not to participate or withdraw. If employees will be enrolled, include a statement that employment status will not be affected should they decide not to participate or to withdraw.

**Contact Persons for Questions**

Provide the participant with the PI's contact information and the student's contact information (if applicable).

**WVU IRB Acknowledgement**

Always include the following statement: The West Virginia University Institutional Review Board's review of this research project is on file with the WVU Office of Human Research Protections.

**Link to Survey**

Include the link to the participant survey (if applicable).

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 [Insert Major].

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.)

[Choose one of the following] There are no known risks to participating in this study. – or – Although we have tried to minimize this, some questions may make you upset or feel uncomfortable and you may choose not to answer them. (If applicable) If some questions do upset you, we have included resources for counseling services you can contact below.

[If collecting identifiable information] Your participation in this project will be kept as confidential as legally possible. [Choose one of the following] Additionally, your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information. – or – Additionally, identifiable information may be removed from the information collected in this study. After removal, the information may be used for future research or shared with other researchers without your additional informed consent.

[If anonymous] 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.

If using online data collection/survey tools and/or any third-party applications (including AI or digital health technology), list all third-party applications that will be utilized. Additionally, list the following, if applicable: frequency of their access, level of detail they may have, steps to stop collection/sharing of data, whether use of the technology is required for the study.

If using online data collection/survey tools and/or any third-party applications (including AI or digital health technology), also include the language below:

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data transmitted via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of West Virginia University.

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. [Choose one] If you do not want to participate, there are other choices such as [list options] – or – If you do not want to be in the study, there are no other choices except to decline. The West Virginia University Institutional Review Board's review 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. Although you may not personally benefit, it could help us better understand [describe the research goals]. Thank you for your time and consideration.

Sincerely,

[Enter Name of the PI]

Include the following language if applicable:

For Participant: I agree that I have read and understand what this project is about, and by clicking the link below, I agree to participate in the project.

Please follow the survey link here: [Insert Survey Link Here]