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**Washington College**

**Review Board for Research with Human Subjects**

**SUBMISSION CHECKLIST**

*The below items are all required for any submitted proposal – please check the box to confirm each item has been completed*

Instructions have been reviewed and removed *(p. 2-3)* [ ]

Completed Proposal Cover Sheet *(p. 4)* [ ]

Electronic signature from PI(s) and Supervising Investigator [ ]

*Typed e-signatures* ***will not be accepted***

*For help creating an e-signature visit:*

<https://www.washcoll.edu/learn-by-doing/opportunities-research/student-research/research-policy/human-subjects-research.php>

Human Subjects Questionnaire *(p. 5-7)* [ ]

Informed Consent *(sample template on p. 8)*  [ ]

Debriefing Form *(sample template on p. 9)*  [ ]

Attached Measures [ ]

*(e.g., copies of surveys, tests, assessment materials, interview scripts)*

CITI completion certificates for all researchers (faculty, staff, students) [ ]

*Attach certificate(s) to the end of this IRB proposal if possible*

*For more information for completing the CITI training visit:*

<https://www.washcoll.edu/learn-by-doing/opportunities-research/student-research/research-policy/human-subjects-research.php>

Standardized Sex and Gender Demographic Questions [ ]  [ ] N/A

The Washington College IRB recommends the following standardization for all sex and gender demographic questions:

* What is your sex? Please write your response in the space provided or leave the space blank if you prefer not to answer
* What is your gender? Please write your response in the space provided or leave the space blank if you prefer not to answer

Counseling Services Statement [ ]  [ ] N/A

The Washington College IRB recommends the inclusion of the following statement in the debriefing form for research projects that have the potential to lead to emotional distress for students of Washington College.

* If you would like to speak with a staff member of Washington College’s Counseling Center about any issue, they can be reached at 410-778-7261. If you prefer telehealth, you can sign up at app.mantrahealth.com (students receive 6 free sessions). You can also call the Suicide Prevention Hotline at 1-800-273-8255 or text “HOME” to 741741 for free 24/7 crisis support.

**Please send an electronic version of your proposal, including this checklist and all appendices as one document to** **IRB@washcoll.edu**

***Paper copies are not accepted***

**INSTRUCTIONS: DO NOT SUBMIT WITH PROPOSAL**

**All proposals** for research with human subjects must go through the Institutional Review Board (IRB) for research with human subjects.

The purpose of the IRB is to ensure the rights of participants in human research are protected, in line with the federal guidelines. All investigators conducting research with human subjects will submit a proposal to the IRB for review and will only conduct the research **AFTER** the proposal is reviewed and approved.

**Selecting Your Review Category*.*** According to the guidelines of the Department of Health and Human Services (HHS Title 45, Part 46.101 to 46.409) research involving human participants can be divided into three categories: exempt, expedited review and full review. Although you recommend a review category for your proposal, *the determination of review category will be made by the IRB chair*.

**Exempt or Excused**

Research which is exempt or excused from review if:

* the research involves the use of common educational assessment tests
* personal information that could be used to identify the participant is not recorded
* participation in the study carries no appreciable risks
* participants are at least 18 years of age and are not mentally ill
* participants are not coerced to participate in any way

*Examples of exempt or excused research:*

* normal classroom assessment measures using standardized educational tests
* behavioral data collected through observation of public behavior such as unobtrusively counting the number of people entering and leaving the library as a function of time of day
* data about individuals obtained through public records such as courthouse records as long as the data made public *in the research report* cannot be used to identify the individual. For example, public records regarding who is convicted of criminal offenses, frequency of specific offenses, and the sentencing patterns could be discussed in the research report, but the identity of the individuals must not be recorded.

**Expedited Review**

Research which represents no more risk to participants than normal activity. These proposals may be given an expedited Review by the IRB chair and another member. Exempt/expedited proposals will typically be reviewed within five (5) business days of the date they are submitted to the review board.

*Examples of expedited review research:*

* studies that present no greater risk to participants than does everyday activity
* studies that involve anonymous responses
* studies that do not involve disclosure of personal information such as sexual behavior or drug and alcohol use
* studies that do not involve collection of bodily fluids

**Full Review**

Research which involves more risk to the participant than normal activity. These proposals must be given a full review by the entire IRB Board. Proposals requiring full committee review must be submitted by specific dates to be considered at an IRB meeting. A list of current submission dates can be found at: <https://www.washcoll.edu/academics/research-policy/human-subjects-research.php>.

*Examples of full review research:*

* research with participants younger than 18 years of age
* research involving prisoners, or patients receiving inpatient or outpatient mental health care
* any proposal involving the collection of or exposure to bodily fluids such as blood, saliva, or semen
* any proposal involving deception that, in the opinion of the IRB, could have negative consequences
* any proposal in which disclosure of a participant’s responses could leave them liable for criminal prosecution
* any proposal investigating private issues such as sexual behavior
* any proposal investigating clinical disorders such as depression, anorexia, etc.
* any proposal where the participants are videotaped or audio recorded in a way that would permit their identity to be known, if such disclosure could lead to legal, criminal, or financial liability or if such disclosure could lead to humiliation.

**Project IRB Renewal**: Previously approved studies can be renewed by the IRB if no substantial changes in methodology are proposed. Please complete Form C on the Washington College Human Subjects website.

Finally, be aware that the College has no responsibility to legally defend an investigator from capricious legal actions that might arise from a study, if the study was not approved by the IRB.

**CITI Training Requirement:** As of January 24, 2022, all researchers (faculty, staff, students) listed on an IRB proposal must complete the CITI Research Ethics and Compliance Training (citiprogram.org). Full instructions for how to register can be found on the Washington College IRB website.

**WASHINGTON COLLEGE REVIEW BOARD FOR RESEARCH WITH HUMAN SUBJECTS**

**COVER SHEET**

Submitted By *(your name)*:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor/Principal Investigator’s Name *(must be faculty/staff)*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor/Principal Investigator’s Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Research Proposal: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Category *(select one; see explanations of review categories on pages 7-8)*:

Exempt Review \_\_\_\_\_\_\_ Expedited Review \_\_\_\_\_\_ Full Committee Review\_\_\_\_\_\_

**Proposer’s *(your)* Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:** My signature below indicates that I have reviewed this proposal and all of the procedures involved in this project, and I recommend that it be considered by the Review Board for Research on Human Subjects. I will take overall responsibility for the research project.

**Principal Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other co-investigators *(optional)*:

**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**WASHINGTON COLLEGE HUMAN SUBJECTS QUESTIONNAIRE**

*All questions must be answered with types responses*

1. Briefly and clearly describe the purpose of the proposed research. In other words, what research question is the study designed to investigate? *(1-4 sentences)*
2. Provide a clear description of the research design. Describe your methodology and provide the name and source/cite of each of the measures that will be used and submit a copy of each assessment with your proposal. Take as much space as you need to fully describe what you will ask the participants to do. If using your own questions/questionnaire (quantitative or qualitative), describe the questionnaire and attach a copy of it to this proposal.
3. Will this study be conducted in person/face-to-face (rather than online or virtually)?

 [ ]  No

 [ ]  Yes

 If you answered Yes:

1. Provide an explanation for why the study must be done in person rather than virtually?
2. Please include a brief description below of what precautions participants and researchers must take to limit COVID-19 exposure. Specifically, what steps are being taken to meet current CDC guidelines for safety practices.
3. Additionally, complete and submit the supplemental COVID-19 consent form to cover COVID-19 risks and precautions (Form F on the IRB website). Make sure every participant signs this COVID-19 Consent Form (Form F).

1. Will informed consent be obtained in advance of participation (applies to online and in-person data collection)?

 [ ]  No

 If you answered No:

1. Provide a description of why informed consent cannot be obtained.
2. Describe what additional steps you will take to provide participants with information about their participation or to otherwise protect the participants.

 [ ]  Yes

1. Will any of the participants be under the age of 18 years?

 [ ]  No

 [ ]  Yes

 If you answered Yes:

1. Provide a description of the steps you will take to protect young participants from possible risks of your research.
2. Make sure to include a parental consent form as well as an assent form for the minor (if old enough to give consent) with your IRB proposal.
3. Will you be using participants off campus, such as students at another institution or adults residing at a residential treatment facility?

 [ ]  No

 [ ]  Yes

 If you answered Yes:

1. What is the name of the facility/institution/school?
2. HIPPA regulations require that you get approval (possibly through that institution’s IRB or in the form of a letter from the director/head/board chair that represents the facility) from the outside institution. Please provide documentation confirming that you received permission to conduct your research at this facility with your IRB proposal.
3. Will you be recording the voice or image of participants in your research?

 [ ]  No

 [ ]  Yes

 If you answered “Yes”:

1. How will you obtain permission from the participants to record and use their image/voice? *Note: informed consent must be specific about the uses of images, such as class materials, publications, conference presentations, etc.*
2. What type of recordings will be made (audio, visual, or both)?
3. How will the voice and/or image recordings be used for your project? Why are recordings necessary?
4. What procedures will you take to protect the recordings (i.e., where will they be stored, how will they be secured, who will have access)?
5. Will the recordings eventually be destroyed? When? How? *Note: The Office of Human Research Protections requires research records to be kept for three years after the research has finished.*
6. Is deception involved in this study, even if it involves not fully disclosing the true purpose of your study to your participants (to prevent them from acting in accordance with your hypothesis)?

 [ ]  No

 [ ]  Yes

 If you answered Yes:

1. Describe the nature of the deception and its purpose here ***and*** in your debriefing form.
2. There is always some risk, even if minimal, involved in participating in research. Risk can span from boredom to physical or psychological harm/discomfort. Describe the possible risks to the participants here ***and*** in your consent form.
3. Describe the steps you will take to minimize all risks to the participants. For example, for surveys, you can state in your informed consent that participants are free to skip any questions that make them feel uncomfortable. To minimize the risk of boredom, your consent should state that participants are free to end participation at any time.
4. Briefly (in 2-3 sentences) describe the benefits of this research to the participants, either direct (e.g., study skill training) or indirect (e.g., increase in knowledge about topic), and benefits to the field/discipline/society at large. Be sure to include this information in the consent form.
5. Do you feel that the benefits of your research outweigh the possible risks?

 [ ]  No

 [ ]  Yes

**SAMPLE INFORMED CONSENT FORM**

*This form should be edited according to your project information and needs*

Washington College

Consent Form

Project Title**:** Driving in Rural and City Environments

Principal Investigator: Dr. Your Advisor

Co-investigators: Ms. Senior Thesis, Mr. Research Assistant

**You must be 18 years of age or older to participate**

**Purpose:**

The purpose of this study is to investigate rural versus city driving habits. Participants will be asked if they have witnessed rude behavior by drivers and asked to describe it.

**Procedure:**

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

- Fill out a questionnaire asking you about your driving habits

- Complete a questionnaire asking you to describe rude driving behavior that you have observed

The total time required to complete the study should be approximately 15 minutes. You will receive 1 experimental participation credit.

**Benefits/Risks to Participant:**

- Participants may learn something about rude driving behavior.

- Participants might become bored with answering all of the questions.

**Voluntary Nature of the Study/Confidentiality:**

Your participation in this study is entirely voluntary and you may refuse to complete the study at any point during the experiment. There is no penalty if you decline to participate or stop your participation at any time. You may also stop at any time and ask the researcher any questions you may have. You may skip any questions that you do not feel comfortable answering. Your name will never be connected to your results or to your responses on the questionnaires; instead, a number will be used for identification purposes. Information that would make it possible to identify you or any other participant will never be included in any sort of report. The data will be accessible only to those working on the project.

**Contacts and Questions:**

At this time, you may ask any questions you may have regarding this study. If you have questions later, you may contact the student investigator at xxx-xxx-xxxx or sthesis2@washcoll.edu, or the faculty advisor to this project, Dr. Advisor at xxx-xxx-xxxx or yadvisor2@washcoll.edu.

**Statement of Consent:**

I have read the above information. I have asked any questions I had regarding the experimental procedure and they have been answered to my satisfaction. I consent to participate in this study.

Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please print)

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SAMPLE DEBRIEFING FORM**

*This form should be edited according to your project information and needs*

Washington College

Debriefing Form

Project Title**:** Driving in Rural and City Environments

Principal Investigator: Dr. Your Advisor

Co-investigators: Ms. Senior Thesis, Mr. Research Assistant

In this study, we were attempting to learn more about how city drivers and country drivers differ in their driving behavior. To that end, we asked you some questions about your driving habits and rude driving behavior that you may have witnessed.

Your participation was an essential part of our effort to better understand how different environments can affect driving habits.

Before you end your participation, please let us know if:

* The purpose of this study is not clear to you
* You find any aspect of the study odd, confusing, or troubling

If you have any questions about the study, please feel free to ask them of the investigator(s) or of the faculty member who sponsored this research.

If you would like a summary of the final research report, we will be happy to provide one. Simply email the investigator or the faculty advisor with your request.

If you feel that you have been treated in an unprofessional manner or have concerns about your rights as a research participant, you can contact the Principal Investigator or the chair of the Review Board for Research with Human Subjects, Dr. Tia Murphy at tmurphy2@washcoll.edu.

Again, thank you for your time!

Ms. Senior Thesis sthesis2@washcoll.edu

Dr. Your Advisor yadvisor2@washcoll.edu