William Paterson University Institutional Review Board for Human Subject Research

Student Research Protocol FAQ

A. The Student Protocol Review Request and Attachments

1. Q. **What should I submit to the IRB to obtain permission to conduct my research?**

A. A complete protocol includes the following items:

a. The completed **Student Protocol Review Request** that is signed by both the student investigator and the research supervisor, who is generally the professor of the course related to the research**.**

b. Final version of the **Data Collection Instruments**: surveys, questionnaires, interview questions, observation tables, the URL to online survey tool, etc.

c. Final draft of the **Informed Consent Statements** for subjects, parents/guardians. These may not be given to subjects prior to the IRB's review and approval of the protocol.

d. **Letters or text for emails of introduction, invitation or requesting permission** that will be sent to subjects, parents, facility/agency administrators and others related to the study.

2. Q. **How do I submit my protocol?**

A. After your research supervisor has reviewed and signed the complete Student Protocol Review Request and attachments, **the package can be delivered or mailed** to Martin Williams, IRB Administrator / Office of Sponsored Programs / Raubinger Hall Room 107 / William Paterson University / 300 Pompton Road / Wayne, NJ 07470. Protocols can also be submitted electronically or fax; please call the Office of Sponsored Programs for details at 973-720-2852.

3. Q. **When may I begin my research?**

A. You may initiate your research only after the IRB has completed the review of your research and provided you with an approval notice.

4. Q. **How do I learn if it has been approved?**

A. The IRB will email the approval notice to you (using your WPUNJ email address) and your sponsor.

5. Q. **How long with the review take?**

A. The IRB tries to **respond within three business days** once a Student Protocol Review Request is received. The response can be either an approval notice or request for additional information, corrections or the submission of additional items. The sponsor must receive copies and approve any responses provided by the student investigator to the IRB.

6. Q. **Are there particular pieces of information that I should be sure to include in the protocol?**

A. There are several items that a student investigator conveys in the protocol:

a. **Research using Email or Internet-based resources**: Provide specific information on how subjects will be identified, recruited, referred to online survey tools, or asked to return surveys. The protocol must identify the source of email addresses or other contact information must be included, how the email addresses or other contact information will be provided to the investigator, and how the email addresses or other contact information will be used.

The anonymity of a subject, the protection of their confidentiality, the provision of appropriate informed consent, and instructions concerning subjects exiting the research must all be considered and provided. Examples:

i. Using Facebook to recruit subjects may recruit minors for whom a parent/guardian should provide consent for the minor's participation. The protocol should provide information on how that consent will be obtained or how minors will be excluded from the study.

ii. Using email to distribute and then collect a survey divulges a subject's identify through their email address. The protocol should provide information on how the email addresses will be obtained and

used, and how the returned information is separated from the identifying information and how the identifying information is destroyed. Alternately, the research plan could include a method for anonymizing (the stripping away of any identifying information) the information when it is received.

iii. Subjects follow a link to Survey Monkey or a similar resource, receive appropriate informed consent and then proceed into the survey, but the survey does not provide a way for the subject not to answer particular questions. The protocol and then the Informed Consent Statement must indicate that subjects will be instructed that they will be able to exit the survey altogether if they encounter a question that they do not want to answer. An alternative would be to provide an opportunity for "I do not wish to answer this question" as one of the responses.

b. **Research including audio or video recording**: The use of audio and video recording to collect data must be stated in the protocol along with information on how the recordings will be protected, how long they will be kept, and how they will be disposed of at the end of the research. There may be situations where an investigator may want to keep a recording for a prolonged time: details on how subject identify is protected and the recordings will be used must be provided for approval by the IRB. Recording of subjects must also be included in Informed Consent Statements.

c. **Published Surveys**: When a previously published survey or interview tool will be used, as an alternative to providing the full instrument (for which there may be cost), student investigators can provide a complete description of the tool (i.e.: name, author, publisher, date) and an URL for the IRB to use to find additional information or view the tool.

d. **Location**: Provide the specific location of the research, such as: Student Center, William Paterson University; classes with instructor's permission, William Paterson University; School 96, Anytown, NJ; Willowbrook Mall, Wayne, NJ; Bob's Burgers, Anytown, NJ; etc.

e. **Relationship to Subjects**: Provide information on how the investigator may be "related to" the subjects, not from a familial point-of-view, but from association. This would include situations where the subjects are classmates, sorority/fraternity sisters/brothers, teammates, etc; co-workers, supervisors, employees, etc; students in their own class or classes, other students in their school or district, teachers or administrators in their school or district, etc.

f. **Data Management**: What is the investigator's plan for the secure storage of data generated by the study, especially when there are signed Informed Consent Statements or other information that may disclose participants.

g. **Risks**: Subjects are at risk because they are engaged in research. Risks must be defined and ways to manage that risk must be included. This includes both physical and emotional risks, such as distress caused by responding to personal questions.

7. Q. **Who decides if a protocol for students using human subjects in research needs to be submitted to the IRB?**

A. **The WPU faculty or staff who is supervising the student determines what student research should be submitted to the IRB** based on the criteria included in the WPU Policy on the Use of Human Subjects in Research. **Research supervisors** must have completed and provided **Certification of Training in the Use of Human Subjects in Research** to the IRB prior to their supervising student research. **The research supervisor is responsible for all the activities of their students**, from the preparation of the protocol for submission to the IRB to the closure of the research project.

B. Informed Consent

8. Q. **How do I write and Informed Consent Statement?**

A. The IRB provides sample Informed Consent Statements for use in a variety of situations. Students are encouraged to adapt the appropriate type of sample for their research by adapting by filling-in the blanks and adjusting text as required.

9. Q. **Which type of Informed Consent Statement should I use?**

A. **Passive Informed Consent** can only be used for anonymous surveys and questionnaires when you will only have little or no direct contact with subjects. **Active Informed Consent** is used for all other types of research. When a

study includes both a survey and an interview, an Active Consent Statement should be used for a subject's entire involvement in the project.

10. Q. **What is a Passive Informed Consent Statement?**

A. A **Passive Informed Consent Statement** does not require a subject to sign their name in order to participate in a research project. This insures that subjects are completely anonymous and eliminates potential problems with insuring that the subject's participation will remain confidential. A subject's consent is provided when they act on the two alternatives – to continue or stop – presented at the end of the Statement. All other information that is required of a consent statement must still be included: nature of the study, tasks required for participation, voluntary participation, risks and benefits, contact information. A Passive Informed Consent Statement may be included at the beginning of the survey or questionnaire that is given to prospective subjects.

The Investigator must take the time to verbally convey the information in an Active Informed Consent and allow for a conversation with each subject prior to the subject's actual receipt of the Statement and initiation of their participation.

11. Q. **What is an Active Informed Consent Statement?**

A. An **Active Informed Consent Statement** requires a subject to sign their name prior to participating in the research. This insures that there is a record of each subjects agreement to the level of contact with the subject and the tasks that will be required of them, their understanding that their participation is voluntary, their understanding of the risks and benefits of their participation, and their knowledge of who to contact should they have concerns about the way that the research was conducted. The Investigator must also sign an Active Informed Consent Statement. Subjects must receive their own copy of the Consent Statement to keep for future reference.

The Investigator must take the time to verbally convey the information in an Active Informed Consent and allow for a conversation with each subject prior to the subject's actual receipt of the Statement and initiation of their participation.

12. Q. **How do I provide Informed Consent for an Internet-based survey?**

A. Informed Consent is provided twice for anonymous Internet-based surveys (ie: SurveyMonkey, Zoomerang). All of the information normally required for Informed Consent is required for Internet-based research. It is important that information within the Informed Consent Statements for this format and that the instructions provided concerning participation are appropriate.

a. The Informed Consent Statement is provided as part of the recruitment email/notice that is provided to prospective subjects. The instructions here should indicate how to proceed to the online survey (i.e.: "click this link") or end their participation (i.e.: "close and delete this email").
b. Informed Consent is provided as the first page/panel/screen or at the beginning of the page that subjects access. The instructions here should indicate how to proceed with the online survey (i.e.: "click next") or end their participation (i.e.: "close your Internet browser").

13. Q. **What is the "required heading" for Informed Consent Statements and why is it required?**

A. A heading is required to inform subjects that the research is sponsored by and approved by the WPUNJ IRB and to convey information related to who is conducting and supervising the research and how they can be contacted. It is required for student research as well as research conducted by faculty and staff. For student research, the heading must include the title of the research project, the name(s) of the student investigators, the name and phone number of the faculty sponsor, the department, course name and number, and the date that the research was approved. While the IRB provides a format for this information, as long as it all provided, it can be in any format the investigator chooses. Please note that the phone number of the research supervisor is provided because she/he is responsible for the research this his/her student is conducting.

14. Q. **My subjects do not speak or read English very well or may not at all. What do I do?**

A. **Subjects must have the opportunity to learn about the research and provide their consent to participate in the language that they are most comfortable using**. This may require the Informed Consent Statement to be translated into the language appropriate for the study's subjects. The person obtaining subject consent should

then also be appropriately fluent in that language. Both the English and the translated versions must be included with the Student Protocol Review Request when it is submitted to the IRB.

15. Q. **When do I include a witness in the process to obtain Informed Consent?**

A. **Witnesses to Informed Consent** are only used when the prospective subject does not or may not be able to fully understand the nature and tasks of the research, may not have the freedom to choose to participate (prisoner, older minor), or may have another limitation such as language or mobility.

The inclusion of a witness expands the number of people who know who have participated in the research, so witnesses should be used in only limited situations. Further, the witness should also understand their role in protecting the confidentiality of the subject.

16. Q. **What aspects of the research should I be sure to include in the Informed Consent Statement?**

A. Subjects have to know the basic activities that they will be involved in: completing a survey, participating in an interview, being observed in a particular setting, etc. Additionally, subjects must be notified of the following:

a. **Freedom of Participation**: Subjects must understand that their participation is voluntary throughout the course of the research. They must understand that they can end their participation in the research at any time; this may include providing instructions for ending participation.
b. **Audio or video recording:** If this included in the research, subjects must be informed of this and the ultimate disposition of the recordings must be included as well. This is a concern related to insuring subject confidentiality.
c. **Data Protection**: Subjects must be informed about how the data generated by their participation will be protected. This is a concern related to insuring subject confidentiality.
d. **Protection of Confidentiality**: Subjects must be informed how their identity will be protected during the research, after the research, and in reports and publications related to the research.
e. **Response to Research**: If there may be a potential negative reaction by a subject because of the research (topic or method), information must be provided to assist the subject in obtaining treatment or support. This may include a general or specific reference to counseling or health services.
f. **Contact Information**: Subjects must know who to contact if they have questions or concerns related to the research. This includes contact information for the student investigator's supervisor (professor) and the IRB.

C. Changes after Approval

17. Q. **What if I need to make a change to my research after it has been approved by the IRB?**

A. The requested change must first be reviewed and approved by the research supervisor. After this, the change can be emailed as a request to Martin Williams, IRB Administrator, at WilliamsM@wpunj.edu. The email must include the Protocol Number and the title of the research project, a complete description of the changes, and any new or revised forms, letters and/or consent statements that will be used. The IRB will review and respond to requested changes in the same manner that it would the submission of a new protocol.