**Fairleigh Dickinson University**

**Institutional Review Board**

**Investigator Guidelines for Writing a Research Protocol**

Each research project should have a detailed protocol (study design/instructions) that describes how the project is going to be completed. The protocol is reviewed to ensure certain elements are included for the protection of human subjects. The IRB must also document evidence that elements for approval are included to be compliant with Federal Regulations governing research with human subjects.

A research protocol is separate from your dissertation/thesis. It is your How To/Instruction Manual on how you will be completing your research study. The dissertation/thesis will present your findings of your study.

The following guidance provides a suggested template of how your research protocol should be organized. The protocol will also assist you in answering all the questions contained in the new project applications. The application will ask for certain pieces identified below. You may copy and paste information from your protocol in the application if necessary. If your protocol is submitted separate from your application, please provide version dates and page numbers to assist you and the IRB if any amendments/modifications to the project are necessary. Only the current approved research protocol may be used to conduct the study.

*Delete all guidance and instructions after the title of the section you are describing before submitting your protocol for review.*

**I. INTRODUCTION**

1. **Study aims**. State the specific scientific objectives (aims) of the research. Brief references to literature and a statement of problem. The question and hypothesis of research study.

2. **Background.** This paragraph should support the purpose of the study. [Note: References to the literature are appropriate but should be brief.]

3. **Study Design.** Type of study design and principal variables or outcome measure.

**II. RESEARCH POPULATION**

1. **Number of subject**s. State the total number of subjects expected to participate. Explain why this is the right number for your project to be statistically valid.

2. **Gender of Subjects.** Describe the intended gender distribution of the subjects. If there are any gender-based enrollment restrictions, explain the nature of the restriction(s) and provide justification. *Equitable* *inclusion of both men and women in research is important to ensure that both receive an equal share of the benefits of* *research and that neither bears a disproportionate burden. Therefore, subjects of both genders should be included in the* *study unless there are appropriate medical and/or scientific reasons.*

**3. Age of Subjects**. State the age range of the subjects. Provide the rationale for selecting this age range. Participation of adult subjects in research should not be age-restricted unless there is specific justification provided. [Note: The age of majority in New Jersey is 18 and special considerations apply to research with children. If you are conducting research with children, please take into account issues relating to consent/assent detailed below.]

5. **Inclusion Criteria**. Describe what criteria you are looking for specifically for your subjects to be enrolled in the project.

6. **Exclusion Criteria**. Describe what criteria you do not want your subjects to have or subjects you would want ruled out. For some subjects, it may not be safe for them to be included, Describe.

7. **Subject Screening.** Describe the process for subjects to be screened to see if they qualify for your project. Will the subjects have to complete a test or provide some information to you first? Please note that the consent form should explain this process first and let the subject know after the screening it may be determined that it was found the study is not right for him/her to participate.

7. **Vulnerable Subject**s. If vulnerable subjects (e.g., those with limited autonomy or those in subordinate positions) are included, justification must be provided. Children, pregnant women, fetuses, and prisoners are considered vulnerable populations in the federal regulations. However, the elderly, students, employees, and persons with decisional incapacity are also generally considered vulnerable subjects in need of greater protection. Please contact Kim Diccianni, Human Research Compliance Manager at 201-692-2219 for any assistance.

8. **Method of Subject Identification and Recruitmen**t. Describe the method(s) that will be employed in the identification and recruitment of prospective subjects. Note: The identification and recruitment of subjects must protect privacy and be free of undue influence. Recruitment of an investigator’s own staff, students, employees, and patients may be considered potentially coercive, and steps should be taken to minimize undue influence. These steps to minimize coercion should be outlined in the protocol, if you are working with any of the identified populations. All recruitment efforts must also be reviewed and approved by the IRB before use. Efforts include flyers, scripts of verbal recruitment such as recruitment being completed in a class or at a general meeting, posts on the SONA system/websites, e-mail language, telephone call scripts, etc.

Please note: if recruitment is not applicable such as in studies of existing data/specimens, you may address only study population identification. The section of subject identification and recruitment should detail how correct specimens/records are identified to access for your study.

**III. METHODS AND PROCEDURES**

1. **Methods and Procedures.** Summarize the research design and list procedures to be used to

accomplish the specific aims of the project. Procedures/tests/interventions that are considered

experimental and/or procedures performed exclusively for research purposes must be identified and differentiated from those that would occur regardless of the research (i.e., standard of care), if applicable. Point out any procedures, situations, or materials that may be hazardous and the precautions to be exercised to minimize the risks. The outline must identify routine procedures performed solely for research purposes. Identify and address potential biases or problems. If subjects are to be randomized, please detail randomization procedures.

Please note for online studies, Qualtrics must be used for projects collecting protected health information (PHI) and/or personal identifiable information (PII). Google forms, Microsoft forms, etc. may only be utilized if no PHI or PII are collected.

2. **Data Analysis and Data Monitoring.** If the study is designed to test a hypothesis, explain sample size derivation and address appropriate power issues. Summarize the statistical/analytical methods. For studies that involve interventions that entail potential risk to subjects, a data monitoring committee may be considered to protect the safety and/or welfare of subjects. If you will employ a data monitoring committee, please provide a detailed description of its operation (i.e., membership, function, frequency of review, stopping rules).

3. **Data Storage and Confidentialit**y. Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data; including coding data and choosing an appropriate and secure data storage mechanism that will prevent unauthorized access to data. Identify who will have access to the data. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be released and the purpose of the release (e.g., routine verification of case report forms or notification to required State agencies). Strict security must also be used for the collection of PHI and/or PII. No PHI and/or PII should be stored on portable devices such as laptops, phones, USB keys, etc. A plan for the storage and protection of PHI/PII data must be included.

**IV. RISK/BENEFIT ASSESSMENT**

1. **Risk**. Detail the risk that the research presents. (A risk is a potential harm associated with the research that a reasonable person would likely consider injurious.) Describe the potential risks associated with the study. Keep in mind; risks are not only physical, but psychological, sociological, economic and legal as well. If possible, estimate the probability that a given harm may occur and state its potential reversibility.

2. **Protection against Risks**. Describe how the study design will prevent and/or minimize any potential risks or discomfort. Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, monitoring of subjects, withdrawal of the subject upon evidence of difficulty or adverse event (clearly define the exit criteria); and referral for treatment, counseling or other necessary follow-up. State, who will pay for treatment, counseling or follow-up. If compensation is provided to subjects for any adverse event occurring in a study via a grant or a funding source, the language included in the executed contract must match the project’s protocol and consent form.

3. **Potential Benefits to the Subject**s. Describe potential benefit(s), if any, for subjects participating in the research. If there are no anticipated benefits, this should be stated. [Note: Payment to subjects is not considered to be a benefit of research (see Payment section below)].

**IV. CONSENT/ASSENT**

The information detailed in the protocol will provide a base for the information that will be included in the consent document. If the information is not detailed in the protocol the IRB will not have been provided with accurate information regarding the consent process or the detail that should be included in the process or the document. Hence, it is important to consider the categories in this section because investigators have a legal and ethical obligation to ensure that prospective subjects/subjects’ representatives have sufficient knowledge and comprehension of the elements of informed consent.

The information presented to subjects must be clear in order to enable subjects to make an informed and enlightened decision whether or not to participate or allow participation in research.

Please note: if consent is requested to be waived please provide necessary evidence as required in the FDU IRB Waiver of /Alteration to the Consent form. Waiver of consent may be appropriate for certain studies but only studies that are minimal risk and when the IRB can make appropriate and necessary determinations.

1. **Process of Consent**. Describe who will obtain consent and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the subject/subject’s legally authorized representative. Individuals who are authorized to obtain consent must be listed on the protocol and consent form document. If necessary to use ‘Auditor/Witness’ and/or translator, these roles would be described in this section.

**2. Subject Capacity, if applicable**. If not all subjects will have the capacity to give informed consent, describe how capacity will be assessed. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Research with persons who have diminished capacity is allowed only for minimal risk or direct benefit studies.

**3.** **Subject/Representative Comprehension**. In this section, describe how it will be determined that the subject/subject’s authorized representative understood the information presented. This section should clearly document that the investigator has an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. If children and/or impaired adults who lack decision making capacity will be subjects, this section should also include a specific plan to assess comprehension during assent (the subject’s agreement).

4. **Debriefing Procedures**. In psychological studies where any information will be purposely withheld from the subject, state the information to be withheld, justify this non-disclosure and describe the post-study debriefing that will be given to the subject.

5. **Consent Forms**. Consult the IRB Standard Consent Form template for specific sections required for consent documents. The first page of the consent form must be printed on letterhead of the department or institution.

6. **Documentation of Consent**. The PI is responsible for ensuring that valid consent is obtained and documented for all subjects. If not already addressed in item two above (Process of Consent) specifically describe how consent will be documented and how/where documentation will be stored.

7. **Costs to the Subject.** Describe and justify any costs that the subject will incur as a result of

participating in the study. This section should clarify who will pay for procedures associated with the study (e.g., agency grant versus departmental funds). Normally, subjects should not have to pay for research procedures without direct benefit. No charge may be made to subjects if the costs are covered by a grant, contract, or other payment method.

 8. **Payment/Reimbursements for Participation**. Describe any reimbursements or payments such as cash payments, course credit, coupons, and gift certificates that the subjects will receive for participation. List the prerequisite condition(s) that must be fulfilled by subjects to receive these reimbursements. The amount must be justified and not constitute undue inducement of the subject to participate in the research or to continue beyond a point that they would have otherwise withdrawn. Note: The IRB suggests a prorated system for financial payments. This means that payments are accrued as the study progresses and that subjects do not have to complete the entire study to be eligible to receive a payment. This is to protect the subject’s right to withdraw without penalty. If a raffle is to be conducted, the following information must be included: the item being raffled and the amount, who will draw the raffle, how it will be completed, when it will be completed, where it will be completed and how the participant will be notified.

**V. INVESTIGATOR’S QUALIFICATIONS AND EXPERIENCE**

If you are a student investigator your IRB Submission must include a copy of the dissertation committee approval or your program’s equivalent and any additional training certificates needed to complete the research, if applicable.

All research personnel and Faculty Mentors are required to complete training in the protection of human subjects. FDU IRB has a link the CITI internet-based tutorial which may be completed to fulfill the training requirement. Re-certification must be completed every 3 years. You will complete the training for Investigators of either Social Behavioral Human Subjects Research or Biomedical Human Subjects Research. The module should be chosen based on your education, the study components and subject matter.

VI. Appendices

1. Surveys, questionnaires, measures, interview scripts, Application for Waiver of/Alteration to Consent, etc.
2. Recruitment Materials: a) flyers, (b) poster information, (c) e-mail language, (d) recruitment letters, (e) letters of permission from Institutions where research is being completed, (f) TV/Radio Advertisement scripts, etc., (g) scripts of in-person, telephone recruitment.
3. Completed Grant Application, if applicable
4. Any additional information supporting your study and/or any documentation or scripts of verbal information given to study subjects.

*If you have any questions or require assistance, you may contact Kim Diccianni, CIP, Human Research Compliance Manager, Grants and Sponsored Projects at (201) 692-2219 or via e-mail at kim\_diccianni@fdu.edu.*