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| This template is intended to aid investigators and students outline their protocol submissions to the WVU IRB. This is not a required document for submission, it is solely intended to aid in organizing the research project. Each section contains ***italicized text*** with requirements that are most common in exempt and expedited submissions. When using this template, delete the ***text*** and complete each section; if a heading does not apply to your research, please insert ***n/a***. Creating this protocol outline will help simplify the IRB submission and review. **Delete this section before submission.** |

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| **Protocol Number & Study Protocol Title** |
| *Be consistent with the Title throughout your application, protocol, and any other documents as applicable.* |

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| **Table of Contents** |
| *Create this section in order to help team members and reviewers find specific sections of the protocol.* |

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| **Abbreviations List** |
| *List and define common abbreviations and acronyms that are used throughout the protocol. This will help readers interpret the terminology.* |

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| **Section I: Team and Research Summary** |

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| **Study Team Composition** |
| *Anyone that will be actively obtaining data and/or consent must be listed on the protocol and have a role on the study team. Defining the responsibilities of each team member prior to beginning the project may be beneficial. Employees or workers who would be performing their routine job tasks do not need to be added to the protocol (i.e. phlebotomist); workers performing any investigational procedure (i.e. obtaining consent, administering study drug, conducting interviews/surveys)* ***must*** *be added to the protocol.* |
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| ***Principal Investigator*** *– must be a WVU employee or affiliate. The principal investigator may not be an undergraduate, graduate, doctoral, or post-doc student. The PI’s specific position at the university or affiliate site and years of experience conducting research must be listed. Contact information should also be included.* |
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| ***Co-Investigator(s)*** *– may be anyone working on the research project; they may or may not be affiliated with WVU and can be undergraduate, graduate, doctoral, or post-doc student. Contact information should also be included.* |
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| ***Study Personnel*** *– like the Co-I(s), anyone participating in the research may be added as part of the research team. These personnel usually include the regulatory and primary contact person’s for the protocol. Students helping collect, or analyze the data and are not going to be permanent additions to the protocol are typically listed here.*  |

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| **Research Summary** |
| ***Study Population*** *– this section should include the desired study population size, inclusion and exclusion criteria, and a description of whether any vulnerable populations will be included (children, prisoners, pregnant women, and/or mentally handicapped individuals)* |
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| ***Study Design*** *– present an outline of the study design. This section does not need to be detailed, but should be succinct and written so that an educated lay person may understand what is happening (usually written for a 6th grade reading level). Avoid abbreviations and jargon. Include information about how participants will be identified and recruited and how data will be accessed (if applicable) or collected. Include whether there is more than minimal risk involved.*  |
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| ***Study Duration*** *– estimate the length of time that each phase of the research (enrollment, data collection and analysis) will take to complete. This time period is not concrete, and may change if needed. Protocols may be renewed and projects extended.* |

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| **Section II: Design** |

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| **Background & Significance**  |
| *This is an open ended section that is based on your research question and the primary/secondary objective(s). Justify the reasoning behind performing this research; be sure to base any information off of existing knowledge in the field. Explain any assumptions or relationships that are important to your research. Make sure to state and support any hypotheses that you may have for the experiment. Be sure to include citations in the section to the reference list at the end of the outline.* |

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| **Objectives** |
| *Objectives should represent the intellectual activities that the investigator(s) will perform throughout the research project. The purpose of the study should be stated clearly. There may be a single, primary objective, or multiple objectives (secondary, tertiary, etc.) developed and documented by the investigator(s).* |
| ***Purpose*** *– what is the intent of the research? Why conduct the research at all? Support for the purpose of the study should stem from the background information provided on the subject, including work that has been previously completed in the field.* |
| ***Primary Objective*** *– explain the primary objective for the research and the outcome(s) being measured and reported* |
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| ***Secondary Objective(s)*** *– explain, if applicable, any other objectives for the research and the outcome measurements associated with each secondary objective.* |

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| **Study Design & Methodology** |
| *This section is not meant to be a summary. It should be thorough, yet still be comprehensible to a lay person. Include a description of the study type (ex. prospective data collection or retrospective analysis), which is based upon the previously developed objectives. Explain the specific procedures that will be used to meet the objectives that have been set. Include a detailed description of the variables that will be collected and how each variable will be measured in the research project. Address whether or not there is more than minimal risk involved and support your decision. Also include the benefit to the participant(s) from participating in the research, and/or the contribution to the scientific field or general population.* |

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| **Target Population & Recruitment Methods**  |
| *Define a sample size. This can be an overestimate (within reason). Sample size may be increased with an Amendment submitted for IRB approval, at a later date. Explain the rationale behind choosing the sample size, the inclusion and exclusion criteria. Be sure to open enrollment to a diverse racial and ethical backgrounds in order to ensure equitable selection.*  |
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| ***Inclusion & Exclusion Criteria*** *– specify the time period, gender, age (range) and/ or any other defining characteristics that will be considered when identifying potential participants. If conducting a chart review, include what criteria must be present in the medical record in order for the data to be included. Be specific.*  |
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| ***Vulnerable Populations*** *– be specific as to whether any of the following protected populations will be included in the study population: children, cognitively impaired individuals, pregnant women and fetuses, prisoners, WVU/UHA/WVUH employees, or WVU students.****Recruitment*** *– discuss what methods will be used to recruit participants from the above target populations. Be sure to include any advertisements, flyers, and media posts in the final submission for review. Advertisements must clearly state that research is being conducted, the department/agency conducting the research – along with the PI/Co-I contact information, time commitment to the participant, inclusion/exclusion criteria, that participation is voluntary, and that WVU IRB approval is on file.* |

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| **Risk & Benefit** |
| ***Risk*** *– include any risk(s) that will affect the subject while participating in the research project. Risks include anything harmful or stressful that the subject would not normally encounter in everyday life.* |
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| ***Benefit –*** *include any benefits (physical, emotional, or monetary) that the subject would receive for participating in the research project. Benefits may not directly affect the participant; information learned may benefit the scientific field or general population.* |

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| **Statistical Analysis Plan** |
| *What do you plan to analyze from the collected data? How do you plan to analyze the data? It may be beneficial to consult a biostatistician when constructing this section. Include a plan on how to account for missing, unused, and spurious data points.*  |
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| ***Sample Size*** *– include calculations and rationales for the requested sample size. Identify whether this size will provide enough power to deliver significant results. If conducting a multi-site study, include the number of sites and the number that each site plans to enroll in the study.* |
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| ***Data Safety Monitoring*** *– Specify whether there will be a safety data monitoring plan implemented for the project. This is an ongoing review of the study, actions, data collection, and analysis throughout the entirety of the project.* |

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| **Safety Monitoring & Unanticipated Event Reporting** |
| *It is a good idea to be preemptive and establish a method for which the safety of participants will be monitored during the study. Identify who will be monitoring this and the team member they should report to, should a concern arise. The study team should also establish the method for which adverse events and unanticipated events are reported to the IRB. This process should be completed in conjunction with the requirements outlined by the IRB.* |

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| **Study Duration & Timeline** |
| *Create a study schedule and briefly state the stages of the research project. Indicate the length of time each stage is estimated to take to complete. Provide an estimate of the length of time it will take to complete the entire study and offer an approximate end date. In order to facilitate review, it may be helpful to create a flow chart with the objectives and stages of the research project. This section is not typically required for IRB review; however, it may be beneficial when applying for funding.* |

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| **Section III: Informed Consent Process** |

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| **Protected Health Information (PHI)** |
| *Identify whether your research will deal with protected health information (PHI). PHI is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. PHI: This is not limited to only retrospective studies and chart reviews; prospective surveys may also be contain questions regarding PHI.*  |
| 1. ***Names***
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| 1. ***All geographical information (except State)*** *– this includes street address, city, county, precinct, ZIP code, and their equivalent geocodes. The initial 3 digits of a ZIP code are not considered PHI.*
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| 1. ***All elements of dates (except year)*** *– this includes dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older*
2. ***Phone number(s)***
3. ***Fax number(s)***
4. ***Electronic mail (E-mail) addresses***
5. ***Social Security numbers***
6. ***Medical Record numbers***
7. ***Health plan beneficiary numbers***
8. ***Account numbers***
9. ***Certificate or license number***
10. ***Vehicle identifiers and serial numbers***
11. ***Device identifiers and serial numbers***
12. ***Web Universal Resource Locators (URLs)***
13. ***Internet Protocol (IP) address***
14. ***Biometric identifiers*** *– this includes finger and voice prints*
15. ***Full face photographic images*** *– and/or any other comparable image taken*
16. ***Any other unique, identifying number*** *– includes other characteristics or codes. This does not include the unique code assigned by the investigator to ‘code the data set’.*
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| **Informed Consent Process** |
| *Identify who on the study team will explain the consent document and study, where the consent process will take place, and who will be granting consent. The Informed Consent Form (ICF) should be written in lay terms and at a 6th grade reading level. Refer to the Protected Health Information (PHI) section in order to identify whether or not an Informed Consent Document with HIPAA is required.**Depending on the study population, the person granting consent to participate in the research project may vary and may not always be the participant. Address whether or not there assent will be obtained from children under 18 years old and how many parental (or legal guardian) signatures will be obtained.* |
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| ***Retrospective Studies –*** *depending on the study, retrospective data analyses may wish to apply for a Waiver of Consent or a Waiver of Documentation of Consent.*  |
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| ***Prospective Studies*** *– include who, where, and why informed consent will be obtained from the participants. The researcher should always attempt to obtain written consent from their participants; however, they may apply for a Waiver of Consent or a Waiver of Documentation of Consent.*  |
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| ***NOTE:*** *If applying for either a Waiver of Consent or Waiver of Documentation of Consent, these applications should be supported. These are not simply granted because the informed consent process would be too difficult or it is an inconvenience.*  |
| **Confidentiality & Privacy**  |
| ***Confidentiality*** *– All data collected must be kept for a minimum of 3 years after the conclusion of the research project. It may be decided upon by the research team to keep the data for a longer time frame. Physical copies of data collected must be locked in a drawer or file cabinet, within a locked room or office. Digital data should be encrypted or on a password protected database. All participant identifiers should be stored separately from the data collected (ex. ICFs should not be in the same locked drawer as the survey results collected).* |
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| ***Privacy*** *– keeping subjects and participants free from unwanted intrusions and/or interruptions. Include how the data will remain safe and secure and how you will not be unnecessarily intrude on the participant’s privacy.*  |
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| ***Federal Certificate of Confidentiality*** *– this is a certificate that can be applied for through the National Institute of Health’s (NIH) website. It will protect the investigators from disclosing any identifying information in response to legal documents or proceeding regarding the sensitive, health related topic(s) of their research.*  |

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| **Section IV: Other Considerations** |

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| **Conflict of Interest**  |
| *Clearly document any consultative relationship that the PI or Co-I(s) have with outside entities. The type of relationship that team members have with these outside institutions will influence the way in which potential conflicts of interest are handled.* |

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| **Publications, Presentations, & References** |
| *Provide a list of any meetings, conferences, or potential journals where the results of the research will be presented. A list of all references used while constructing this protocol should be created and attached; Endnote and Reference Manager are two common programs used for publishing and managing bibliographies and are used frequently for managing citations.* |

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| **References**  |
| *Correctly reference any material that was presented in the background, or used to formulate the hypothesis, study objectives, and/or design of the research. These should be in a format that is generally accepted in your field of study.* |