PI Last Name:
Study Short Title:
Version:
Date Last Updated by PI:

This protocol template is provided to you ONLY AS A GUIDE for how to design a research project. DO NOT SUBMIT THIS TEMPLATE AS IS FOR YOUR IPPS GRANT APPLICATION. Components of this can be used to create your IPPS grant application, however it has to fit within the specified page limit. Many sections described here may not be applicable to your IPPS grant application, however, they may be helpful to you when completing more complex protocols such as those used for IRB applications. Instructions are provided in red and green and these instructions should be deleted. We do not recommend deleting the blue subheadings unless they are not applicable to your project.

Additional research design checklists and guidelines that we recommend you consult are available at:

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) at: https://strobe-statement.org. STROBE checklists available for cohort, case-control, and cross sectional studies.

Consolidated Standards for Reporting Trials (CONSORT) which is designed for randomized controlled studies and other clinical trials at: www.consort-statement.org.

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) at: www.prisma-statement.org.

Additional research resources available to you include the Research Course which is held annually at the IPPS Annual Scientific Meeting.

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Title:

- *Indicate the full study title*
- *Be consistent with the Title throughout your application, protocol and all the regulatory Documents*
- *Be sure to update the version number and date in the footer*

Principal Investigator and collaborators:

- *Principal investigator name and title*

click on contents to format this and auto populate, headings already formatted for this table

Contents

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Abstract:

- *Recommended < 500 words*
- *Write this last, after you have written your protocol. The abstract is basically a summary of your protocol*
- *Written in terms a lay person could understand*
- *Study title*
- *Brief introduction*
- *Study Objectives/Aims/Hypotheses, state this clearly in terms of the study question and the comparison groups (if any) as well as the outcomes*
- *Study Design: Observational study, cross-sectional, chart (retrospective or prospective) or interventional trial (randomized non-randomized).*

List of Abbreviations:

- *List all the abbreviations used in the protocol*

Funding Organization Information:

Disclosures:

In this section note potential conflicts of interest and clearly define them.

Study Personnel

- *Please identify ONE person who is the principal investigator for this study. Co-Investigators*
- *Study team and contact information*
- *Study site*
- *Provide a brief description of each individual's role in the study. Be sure to indicate who will have access to protected health information*
- *If applicable provide information on any services that will be performed by contractors including what is being contracted out and with whom. NOTE: IF YOUR PROJECT INVOLVES EXTERNAL COLLABORATORS YOU WILL LIKELY NEED SPECIAL COLLABORATIVE RESEARCH AGREEMENTS (CRADA)*

Introduction and Scientific rationale

- *Provide scientific background and rationale for study. This should include an assessment of the impact of disease*
- *Include summary of gaps in current knowledge, relevant data, and how the study will add to existing knowledge.*
- *Include rationale for including or excluding certain populations – in particular vulnerable populations or veterans*

Specific Aims/Purpose

- *Briefly describe the purpose of the study. List the broad, long-term objectives and describe concisely and realistically what the specific research described in your proposal is intended to accomplish, and the hypothesis to be tested. You should differentiate between the overall goal of the research and the specific aims of this project as follows:*
  - ***Purpose of the study:***
  - ***Specific Aims/Objectives:*** *List the specific aims or research question of the study, clearly list your comparison groups if applicable*
  - ***Hypothesis:*** *Explicitly state the study hypothesis, or your expected findings*

Research Design and Methods

Study Design

- *Your protocol should state the study design, for e.g. case report, case series, cross-sectional survey, case-control, cohort (retrospective or prospective), interventional trial (randomized or non-randomized).*
- *For each study design you should make sure your study fulfills published study design guidelines such as: CONSORT for RCTs and STROBE for observational or cohort studies.*
- *Make sure you clearly define the population you are studying and what groups you are comparing, what outcomes you are measuring, and how you are defining the comparison groups and the outcome.*
- *If the project uses such methods as control groups, placebo, or deception, is their use adequately justified?*
- *Describe all steps of screening, recruitment, and enrollment, allocation of study group to include randomization (if applicable), inclusion and exclusion criteria, follow-up, data collection and data analysis.*
  - *PROVIDE A FULL DESCRIPTION OF HOW YOU WILL SCREEN SUBJECTS AND IDENTIFY STUDY PARTICIPANTS. This may involve maintaining a screening log. It may also involve describing an anticipated population size, sample size, expected response rates and expected loss to f/up.*
  - *Describe the number of subjects to be included in the study, and describe the **characteristics of the subject population**, including inclusion of minorities, women, or vulnerable populations **if applicable**:*
- *Describe each step of the project, paying particular attention to describe tasks that will be performed by study staff as well as timelines for completing these tasks. Also discuss competencies and qualifications if applicable. Flow charts and timeline charts are very helpful.*

- *If the project involves the use of questionnaires, survey instruments, or telephone scripts, are any concerns with the contents of those tools adequately addressed? Try to use validated survey instruments whenever possible. All of these instruments will need to be provided for review.*
- *Is there a clear identification of which procedures are standard of care versus being done solely for research purposes?*
- *Discuss potential difficulties and limitations of the proposed procedures.*

Study Resources and Collaborations

- *Describe the staff, space and equipment that you will need.*
- *If your project involved different departments, you will need approval from the department chiefs.*
- *If you are collaborating with other investigators make sure you have collaborative letters and letters of support as well as a CRADA-see section on "Multi-Site Concerns" and Cooperative Research and Development Agreements (CRADA).*

Study Evaluations/Outcome Measures

- *Describe all evaluations/data to be conducted/collected and data collection methods. Include materials/measures as an appendix or separate attachment.*
- *Clearly define the outcomes and the independent variables. Provide a list of all the data that will be collected, pay particular attention to identifiable data such as SSN, DOB, Names, etc. The 18 potential HIPAA identifiers are listed below,*

The removal of the following eighteen identifiers from data meets Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements for de-identification of data (Title 45 Code of Federal Regulations (CFR) 164.514).

1. Names;
2. All geographic subdivisions smaller than a state, except for the initial three digits of the zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;
3. All elements of dates except year and all ages over 89;
4. Telephone numbers;
5. Fax numbers;
6. E-mail addresses;
7. Social Security Number (SSN);
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate or license numbers
12. Vehicle identifiers and license plate numbers;
13. Device identifiers and serial numbers;
14. Uniform Resource Locator (URLs);
15. Internet Protocol (IP) addresses;
16. Biometric identifiers;
17. Full-face photographs and any comparable images; and
18. Any other unique, identifying characteristic or code, except as permitted for re-identification in the Privacy Rule.

Data Analysis

- *Is there an adequate summary of the methods of statistical analysis? YOU NEED TO PROVIDE A FULL STATISTICAL ANALYSIS INCLUDING A JUSTIFICATION FOR THE SAMPLE SIZE. List how many subjects you need to screen to obtain your sample size. <u>These numbers should be the same as they are on your IRB project application form.</u>*

- *If this is a retrospective records review and/or specimen analysis only, indicate how many records and/or specimens will be included in the study's data set.*
- *Describe means by which the data will be collected, analyzed and interpreted. Provide a description of your statistical analysis. Provide a very clear description of what type of data will be collected. State where the data will be obtained from e.g. electronic medical records, patients, etc.*
- *Provide sample size determination and power analysis (include anticipated rate of screen failures and loss to follow up).*
- *Describe how, where and by whom the data will be analyzed.*
- *Detail the methods of statistical analyses for each aims/hypotheses listed*
- *If you plan to share the data with collaborators state what data will be shared and whether that data is shared with identifiers or without.*

Study Timeline:

- *Take the opportunity here to outline, in a step-by-step manner, how this project will be conducted. This is a good place to insert a flow chart, timeline table or Gantt chart as discussed above. Anticipate that all steps of research will take longer than expected. Timelines should be very specific.*

Data Management, Safety and Transfer of Data Ownership:

- *Note that most research institutions haves specific guidelines for data storage, transfer and disposal. Familiarize yourself with these guidelines first before you start writing this section.*
- *Describe how that data will be stored, how the data will be protected, and how the data will be stored (or destroyed) after the project is completed.*
- *Also describe your publication and presentation plans, including how the data will be disseminated after the study is complete.*
- *Note a Data Management and Access Plan is required for all research (DMAP)*

Potential Risk/Benefits Analysis:

- *Describe any **potential risks to subjects or others --physical, psychological, social, legal, or other --** and assess their likelihood and seriousness. If applicable you should also describe risks to personnel and staff.*
- *Describe the **procedures for protecting against or minimizing any potential risks**, including risks to confidentiality, and assess their likely effectiveness.*
- *Discuss **why the risks to subjects are reasonable in relation to the anticipated benefits** to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.*
- *If you are doing human subject research that involves more than minimal risk what is you data safety monitoring plan?*
    a. *For interventional studies, include, at a minimum, the following REQUIRED items:*
        i. *What safety information will be collected including serious adverse events and unanticipated problems involving risk?*
        ii. *How the safety information WILL be collected, e.g., case report forms, at study visits, by telephone, etc.*
        iii. *The frequency of data collection including when safety data collection starts.*
        iv. *The frequency or periodicity of review of cumulative safety data.*

v. *If there will not be a data monitoring committee, and if applicable, what statistical tests will be used to analyze safety data and determine if harm is occurring?*
vi. *Who will oversee safety data?*
vii. *Which conditions would trigger an immediate suspension of the research, if applicable?*

b. *For retrospective studies, including studies involving pre-existing data and biological specimens, include a discussion of potential study outcomes that may have an effect on the subject's health or well-being and a procedure to determine when and how to notify individual subjects or their health care providers of findings that may affect the subjects' health.*

Human Participant Information:

Make sure to address the following:

1. *Are the number of participants to be enrolled and the duration of their participation appropriate for the purposes of the research?*
2. *Is the selection of human participants equitable?*
3. *Is the population targeted appropriate for the proposed research?*
4. *Is there a vulnerable or other special population involved in the research? If yes, the following additional questions must be answered.*
   a. *Has the use of the vulnerable population or other special population been adequately justified?*
   b. *Are the additional safeguards in the project sufficient to ensure the participants are adequately protected?*

Informed Consent Document (ICD)

Make sure to address the following:

- *The informed consent document must be completed separately. You will need your protocol to complete the ICD. The ICD needs to be through but written at a 6th grade reading level. When you are completing the ICD document, erase the instructions but all black text must remain intact (see ICD instructions).*
- *If informed consent **is not being sought**, there an **Application for Waiver or Alteration of the Informed Consent Process Form**, that must be included with the application*
- *If a **waiver of informed consent is being sought for recruitment purposes only**, is there an **Application for Waiver or Alteration of the Informed Consent Process Form** that must be included with the application and adequate justification provided*

HIPAA Authorization:

- *HIPAA authorization is separate from informed consent. The informed consent gives you permission to do the study. The HIPAA authorization gives you permission to access personal identifiers. At some institutions both the HIPAA consent document is separate from the Informed consent document.*
- *Explain which HIPAA identifiers will be utilized (in any way) in this study and **be sure to be consistent with the HIPAA authorization**, if applicable. Explain here why the identifiers and health information collected (i.e., the PHI that will be utilized for this study) are the minimum necessary needed to conduct the research and can't be further reduced.*
- *If applicable, explain how these identifiers will be protected and disposed of at the end of the study.*
- *If a waiver of HIPAA authorization is being requested, complete the Application for Waiver of HIPAA Authorization Form and include it in the application.*

Participant Recruitment Information:

If your study involves participant recruitment make sure you address the following:

- *Are recruitment materials included?*
- *Are final copies of model recruitment materials (e.g., including telephone scripts, printed ads, audio or videotaped ads, brochures, letters, etc.) that are to be used provided? If yes, the following additional questions must be answered.*
- *Are the model recruitment materials an appropriate means of communication for the target populations ?*
- *Do recruitment and/or advertising materials clearly state that the project involves research?*
- *If using an investigational product, do the advertisements clearly state that the product is investigational?*
- *Is the condition under study or the purpose of the research clearly stated?*
- *Is time or other commitments that will be required of potential participants clearly indicated, as well as the location where the research will take place?*
- *Is a brief list of procedures to be performed included?*
- *Is a clear summary of inclusion/exclusion criteria provided?*
- *Are points of contact for further information about the project prominently displayed (e.g., name, address, and phone number of the Principal Investigator or space for local site project personnel contact information ?)*
- *Are the recruitment materials free of any unfounded claims, to include any claims of "free" treatment; exculpatory language, or unjustifiable suggested benefits for project participation?*
- *If payment is being provided, is the information provided regarding the payment and the amount not overemphasized?*
- *If the study includes an investigational product, are the advertisements consistent with the product labeling?*

Payments to Participants:

Will participants be paid for their participation? If yes, the following additional questions must be answered:

- *Is the payment reasonable, commensurate with the subject's participation, and not coercive in nature in relation to the amount, method, and timing of the payment?*
- *Is the payment strategy clearly indicated by the investigator?*
- *Who is funding the payments and how will these funds be managed / protected?*
- *Who will be authorized to receive or disburse funds?*
- *Is the payment pro-rated as the study progresses and is any "bonus: or completion payment not so large as to unduly influence the participant to stay in the study until completion?*
- *Is the payment strategy appropriate for the population being targeted?*
- *If transportation costs are being reimbursed, are these costs incurred outside the participant's normal course of treatment?*
- *Note , payments may require collection of identifiable data such as name and SSN so that they can be appropriately reported to governing institutions. Check with the research office how this can be done.*

Biological Specimens:

Make sure to address the following if applicable:

- Is a Clinical Lab Collaboration Letter included?
- State specifically what labs will be collected or analyzed and by whom.
- Is the source of the material and other lab supplies provided by the study?
- If data is not coded or linked, is only the information to be shared devoid of any unique identifiers?

- *If the specimens are to be de-identified, are these procedures adequate to ensure participant anonymity and are they in accordance with HIPAA and the Common Rule?*
- *Is the investigator taking sufficient and appropriate measures to minimize the potential harm from breaches of confidentiality and privacy?*
- *If labs are collected outside normal care procedures, is there an adequate plan for destruction of the specimens?*

Privacy and Confidentiality:

You will be asked to address the following questions in this section:

- *Does the investigator adequately explain how the project team will access information from or about the participants?*
- *Does the investigator adequately explain how the participant's identifiable private information will be handled, stored and disseminated?*
- *Are there adequate provisions to protect the privacy of the participants?*
- *Are there adequate provisions to maintain the confidentiality of the identifiable data?*
- *Will names, addresses, and social security numbers (real or scrambled) be replaced with a code and will documentation of the procedure by which the data was coded be protected?*
- *Is the research personnel who retains the code clearly identified in the project?*
  Is there an appropriate plan for project closure and the retention of the project files and data?
- *Is there a plan for the ultimate destruction of the identifiable data?*

Investigational Drugs and Other Products:

If your project involves an investigational drug make sure to address the following for prospective studies:

- *Are investigational drugs or devices used in this project? If yes, the following additional questions must be answered.*
- *Is a Pharmacy Collaboration Letter included?*
- *Is the source of the drug or device clearly stated?*
- *Has a copy of an FDA letter been received stating wither receipt of the IND application or approval of an IDE application?*
- *If an IND/IDE number is provided, does it match the project or correspondence supplied in the rest of the project materials?*
- *Is the name of the IND or IDE holder specified?*

If the investigator is claiming an IND or IDE exemption, does the project comply with the requirements at 21 CFR 312.2(b) for drug exemptions and 21 CFR 812.2(c) for device exemptions)?

- *If an investigational brochure has been provided, do the risks described in the informed consent document adequately reflect the risks described in the brochure?*
- *Is the plan for drug or device accountability adequate?*
- *For investigational drugs, if Investigational Drug Information Record is provided, is it consistent with the informed consent document?*
- *If this is a non-significant risk device study, is there an explanation stating why the device is not a significant risk device and is it accurate?*

Multi-Site Study Concerns:

- *If the research will be conducted at multiple institutions , state explicitly what will be conducted at each institution.*
- *Identify what components of the study will be conducted at each institution.*
- *If it is, indeed, a multi-site study, it is REQUIRED that the protocol/addendum list the other sites and their contact information, which can be accomplished in this section.*
- *Creating CRADAs will require the assistance of the research and legal teams.*

References & Literature Cited:

Compile a judicious list of relevant literature citations. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication. Use a reference manager since it is likely that the study protocol will require multiple revisions.

Appendices

Attach data collection forms/sheets, recruitment materials, logs, telephone text, email text and whatever else is applicable to the proposed research.

Acknowledgements: