



SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY RESEARCH PROTOCOL

PROTOCOL TITLE

INSTRUCTIONS (to be deleted):

This template is provided for individual investigator initiated studies. It is **NOT REQUIRED** when the sponsor has provided a protocol. Please replace instructional text with the specific information for the protocol or write N/A for those sections that may be not relevant to the study.

For general, technical, or policy questions, please consult the IRB at irb@downstate.edu

Please follow this guidance for writing the research protocol or consult with your Department Chair or Scientific Review Committee Members. For a list of Scientific Review Committee Members in your Department, please refer to the "Guidance - SRC Members SUNY DMC / KCHC posted within the "Forms & Templates" page inside IRBNet (www.irbnet.org).

For research design or statistical questions, please consult a biostatistician in your department or Jeremy Weedon, PhD (Biostatistician) at Jeremy.Weedon@downstate.edu

VERSION

Enter version control number and/or date.

PRINCIPAL INVESTIGATOR

Enter PI Name.

INTRODUCTION/BACKGROUND INFORMATION

Provide a statement about the history of the problem/disease (what is known, what is not known) and why it is important to study this particular problem/disease. Discuss how the problem/disease affects the population, how many people are potentially affected, how answers generated by the study potentially may be useful for improving understanding of the problem/disease or for guiding patient management or other relevant aspects of decision making ("scientific significance").

Describe and provide the results of previous animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the problem/disease to be studied, where applicable.

AIMS & OBJECTIVES

Provide the specific aims and/or objectives of the study. Indicate which is: primary vs secondary.

Indicate whether the study is designed:

- **for hypothesis generation or hypothesis testing**
- **as a feasibility pilot or for proof of concept**

HYPOTHESES

The specific questions and the hypothesis to be tested (if any) should be clearly stated.

METHODS

OVERVIEW OF THE STUDY DESIGN

Describe the study design. Indicate whether it is retrospective, prospective or cross-sectional; whether it is designed to examine:

- **the relation of a risk factor or naturally-occurring exposure to an outcome of interest (observational study)**
- **the impact of a purposively-applied intervention**

Describe the variables in the study

Describe methods to blind subjects and investigators to treatment group, if applicable

Describe nature and length of washout periods, if any.

STUDY POPULATION

Describe the study population.

INCLUSION AND EXCLUSION CRITERIA

Provide a list of inclusion and exclusion criteria.

CAUTION: If non-English speaking patients are excluded from study in which there is potential therapeutic benefit, such exclusions must be well-justified.

SAMPLE SIZE

Indicate the sample size required.

Provide a statistical justification for the sample size (considerations include desired power and, as appropriate, assumed effect sizes for a hypothesis testing study; precision for a study whose objective is to estimate a population parameter.)

Include the number that needs to be screened to achieve the desired result.

Estimate the number likely to agree to participate and how sample size will be adjusted for potential refusals.

For longitudinal studies, indicate the number of potential drop outs and how sample size is adjusted for potential loss to follow-up.

METHOD FOR SCREENING FOR ELIGIBILITY

INCLUSION OF VULNERABLE POPULATIONS

Please provide the rationale for including any vulnerable populations described in the IRB application and list all additional protections in place to protect these individuals.

STATISTICAL CONSIDERATIONS

ANALYSIS PLAN

Specify the statistical tests that will be used to test the research hypotheses. Include whether tests are 1-sided or 2-sided and specify your critical alpha level for defining statistical significance.

It is strongly recommended that a Downstate statistician be consulted before this section is finalized.

SAMPLE SIZE JUSTIFICATION

Indicate how your sample size was determined (include/explain all statistical assumptions). Such assumptions should include the expected number of study-eligible patients within the identified enrollment period and expected loss-to-follow-up (prospective studies). For studies involving tests of hypotheses, assumptions should include presumed effect sizes, strength of association or related estimates, as well as statistical power. For those involving estimation of population parameters, assumptions should indicate expected level of precision. (For all types of studies, adequate

consideration should be given to evaluation and statistical management of potentially missing data.) For clinical trials, rules for interim monitoring and early stopping should be specified and statistical implications given. Whether your study is interventional or observational, your analysis plan should describe the inferential statistical tests to be used for each statistical hypothesis (Input of a statistician is advisable). For pilot studies, descriptive summaries rather than inferential statistics are appropriate. It is strongly recommended that a Downstate statistician be consulted before this section is finalized.

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PROCEDURES AND DATA COLLECTION

List all procedures to be performed (differentiate between standard of care versus the procedures performed solely for research purposes). List the study visits needed (attach a table or chart for longitudinal studies with multiple visits); list and any, and all, study sites to be included in the research.

List all information to be collected and the sources of these data. List and attach copies of research instruments to be used (e.g., survey, questionnaire etc).

Indicate whether specimens will be collected and whether these will be preserved or discarded after conclusion of the study. If data/samples collected for this study will be saved/banked/archived for future uses beyond the scope of this study, describe plans for identifying and storing data/samples for such future uses.

FOLLOW-UP

List any plans for follow-up with research participants.

DURATION OF STUDY

List the duration of the study and any important time points or milestones to be achieved.

HUMAN RESEARCH CONSIDERATIONS

Provide an overview of human research considerations.

RECRUITMENT PROCEDURES

Who will contact potential study subjects? How will the subjects be contacted? What recruitment materials will be used (flyer, brochure etc.) Materials used to support recruitment should be submitted together with the research protocol for IRB Approval.

RISKS/DISCOMFORTS

Describe the anticipated risks and discomforts to research participants.

Discuss why the risks to research participants are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Also, where appropriate, describe the provisions for monitoring the data collected to protect privacy and to optimize the safety of subjects.

POTENTIAL BENEFITS

Describe the potential benefits of the research (if any) to subjects, patient class, science/society (whether direct or indirect). Describe any potential direct benefits to the subject first, then any benefits to others. If benefits may not continue after participation in the study is over, be sure to inform the subject. Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained. Monetary compensation for participation should not be listed as a benefit.

INFORMED CONSENT

Detail instructions for obtaining legally valid written informed consent (and HIPAA Authorization, when applicable) from each prospective research participant.

Detail the procedures for obtaining informed consent. Describe the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

Describe any waivers for the requirements of informed consent.

CONFIDENTIALITY

Describe methods for preserving subject confidentiality, how data will be kept confidential and used for professional purposes, whether data will be coded, kept in locked files, maintained electronically, etc. Indicate what protected Individual's Identifiable Health Information (IIHI) will be used or shared with outside entities for purposes of the research. List all outside entities to whom IIHI may be disclosed.

DATA AND SAFETY MONITORING

When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of research participants. In general, research that is more than minimal risk, usually requires a data and safety-monitoring plan.

The initial plan submitted to the IRB should describe the procedures for safety monitoring, reporting of adverse events and/or unanticipated problems involving risks to research participants or others, descriptions of interim safety reviews and the procedures planned for transmitting the results to the IRB.

This description should include information regarding an independent Data and Safety Monitoring Board (DSMB), if one exists, or an explanation why an independent DSMB is not necessary.

Monitoring activities should be appropriate for the study, study phase, population, research environment, and degree of risk involved. In general, it may be desirable for a DSMB to be established by the study sponsor for research that has some of the following characteristics:

- **blinded**
- **multiple sites with a large study population**
- **includes vulnerable research participants**
- **high-risk interventions**
- **highly toxic therapies**
- **high expected rates of mortality**
- **high probability of early termination**
- **placebo arm**

For some studies the National Institutes of Health (NIH) require a DSMB. The IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed. When DSMBs are utilized, the conduct of continuing review of research may rely on a current statement from the DSMB indicating that it has and will continue to review study-wide adverse events, interim findings, and any recent

literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB.

DISCONTINUATION OF RESEARCH PARTICIPANTS/WITHDRAWAL

Provide a description of reasons/conditions where potential research participants may be withdrawn from the study (e.g., illness, lack of adherence). Discuss research participant replacement, if applicable

Include a statement that the study may be discontinued at any time. Describe any actions that may follow such discontinuation including, but not limited to, follow-up care and evaluation, disposition of previously collected study data, etc.

RECORD RETENTION

List the duration of record retention and the method for destruction or the possibility of indefinite archiving of information.

Records may not be destroyed unless in conformity with the General Retention and Disposition Schedule for New York State Government Records with respect to categories of state government records included therein or with the State University of New York Records Retention and Disposition Schedule with respect to education and other SUNY-specific records.

Requests to destroy paper records after transfer from paper to digital form must be approved by the State Archives unless such dispositions are pre-approved under the SUNY Records Retention Schedule for that category. For more information, please see the Record Retention and Disposition policy of SUNY.

Records relating to individual research must be kept for 3 years after Research concluded or otherwise terminated.

Research records involving new drug investigations must be retained 2 years after the marketing application is approved or, if no application is filed or if the application is not approved, until 2 years after the investigation is discontinued and FDA is notified.

Research participants' signed HIPAA Research Authorization forms must be kept for a minimum of 6 years after such authorization last was in effect.

Records concerning controlled substance research must be maintained for five years after completion of the study and must comply with regulations set forth in 10 NYCRR 80.100.

CONFLICT OF INTEREST

The PI is responsible for stating whether or not he or she has a conflict of interest with respect to the research study. All conflicts should be disclosed to the IRB and sponsor.

REPORTABLE EVENTS

As required by Policy IRB-01, all reportable events will be reported to the IRB within the specified deadlines. Additional information is provided in the IRB Guidance on “Reportable Events.” Events are defined in the IRB Guidance on “Acronyms and Definitions.” For additional information see: <https://research.downstate.edu/irb/policies.html>

ADDITIONAL INFORMATION

Please include any additional information that should be considered by the IRB.

APPENDICES

If applicable, provide a list of tables, figures, description of special procedures, publications, diagrams etc.

REFERENCES/BIOGRAPHY

Provide a list of references directly related to the study. It should be organized as any standard bibliography.