Newton-Wellesley Hospital
Institutional Review Board

Protocol Summary

PRINCIPAL INVESTIGATOR:

PROTOCOL TITLE:

FUNDING:
SOURCE:
AMOUNT:

SPECIFIC AIMS: State the Objectives of the study and the hypothesis being tested

BACKGROUND AND SIGNIFICANCE: Provide a brief paragraph summarizing prior experience, research and publications important for understanding the proposed study and procedures.
.

RESEARCH DESIGN AND METHODS: (1)Briefly describe the study design and anticipated enrollment. Specify: (2) the number of subjects to be enrolled, study wide, and (3) at NWH in particular.
1.
2.
3.
Provide a brief explanation of inclusion/exclusion criteria:
For studies involving treatment or diagnosis, indicate how the study procedures differ from standard clinical care or diagnostic techniques for the disease or condition being studied, and provide information on alternative treatments or methods of diagnosis.
Describe study endpoints.
For studies of diagnostic and treatment modalities when there is an approved and available treatment modality, describe explicitly how the safety and progress of study participants will be monitored. Include objective criteria for determining treatment failure, where possible.
An incidental finding (IF) is an unexpected finding concerning an individual research participant that has potential health or reproductive importance, is discovered in the course of conducting research, but is beyond the aims of the study. If this study has the potential to uncover an IF, please describe how the IF will be managed and communicated.

EQUITABLE SELECTION OF SUBJECTS: (1) Explain the rationale for the inclusion or exclusion of particular classes of vulnerable subjects, such as children, pregnant women, fetuses, neonates, prisoners, individuals with impaired decision-making capacity and describe safeguards that have been included to protect their rights. (2)Describe safeguards for others likely to be vulnerable to coercion or undue influence (e.g. the economically or educationally disadvantaged, patients from the medical practice of the

investigator(s), medical students, hospital employees, etc). (3)Address whether any one group will likely bear a disproportionate share of the burdens of the research, or whether the benefits, to the extent anticipated, will be distributed fairly. Specifically address the enrollment of women and minorities. (4)When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and have an interpreter present.
1. 2. 3. 4.

FORESEEABLE RISKS AND DISCOMFORTS: Provide a brief description of any foreseeable risks and discomforts to research participants.
EXPECTED BENEFITS: If direct benefit to individual subjects is anticipated, provide a brief, realistic summary of these potential benefits (e.g. "We hope that the treatment will result in a reduction in tumor size in at least 25% of the enrolled subjects.") If no direct benefit to individual subjects is anticipated, explain how the results of the research will benefit society through increased knowledge of human physiology or behavior, improved medical safety or technological advancement.

RECRUITMENT PROCEDURES: Provide a detailed explanation of the specific methodology to be used to recruit subjects at NWH. (1) Specify how, when, where, and by whom subjects will be identified and approached for participation. (2) Provide details of remuneration, if applicable. (3) Explain all methods that will be used to enhance recruitment of women and minorities.
1.
2.
3.

CONSENT PROCEDURES: (1) Explain in detail how, where, and by whom informed consent for participation is to be obtained. (2) Specify how long potential subjects will be given to consider whether or not to participate. (3) If subjects are unable to give informed consent due to age (minors) or physical or mental incapacity, indicate the designated individual(s) from whom informed consent will be obtained (e.g. parent(s), legally authorized representatives, next-of-kin, etc.). (4) For subjects who are unable to give informed consent at the time of enrollment, explain how the ability to give or revoke consent will be assessed during study participation, and how informed consent will be obtained if and when subjects regain the capacity to give informed consent on their own behalf. (5) When subjects are to be enrolled from among the investigator's own patients or might otherwise be vulnerable describe how the potential for coercion will be avoided. (6) Describe the consent process for non-English speaking subjects
1.
2.
3.
4.
5.

6.

CONFIDENTIALITY: Describe methods to be used to maintain subject confidentiality. Note that in most clinical research this includes routine practices such as: e.g. substituting codes for identifiers, removing face sheets containing names and addresses from instruments containing subject data, properly disposing of computer printouts and other papers, limiting access to data containing identifiers, educating research staff about the importance of confidentiality, and storing research records in locked cabinets. Additional measures, such as obtaining a Certificate of Confidentiality, may be required if the research involves sensitive matters such as sexual, criminal or illegal behavior. In all cases, (1) address where individually identifiable information will be stored and who will have access to this information; (2) if information on subjects, biological samples or individual test results will be sent to individuals outside of NWH and the Partners network, indicate what information will be sent and how confidentiality will be maintained; (3) indicate whether any data and/or specimens will be maintained at NWH or other Partners or non-Partners sites for future uses not described in the protocol.

PRIVACY: Describe methods used to protect the subject's right to privacy. Describe process for subject selection, are subjects recruited through their physician or health care provider involved in their care? Are study related visits and discussions conducted in a private setting? If subjects are being contacted, what provisions are being made to protect their privacy? Is all information being collected as part of this study necessary for the research? Have/will all subjects receive a privacy notice?

USE OF SPECIMENS AND DATA FROM OUTSIDE INSTITUTIONS AND INDIVIDUALS: If human material (i.e. samples or specimens) or data from non-Partners sites will be used in this research, indicate whether the samples or data will contain identifiers that could be used to link the sample or data to individual subjects. Indicate where and how the samples or data will be obtained and how they will be labeled.

If another IRB has reviewed this research, attach a copy of the institution's IRB approval and IRB-approved consent form, if applicable, with the submission.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS: If specimens or data collected by Partners Investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimen/data to individual subjects. Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

DATA AND SAFETY MONITORING: Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending on the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting unanticipated events including adverse events and protocol violations/deviations to the IRB.

MONITORING AND QUALITY ASSURANCE: Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, describe who will review the accuracy and completeness of case report form entries, source documents, and informed consent. Note: regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB protocol, and applicable regulations and requirements of the IRB.

ABBREVIATIONS: Define any abbreviations used in the Protocol, Application Form, or Protocol Summary. (Please put in alphabetical order)

Form Version:12.06.2016