

INSTRUCTIONS for Completion Of

Wills Eye Hospital IRB Form-1  
“RESEARCH STUDY PROPOSAL”

A. Complete the fill-in items on the Research Study Proposal Form-1 as directed by the following instructions:

**NOTE: THIS FORM IS NOT TO BE USED FOR RESEARCH INVOLVING ONLY EXISTING PATIENT RECORDS AND/OR SPECIMENS. FOR THIS TYPE OF RESEARCH, USE FORM-1A.**

**1. Research Study Identifying Information:**

Fill in the blanks on the form for the Study Title, the name of the Principal Investigator (Residents/Fellows conducting a study must have an Attending Physician act as Principal Investigator), the name(s) of the Co-Investigator(s), and the name of the principal Service/Department.

Industry sponsored studies will be invoiced for a one-time review fee.

NOTE: If you wish to add additional Co-Investigators after your Research Study Proposal has been approved by the IRB, you must submit a Form-6 Addendum certifying that the person has met the requirements for Co-Investigator status, is sufficiently qualified to be added to your study as a clinical investigator, and has completed the mandated training program. Each new Investigator must sign and submit a Co-Investigator Statement.

**2. What type of IRB review are you requesting for this Research Study Proposal?**

Check either **Standard Review** or **Expedited Review**. Expedited Review is applicable only to Research Studies that pose Minimal Risk and fall into specific enumerated categories. Please review the IRB’s Policy Regarding Expedited Review for these categories. If you request Expedited Review, you will need to compose a separate letter to the IRB Chairman to indicate why the Research Study Proposal qualifies for expedited review.

**3. Was this Research Study Proposal ever reviewed previously by the Wills Eye Hospital IRB?**

Check either **YES** or **NO**. If your answer is **YES**, provide the IRB # of the original Research Study Proposal.

**4. Does the study involve research activities (including enrollment, consent, and study treatment) to be conducted at the Wills Eye Emergency Room?**

Note that the Wills Eye Emergency Room is located in the Jefferson Hospital for Neuroscience building and is a part of Jefferson Hospital. Therefore, any research activities conducted at Jefferson (including but not limited to access of Jefferson EMR, subject enrollment, consent interviews, and study related treatment) requires joint approval of both IRBs. Contact the Wills IRB Office immediately for additional guidance.

## **5. Are you requesting a waiver or alteration of the Written Informed Consent Form or Process?**

Check either **YES** or **NO**. If your answer is **YES**, you will need to compose a separate letter to the IRB Chairman outlining the reasons for the alteration or waiver of the Informed Consent Form and submit this letter to the IRB when you submit the completed Research Study Proposal.

**Studies Regulated by the FDA.** The IRB may waive, on a case-by-case basis, the requirement that the Research Investigator document consent by means of a signed consent form for some or all subjects if the IRB determines that: (1) the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality and each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; (3) in cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The written statement must be approved by the IRB.

**Studies Not Regulated by the FDA.** The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waive the requirement to obtain informed consent if it finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- i. Programs under the Social Security Act, or other public benefit or service program;
- ii. Procedures for obtaining benefits or services under these programs;
- iii. Possible changes in or alternatives to those programs or procedures;
- iv. Possible changes in methods or levels of payment for benefits of services under those programs; or

2. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirement to obtain informed consent provided that the IRB finds and documents that:

- i. The research involves no more than minimal risk to the subjects;
- ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- iii. The research could not practicably be carried out without the waiver or alteration; and

- iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**6(a). Does this Research Study Proposal involve the use of drugs/biologics/vaccines in humans?**

Check either **YES** or **NO**. If your answer is **YES**, list the drugs/biologics/vaccines to be used in the study.

**6(b). Are these drugs/biologics/vaccines (i) approved by the FDA, (ii) for the use indicated, and (iii) the dose indicated?**

Check either **YES**, **NO**, or **N/A**. If your answer is **NO** for any of the above, you must submit a Form-1 IND.

**6(c). Are the drugs/biologics/vaccines listed in the Wills Eye Hospital Formulary?**

Check either **YES**, **NO**, or **N/A**.

**6(d). If the drugs/biologics/vaccines are not listed in the WEH Formulary, will the drugs/biologics/vaccines be dispense on the 7th Floor of Wills?**

Check either **YES**, **NO**, or **N/A**. If your answer is **YES**, complete a Form-2 Drug Statement.

**6(e). If the drugs/biologics/vaccines are not listed in the WEH Formulary, will the Sponsor provide the drugs/biologics/vaccines to be dispensed by the Investigator?**

Check either **YES**, **NO**, or **N/A**. If your answer is **YES**, complete a Form-2 Drug Statement.

**7(a). Does this Research Study Proposal involve the use of medical devices?**

Check either **YES** or **NO**. If your answer is **YES**, list the devices to be used in the study.

**7(b). Has the device been approved by the FDA for the use indicated?**

Check either **YES**, **NO**, or **N/A**. If your answer is **NO**, provide the Investigational Device Exemption (“IDE”) Number and, if applicable, Sponsor for each device. Or, you must provide a letter from the Sponsor or evidence from the scientific literature justifying why an IDE is not needed, and provide a description of that justification in the space provided.

**7(c). Is this a Non-Significant Risk (NSR) or Significant Risk (SR) Device?**

Check either **NSR** or **SR**. This determination is initially made by the Sponsor and/or Principal Investigator. The IRB may agree or disagree with the Sponsor’s initial

assessment and may consult FDA for its opinion. If a device is deemed SR, the Sponsor must submit an IDE (Investigational Device Exemption) application to FDA.

A Significant Risk device is a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents a potential for serious risk to the health, safety or welfare of the subject.

A Non-Significant Risk device is one that does not meet the definition for a Significant Risk device.

**8. Does this Proposed Research Study involve an investigational procedure?**

Check either YES or NO. If your answer is YES, provide a description of the procedure in the space provided.

**9. Does this Proposed Research Study involve radiation exposure(s); or the use of any radioactive substance(s) other than standard radiography, radionuclide scanning or radiation therapy; or require additional radiation exposure(s) from any of the foregoing solely as a result of participation in the Study?**

Check either YES or NO. If your answer is YES, you must obtain approval for the proposed radiation exposure(s) and/or use of the radioactive substance(s) from the appropriate Radiation Safety Committee prior to your submission of your Research Study Proposal to the IRB and you must submit a copy of your approval letter from that committee to the IRB when you submit the completed Research Study.

**10. Does this Proposed Research Study involve use of rDNA, synthetic nucleic acid, nanotechnology, stem cells, infectious agents (pathogens), or biological toxins?**

Check either YES or NO. If your answer is YES, you must obtain approval for the exposure(s) and/or use of the substance(s) from the appropriate Institutional Biosafety Committee prior to your submission of your Research Study Proposal to the IRB and you must submit a copy of your approval letter from that committee to the IRB when you submit the completed Research Study Proposal. It may be possible to have these reviews occur simultaneously. Contact the IRB Office for additional guidance.

**11. Does this Research Study Proposal involve research to be performed at/in/with another institution?**

Check either YES or NO. If your answer is YES, list the other institutions in the space provided. Note that Wills Eye Hospital IRB only reviews research activities that takes place at Wills. Outside institutions often have separate IRBs, and review by the local IRB may be required. If any research activity will involve Jefferson (its personnel, patients, data, specimens, etc.), check YES and provide an explanation in the Protocol of which activities will take place at Wills. Note that joint approval of both IRBs will be required. Contact the IRB Office for additional guidance.

**12. Does this Research Study Proposal involve research involving any of the following special subject populations?**

Check all categories that apply. If your answer is **YES**, describe the additional risks or discomforts you anticipate for the proposed population. Note that research regulations require additional protections for Children, Prisoners, and Pregnant Women/ Fetuses/ Neonates. Other subject populations may require additional protection, including but not limited to: economically or educationally disadvantaged individuals, cognitively impaired individuals, the very sick, comatose, or traumatized individuals. Be sure to address the subject populations in your Protocol and describe any additional safeguards to be followed.

**13. What is the level of risk for participants in the study?**

Check either **Minimal Risk** or **Greater Than Minimal Risk**. A risk is minimal if the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that encountered in daily life or during the performance of routine physician or psychological examinations or tests.

**14. Will notices or advertisements be employed to recruit participants into this Study?**

Check either **YES** or **NO**. If your answer is **YES**, the IRB must review and approve the recruitment materials prior to implementation. Recruitment materials include but are not limited to: newspaper, radio, television, internet, bulletin boards, posters, and flyers that are intended to be seen by prospective subjects. Attach a copy of the notice or advertisement when submitting this Form-1.

**15(a). Are you, or any co-investigator, receiving any compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of this study or in the form of compensation tied to sales of the product, such as a royalty interest?**

Check either **YES** or **NO**. If your answer is **YES**, provide an explanation.

**15(b). Are you, or any co-investigator, when aggregated with a spouse and any dependent children, have any ownership interest (including stock and stock options) or other financial interest in the sponsor of this study whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation), or any equity interest in the sponsor of this study which is publicly traded that exceeds \$5,000 determined through reference to public prices or other reasonable measure of fair market value (and does not represent more than a five percent ownership interest in any single entity) during the time of the study and for one (1) year following completion of the study?**

Check either **YES** or **NO**. If your answer is **YES**, provide an explanation.

**15(c). Do you have any property or other financial interest in the product, including, but not limited to, a patent, trademark, copyright, royalties, or licensing agreement?**

Check either YES or NO. If your answer is YES, provide an explanation.

**15(d). Have any payments or contributions been made, directly or indirectly, by the sponsor of this study to you or to any co-investigator (when aggregated with a spouse and any dependent children), or to the institution, of \$5,000 or more to support activities, exclusive of the cost of conducting the clinical study or other clinical studies (e.g., a salary, royalty, grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria, or other payments) during the time of the study and for one (1) year following the ?**

Check either YES or NO. If your answer is YES, provide an explanation.

## **B. Research Study Protocol**

Describe your Proposed Research Study according to the following format. Be as concise as possible without omitting necessary information.

### **1. Specific Aims**

Describe the purpose(s) of your Proposed Research Study and the hypothesis to be tested.

### **2. Background**

Describe prior studies and observations pertaining to your Proposed Research Study and cite pertinent references. If a drug/biologic/vaccine or a medical device is to be used, indicate its current FDA status.

### **3. Materials and Methods**

Describe the materials and methods of your Proposed Research Study, including at least, the following:

- a) Physical requirements of the subjects;
- b) Anticipated duration of the study;
- c) Likely effects, potential benefits, and risks of the research on the subjects;
- d) What are the alternatives to the proposed research subjects;
- e) Follow-up requirements of the subjects;
- f) Requirements of confinement of the subjects during the study;
- g) Precautions to be observed by the subject before, during, and following the study;
- h) Methods of data analysis;
- i) Projected number of subjects that will be figured for the study; and
- j) Methods of assignment of subjects to different options in the study.

### **4. Human Subjects**

If the subjects of your Proposed Research Study are humans, describe the following:

- a) The source of potential subjects, derived materials, or data;
- b) The characteristics of the subject population(s), including expected age range, sex distribution, ethnic background, race, state of health, and any other pertinent factors;
- c) The criteria for inclusion and exclusion of potential subjects;
- d) The rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, or other distinct groups;
- e) The recruitment and consent procedures to be followed, including the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the method of documenting consent;
- f) Real or potential physical, psychological, social, legal, or unspecified risks to the subjects as a result of their participation in the study and comment on the likelihood and seriousness of these risks;
- g) Standard options to the proposed research and the reasons why you believe them to be unsatisfactory;
- h) The procedures for protecting against or minimizing any potential risks and comment on their probable effectiveness;
- i) Confidentiality safeguards that will be taken;
- j) Arrangements for providing medical treatment of subjects for problems arising out of their participation in the study;
- k) The potential benefits of your proposed research to the subjects or to society in general;
- l) The risks in relation to the anticipated benefits of your research to the subjects and society;
- m) The cost may not be covered by insurance companies because of the research status; and
- n) Advertisements for recruitment must be submitted and reviewed by the IRB Committee.

**5. Will this Research Study involve payment(s) to participants or involve material inducements for participation in the Study?**

If your answer is **YES**, please describe the amount of payment and partial payment, in the event the study is not completed, and include any material inducements and the terms under which they are offered to participants.

**6. Conflicts of Interest**

Potential conflicts of interest and conflicts of interest must be disclosed by the Principal Investigators, Co-Investigators, and other key personnel with respect to all research studies. Please review the IRB's Policy Regarding Conflict of Interest Disclosure. Conflicts of interest can exist when the Principal Investigator, Co-Investigator, or key personnel has an ownership or investment interest in the entities supporting the clinical trial, when any of them accept compensation, gifts, gratuities from that sponsor and if the immediate family member of any of these personnel acts as a paid or unpaid manager,

scientific advisor, or board member of that sponsor. These are very serious matters and should be given adequate and thoughtful consideration and disclosure must be made in all instances. By executing this Research Study Proposal, the Principal Investigator is certifying that this research project has been evaluated under the IRB's Policy on Disclosure of Conflicts of Interest and that no conflicts exist.

### **C. Written Informed Consent**

Compose a Written Informed Consent Form for your study according to the IRB's Policy and Procedure regarding Informed Consent and Form of Informed Consent, or attach a letter requesting an Alteration or Waiver of the informed consent requirement.

### **D. Principal and Co-Investigator Investigators' Statements**

You and every Co-Investigator must read the appropriate Investigator's Statement and sign your name legibly on the appropriate line of the form and date the form before submitting the completed Research Study Proposal to the IRB.