INSTRUCTIONS for Completion Of

Wills Eye Hospital IRB Form-1A
**"Research Study Proposal"**

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

NOTE: THIS FORM IS FOR RESEARCH INVOLVING EXISTING PATIENT RECORDS AND/OR SPECIMENS *ONLY*. FOR ALL OTHER TYPES OF RESEARCH, USE FORM-1.

**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 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. Proposal for research involving:**

Check the applicable box(es).

**3. Where are the data/specimens located now?**

Provide the physical location of all data/specimens, before any research activity is undertaken.

Please note that Wills Eye Hospital Institutional Review Board review is limited to research conducted at Wills Eye Hospital. If your study requires use of data/specimens that are physically located outside of Wills Eye Hospital, separate review by the local IRB of each involved entity may be required.

**3(a). Do you require access to Jefferson EMR (EPIC) for this study?**

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

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 of the Wills Eye ER records requires access to Jefferson's EMR and requires joint approval of both institutions. Contact the IRB Office immediately for additional guidance.

**4. The data/specimens were originally gathered for:**

Check **Clinical Use, Research Use,** or **N/A**.

Please Note: If data/specimens were originally gathered for research use, that original research must be IRB approved, and the purpose (whether clinical or research) for which the specimens were originally gathered must be met, as certified by the pathologist in charge or the clinical laboratory director.

**5. Will any of the following identifiers be recorded from the medical record and/or used to label specimens?**

Check either **YES** or **NO**. If your answer is **YES**, specify which identifiers will be recorded from the medical record or used to label specimens, and then specify what additional patient data will be recorded. Additionally, you must describe how privacy and confidentiality will be protected.

**6. Do you plan, as part of this research, any intervention or interaction (e.g. questionnaire, interview) with the persons whose data and/or specimens will be used in this research?**

Check either **YES** or **NO**. If your answer is **YES**, STOP HERE. A full research application may be required. Contact the IRB Office for additional guidance.

**7. Do you request a waiver of the requirement to seek the informed consent (including HIPAA written authorization to use and disclose protected health information) of subjects?**

Check either **YES** or **NO**. If an alteration is requested, you must specify in your Protocol which element(s) of informed consent is being altered, and you must fully describe the methods used to obtain and document consent.

If you are seeking a waiver or alteration, complete sections (a) through (d). If you are not seeking a waiver or alteration, go on to Question #8.

**7(a). Will the research involve more than minimal risk to the health of subjects?**

Check either **YES** or **NO**. If your answer is **YES**, your study does not qualify and your request will be denied.

**7(b). Will the research involve more than minimal risk to the privacy of subjects' protected health information?**

Check either **YES** or **NO**. If your answer is **YES**, your study does not qualify and your request will be denied.

**7(c). If you had to obtain written informed consent and HIPAA authorization from each subject, would it still be feasible to conduct the study?**

Check either **YES** or **NO**. If your answer is **YES**, your study does not qualify and your request will be denied. If your answer is **NO**, you must provide justification for why such a requirement would make the research impracticable. Please Note: impracticability is not to be understood as merely *difficult* or *inconvenient*.

**7(d). Will the research yield information of direct clinical relevance for the subjects whose data is to be used in this study?**

Check either **YES** or **NO**. If your answer is **YES**, and you wish to conduct the study without first obtaining the informed consent of the patients whose records/specimens you wish to use, please describe the manner in which the information of direct clinical relevance will be disclosed to the subjects whose data was used in the study. Specify what information you anticipate will be relevant to the subject, who will disclose that information, and when.

**8. If the answer to Question #7 is "no," will informed consent be Written or Oral?**

Check either **Written** or **Oral**. If your answer is **Written**, you must provide a copy of the informed consent form proposed for use in this study. If your answer is **Oral**, you must provide a copy of the consent script proposed for use in this study, with a detailed description of how oral consent to participate in a research study will be documented. Please Note: oral informed consent is not sufficient for patient privacy (for use and disclosure of protected health information) purposes. Use the standard Wills Eye Hospital written authorization form for use and disclosure of protected health information or seek a separate waiver of HIPAA written authorization if you wish to use oral informed consent.

**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 any of the data/specimens were originally collected for research use, provide the name of the IRB that reviewed and approved the original data/specimen collection, and the IRB Control # if applicable. If your study involves specimens, the original purpose (whether clinical or research) for which the specimens were collected must be met prior to the removal of any excess, as certified by the pathologist/laboratory director in charge of those specimens.

**3. Materials and Methods**

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

a) Physical location of the data/specimens prior to initiation of research;
b) Physical location where research activities will take place, including data collection and analysis;
c) Anticipated duration of study;
d) Number of records/specimens to be reviewed;
e) Range of dates of records/specimens to be reviewed; and
f) Methods of data analysis.

## 4. Human Subjects

If your study requires the use of data/specimens of living individuals, describe the following:

a) The characteristics of the subject population(s) under investigation, including expected age range, sex distribution, ethnic background, race, state of health, and any other pertinent factors;
b) Inclusion and exclusion criteria for determining which data/specimens will be used;
c) A list of the data that will be recorded from the medical record/specimen;
d) The 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; or a statement that a waiver/alteration of the requirement to obtain and/or document consent is also being sought;
e) 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;
f) The procedures for protecting against or minimizing any potential risks and comment on their probable effectiveness;
g) Confidentiality safeguards that will be taken;
h) The potential benefits of your proposed research to the subjects or to society in general;

## 5. 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. Research Study Informed Consent

Compose an Informed Consent Form or Informed Consent Script for your study according to the IRB's Policy and Procedure regarding Informed Consent. If Oral Consent will be used, you must describe the process for documenting consent, AND you must use the standard Wills Eye Hospital written HIPAA authorization for use and disclosure of personal health information or else seek a separate waiver of the 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.