Institutional Review Board (IRB)
840 Walnut Street
Philadelphia, PA 19107
Phone: 215-440-3155
Email: IRB@willseye.org

Form-1A: New Study Submission

This Form-1A is to be used for research involving only existing patient records and/or specimens.
All other research proposals must be submitted on Form-1.

A. Complete the following fill-in items according to the instructions given in INSTRUCTIONS FOR COMPLETION OF WILLS EYE HOSPITAL IRB FORM-1A.

1. **Research Study Identifying Information**

Study Title:

Principal Investigator:

Service or Department:

Preferred Mailing Address:

PI Phone: PI Email:

Coordinator Name: Coordinator Email:

Co-Investigator(s):

Sponsorship:
Industry Sponsored studies will incur a one-time Review Fee

- ○ Industry: _____
- ○ Federal/State/Local Government: _____
- ○ Research Foundation/Grant: _____
- ○ None

2. Proposal for research involving:

   ☐ Existing Data from Medical Records

   ☐ Existing Patient Specimens (Tissues, blood, serum, etc.)

3. Where are the data located now?

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

   ◯ NO

   ◯ YES

   ◯ N/A

   If YES, approval of Jefferson IRB is required for this study. Contact the IRB Office for additional guidance.

   Where are the specimens located now?

4. The data were originally gathered for:

   ◯ Clinical Use

   ◯ Research Use

   ◯ N/A

   The specimens were originally gathered for:

   ◯ Clinical Use

   ◯ Research Use

   ◯ N/A

   If data/specimens were originally gathered for research use at Wills Eye Hospital, was this research approved by Wills Eye Hospital IRB?

   ◯ NO

   ◯ YES

   ◯ N/A

   If YES, provide the IRB #:

Do you certify that the purpose for which the specimens were originally collected has been met before removal of any excess?

- ◯ NO
- ◯ YES
- ◯ N/A

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

- ◯ NO, none of the identifiers below will be recorded from the medical record or used to label specimens
- ◯ YES, the following identifiers will be recorded from the medical record or used to label specimens **(check all that apply)**

- ☐ Name, Initials, or Code derived from name
- ☐ Geographical subdivision smaller than State (e.g. Street Address or Zip Code)
- ☐ Age or Date of Birth
- ☐ Dates associated with service (e.g. admission, discharge, testing, imaging)
- ☐ Phone number
- ☐ Fax number
- ☐ Email address
- ☐ Social Security number
- ☐ Medical Record number
- ☐ Health beneficiary number
- ☐ Account number
- ☐ Certificate or license number
- ☐ Vehicle identifiers and serial numbers, including license plates
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers (e.g. finger prints and voice prints)
- ☐ Full face photographic images
- ☐ Any unique identifiers not mentioned above:

Could the research be carried out without accessing or using information or biospecimens in an identifiable format?

- ◯ NO, the study requires accessing and using identifiable information or biospecimens because:

- ◯ YES, the study could reasonably be carried out without using identifiers (If this option is chosen, your study WILL NOT qualify for a waiver of the consent requirement)

What specific patient data will be recorded from the medical record/specimen?

Describe how patient privacy and confidentiality of their data 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?

   ◯ NO
   ◯ YES

   If the answer to #6 is "yes," STOP HERE. A full research application may be required. Contact IRB Office for assistance.

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 the subjects?

   ◯ NO
   ◯ YES

   If the answer to #7 is "yes," complete questions a through e. If the answer to #7 is "no," go on to Question #8.

   (a) Will the research involve more than minimal risk to the health of subjects?
   Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   ◯ NO
   ◯ YES
   ◯ N/A

   (b) Will the research involve more than minimal risk to the confidentiality of the subjects' protected health information?
   Minimal risk is based on, at least, the presence of the following elements:
   (i) an adequate plan to protect the identifiers from improper use and disclosure;
   (ii) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   (iii) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this policy or

HIPAA. Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.

- ◯ NO
- ◯ YES
- ◯ N/A

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

- ◯ NO
- ◯ YES (If you respond YES, your request for a waiver will be denied.)
- ◯ N/A

If NO, why not? **(check all that apply)**

- ☐ All patients cannot be readily accessed due to relocation, lost to follow up, death.
- ☐ Research is minimal risk and patients opting not to participate would skew results.
- ☐ Research is minimal risk and informing patients of data collection might bias their behavior and skew results.
- ☐ Research does not involve face-to-face interaction. Consent may or may not be obtained by other means.
- ☐ Time-frame of research does not allow for the process of obtaining written authorization.

Other reason (please explain):

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

- ◯ NO
- ◯ YES
- ◯ N/A

If YES, please describe the kind of information you believe might have direct clinical relevance for those whose information is being used, and a plan for disclosing this information.

8. If the answer to Question #7 is "no," will informed consent be

   ◯ Written
   ◯ Oral

   If written, attach a copy of the informed consent form proposed for this study.

   If oral, attach a copy of the consent script with a detailed description of how oral consent will be documented. Please note that oral informed consent is not sufficient for patient privacy purposes. Use the standard Wills Eye Hospital written authorization for 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 in a separate document according to the **Instructions for Completion of Wills Eye Hospital Form-1A.** Submit this document when you submit this Form-1A.

C. **Research Study Informed Consent (not applicable if waiver was requested).** Compose your Informed Consent Form or Oral Consent Script according to the **IRB's Policy and Procedure Regarding Informed Consent.** Attach the completed informed consent document when you submit this Form-1A.

Principal Investigator's Statement. I certify that the above information is correct, that it will apply throughout the performance of the proposed research, and that I will be responsible for safeguarding the confidentiality of the human subjects who are involved. I am aware of the confidential nature of the contents of this information and will vouch for any person other than myself who will work with this information under my direction. The names of these persons are:

I agree to a continuing exchange of information with the Wills Eye Hospital IRB. I agree to obtain IRB approval before making any significant changes or additions to the project. I will provide progress reports at least annually, unless exempt from continuing review.

Signature of Principal Investigator Date

Instructions: Have each Co-Investigator sign an Investigator Statement Form and submit the completed application with all required signatures present and all required documentation. Incomplete applications will be returned and must be resubmitted in full.

Submission Checklist

* required

Form-1A with Form-1Addendum for each Co-Investigator *
Protocol*
Supplementary Documents (where applicable)
Recruitment Materials e.g. ads, brochures, letters, phone scripts
Data collection sheets, e.g. survey, questionnaire, form

Submission Instructions:

Email to:

IRB@willseye.org
Email with "IRB New Study Submission" in the Subject line.
Attach all required forms and documentation. All signatures must be present.