

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:

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.

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 d. 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?

(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 #6 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 form 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.** 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 (and, if applicable, a letter to the IRB Chairman requesting a waiver or alteration to the requirement to obtain informed consent) 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*

Informed Consent or Letter Requesting Waiver/Alteration*

Supplementary Documents (where applicable)

Investigator Brochure

Drug/Device Information

Correspondences (FDA, OHRP, between investigators, sponsor, advisor, etc.)

Recruitment Materials (ads, brochures, letters, phone scripts, etc.)

Data collection sheets, e.g. survey, questionnaire, form

Submission Instructions:

Mail to:

Wills Eye Hospital IRB

840 Walnut Street

Philadelphia, PA 19107

OR

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.