

INSTRUCTIONS for Completion Of

Wills Eye Hospital IRB Form-2
“Non-Formulary Drug Statement”

This form is to be completed and submitted to the IRB along with WEH IRB Form-1 if you have answered YES to Questions on Form-1 indicating that this form is required:

Complete the following fill-in items on Wills Eye Hospital IRB Form-2 as direction by the following instructions:

- 1. Name(s) and/or code number of drug:** Obtain the name and/or code number of the drug from the manufacturer and enter this information on the lines provided.
- 2. Form(s) and strength(s) of drug:** Obtain this information from the manufacturer and enter this information on the lines provided.
- 3. Drug(s) supplied by whom?** Enter the name and location from which drug(s) will be obtained.
- 4. Mixing, reconstitution and/or dilution of drug(s):** If any mixing, reconstitution and/or dilution of drug is necessary, attach a form stating the size/strength of the original drug and size/strength of drug to be dispensed. All calculations for dilutions, mixing, and/or reconstitution must be approved by the Directors of Research and Pharmacy. Attach a copy of approval letter(s).
- 5. Therapeutic Application:** Obtain this information from the manufacturer and enter this information on the lines provided.
- 6. Dose(s) of drug -- Include normal dose per protocol and any variation from that dosage:** Obtain this information from the manufacturer and from previous experimental studies and enter this information on the lines provided.
- 7. Special storage requirements for drug:** Obtain this information from the manufacturer and from previous experimental studies regarding special storage requirements (include the need for refrigeration, humidity control, avoidance of light exposure, etc.) and enter this information on the lines provided.
- 8. Basic pharmacologic category of drug, chemical formula, generic name, and pharmacologic activity:** Obtain this information from the manufacturer and from previous experimental studies and enter this information on the lines provided.
- 9. Medication to be used by whom?** Check one of the three categories in the appropriate space.
- 10. Medication stored by whom?** Check one of the three categories in the appropriate space. If you check “Other,” specify the name and location where medication will be stored on the line provided to this right of this option.
- 11. Medication dispensed by whom?** Check one of the three categories in the appropriate space. If you check “Other,” specify the name and location where medication will be dispensed on the line provided to the right of this option.

12. In case of emergency, name of area and individual (other than pharmacy) where medication records are available (drug code, patient/drug records, etc.): Enter this information on the lines provided.

13. Name(s) of investigator(s) authorized to order medication: Indicate the name(s) of the investigator(s) who may order the drug(s) to be used in this study on the lines provided. If other than the Principal Investigator, these names should be listed on WEH IRB Form-1, Page 1, “Co-Investigator(s).”

14. What type of study is this? Indicate the type of study being conducted (e.g. single blind, double blind, randomized, sham-controlled, etc.) on the lines provided.

15(a) What are the recognized, reported, or possible ophthalmic/topical side or toxic effects of medication? Attach reports and/or bibliography. Obtain this information from the manufacturer and from previous experimental studies. Enter this information on the lines provided and attach materials as indicated.

15(b) What measures are to be taken if these effects are manifested? Obtain this information from the manufacturer and from previous experimental studies regarding what to do in the case of ophthalmic/topical side or toxic effects of the drug(s), and enter this information on the lines provided.

16(a) What are the recognized, reported, or possible systemic side or toxic effects of the medication? Attach reports and/or bibliography. Obtain this information from the manufacturer and from previous experimental studies. Enter this information on the lines provided and attach materials as indicated.

16(b) What measures are to be taken if these effects are manifested? Obtain this information from the manufacturer and from previous experimental studies regarding what to do in the case of systemic side or toxic effects of the drug(s) and enter this information on the lines provided.

17. What classes or specific medications are contraindicated during the course of this study? Obtain this information from the manufacturer and from previous experimental studies regarding those drug classes or particular drugs which would be rendered improper or undesirable during the course of this study, and enter this information on the lines provided.

18. What preexisting conditions or medication will exclude the patient from this study? Obtain this information from the manufacturer and from previous experimental studies regarding those pre-existing conditions and/or medications which would render a subject ineligible for the study, and enter this information on the lines provided.

19. Approval signature: Have the Principal Investigator sign and submit with Form-1 Research Study Proposal.