IRB Appendix F - Drugs or Biologics

Rev. August 2016

Complete this form to request inclusion of drugs or biologics (e.g., vaccines, cellular products, blood- or plasma-derived products) in the proposed research. *Include only those drugs or biologics that are to be administered as part of the research protocol (i.e., not those administered for routine care or evaluation)*. Use a separate form or section for each agent.

- Provide a copy of the drug or biologic manufacturer's approved labeling (i.e., package insert), Investigator's Brochure (IDB), or other equivalent information. *For approved products, ensure that the package insert is readable. See **Drugs at FDA** or the manufacturer's website for printable versions.*
- Provide documentation of all applicable FDA approvals for the investigational/research use of these drugs or biologics, as requested below. Copies of any correspondence to and from the FDA must be provided to the IRB. *Final IRB approval cannot be granted until regulatory status is confirmed.*

Principal Investigator: _____

Protocol Short Title: _____

Please select the category (A or B) for your drugs or biologics. Within that category, all questions must be answered.

☐ A. FDA Approved Products

☐ B. Investigational Drugs/Biologics or Investigational/Research Use of FDA Approved Products

Section A. FDA Approved Products - Includes drugs or biologics approved for this indication, route/dose, or study population

Note: If the research involves more than one FDA approved drug/biologic, print an additional page of this appendix and label as "FDA approved drug #2."

1. Provide the following information:

Name of Drug or Biologic:	
Generic Name or Active Ingredient:	
Brand Name:	
Dose and Dosage Form: (e.g., 10mg tablet)	
Frequency and route of administration	

2. Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

3. Provide the proposed rationale for choice of this agent in the research (compared to other drugs that could have been used).

4. Summarize the potential side effects (including serious warnings and more common side effects).

5. Is preparation or repackaging of the supplied product necessary before administration or dispensing?

◯ Yes
◯ No

If **Yes -->** state who will perform these activities and where they will be performed.

Section B. Investigational Drugs/Biologics or Investigational/Research Use of FDA Approved Products - Includes drugs or biologics that are not approved for this indication, route/dose, or study population

Note: If the research involves more than one investigational drug/biologic, print an additional page of this appendix and label as "Investigational drug #2."

1. The drug/biologic is (check one box):

☐ **Investigational** - Provide a copy of the Investigator's Brochure or equivalent information if not available.

☐ **Approved, but its use in this research is investigational** - Provide a copy of the drug or biologic manufacturer's approved labeling (i.e., package insert).

2. Provide the following information:

Name of Drug or Biologic:	
Generic Name or Active Ingredient:	
Brand Name, if applicable:	
Manufacturer:	
Dose and Dosage Form: (e.g., 10mg tablet)	
Frequency and route of administration	

3. Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

4. Does the drug/biologic have an Investigational New Drug (IND) number?

IRB approval cannot be granted until documentation of the IND (or exemption) has been provided.

☐ **Yes -->** Provide protocol-specific documentation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) of the IND number. ***Note: The investigator's drug brochure is not a protocol-specific document.***

a. Investigational New Drug #:

b. State who holds the IND: (sponsor, investigator, other)

c. Describe the process for investigational drug accountability, storage, and recordkeeping to ensure that the drug will be used according to the approved protocol, under the direction of approved investigator(s).

d. For an investigator-held IND, describe the process for assuring compliance with FDA regulations pertaining to sponsors (e.g., record keeping, reporting).

☐ **No** --> Explain how use of the drug/biologic in this research meets one of the FDA exemptions from the requirements for an IND or provide documentation of exemption from FDA (i.e., letter indicating an IND is not required).

5. Study phase:

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV (post marketing)

☐ Other, specify (e.g., I/II):

6. Provide the proposed rationale for choosing this agent (compared to other drugs that could have been used in this research).

7. Summarize the potential side effects (including serious warnings and more common side effects).

8. Is preparation or repackaging of the supplied product necessary before administration or dispensing?

◯ Yes
◯ No

If **Yes -->** state who will perform these activities and where they will be performed.

9. Upload all FDA correspondence to IRBNet