**APPENDIX U: Drugs, Biologics, Dietary Supplements, Food**

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| **IRB Study Number:** | Click or tap here to enter text. |

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| Complete this form for studies that require participants to use a drug, biologic, dietary supplement, or food as part of study participation *and* the safety or efficacy of that product is being evaluated as part of the study.  Provide a copy of the drug or biologic manufacturer’s approved labeling (i.e., package insert), Investigator’s Brochure (IB), or other equivalent information on the Drugs page of the SmartForm. For approved products, ensure that the package insert is readable. See [***Drugs@FDA***](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm) 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 on the Drugs page of the SmartForm. 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. | | |
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| 1. Will the study be conducted under an IND number(s)? | | |
| Yes | 1. On the Drugs page of the SmartForm, specify the IND number, indicate who holds the IND, and provide protocol-specific documentation (e.g., sponsor’s protocol cover sheet, FDA or sponsor correspondence) of the IND number. Note: The investigator’s drug brochure is not a protocol-specific document. 2. 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).   Click or tap here to enter text.   1. For an investigator-held IND, describe the process for assuring compliance with FDA sponsor regulations (e.g., recordkeeping, reporting):   Click or tap here to enter text. | |
| No | 1. 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).   Click or tap here to enter text. | |
| 1. Provide the following information:   *Note: If the research involves more than one drug/biologic, complete an additional appendix and label as “Drug 2.”* | | |
| Name of the product: | | Click or tap here to enter text. |
| Dose and dosage form (e.g., 10mg tablet): | | Click or tap here to enter text. |
| Frequency and route of administration: | | Click or tap here to enter text. |
| 1. Provide a brief description of the drug/biologic (e.g., drug class, mode of action).   Click or tap here to enter text. | | |
| 1. Provide the proposed rationale for choice of this agent in the research (compared to other drugs that could have been used).   Click or tap here to enter text. | | |
| 1. Summarize the potential side effects (including serious warnings and more common side effects).   Click or tap here to enter text. | | |
| 1. Is preparation or repackaging of the supplied product necessary before administration or dispensing?   Yes  If yes, state who is performing these activities and where they will be performed:  Click or tap here to enter text.  No | | |