



# Appendix B: Drugs and Devices

The form should be used when the Human Research is a 'clinical investigation' of a drug or device, which is “any experiment that involves a test article on one or more human subjects that either 1) requires FDA approval, or 2) is intended to be submitted to or inspected by the FDA for research or a marketing permit.”

- Drug - The drug is the purpose of the research and will involve a change or alteration of the label, route of administration, conditions of use or population.
- Device - The device is the purpose of the investigation, and will be used to evaluate safety or effectiveness in the diagnosis of disease or other conditions; or the cure, mitigation, treatment, or prevention of disease.

**Note: Drugs and devices may be used in research but may not be the purpose of the investigation (e.g. As an adjunct to a standard procedure or test for screening). Information about these drugs or devices must be included in the 'Procedures' section of the HSPP application so an assessment of risk and safety to subjects can be made. It is not necessary to complete this appendix.**

Used for drugs and devices	
<b>IRB Project No.:</b>	_____
<b>Project Title:</b>	_____
<b>Investigator:</b>	_____
<b>Investigator UA NetID:</b>	_____
<b>Investigators Contact's Information:</b>	_____
<b>Alternate Contact</b>	_____
<b>Alternate Contact's Information:</b>	_____
General Questions	
Is the purpose of the research to conduct a clinical investigation of a drug/device?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are you using a drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are you using a device?	<input type="checkbox"/> Yes <input type="checkbox"/> No