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| **Appendix B** |
| **Drugs** |
| **List *all* drugs whose use is *dictated* as by the research.** |
| **Generic Name** | **IND #** | **Does a UML Investigator hold the IND?** | **If Yes, UML Investigator Name** |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
|       |       | Yes [ ]  No [ ]  |       |
| For each approved drug include a copy of the package insert.For each drug with an IND number, ensure that the application includes one of the following:* Current investigator brochure
* Sponsor protocol with the IND number (if sponsor protocol does not include the IND number, then include one of the following:
	+ - Communication from the sponsor with the IND number
		- Communication from the FDA with the IND number
* If the study obtained and IND exemption, please attach documentation.
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| **Devices** |
| **List all devices being evaluated for safety or effectiveness:** |
| **Name** | **IDE/HDE #****(or none)** | **Claim of an Abbreviated IDE** | **Humanitarian Use Device (HUD)** | **Does a UML Investigator hold the IDE or HDE?** | **If Yes, name of UM Investigator** |
|       |       | Yes [ ] No [ ]  | Yes [ ] No [ ]  | Yes [ ] No [ ]  |       |
|       |       | Yes [ ] No [ ]  | Yes [ ] No [ ]  | Yes [ ] No [ ]  |       |
|       |       | Yes [ ] No [ ]  | Yes [ ] No [ ]  | Yes [ ] No [ ]  |       |
| For each approved device include a copy of the product labeling.For each device with an IDE/HDE number, ensure that one of the following are included in the attachments pages: * Sponsor protocol with the IDE/HDE number
* Communication from the sponsor with the IDE/HDE number
* Communication from the FDA with the IDE/HDE number
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