|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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. | | | | | | | | |
| **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 | | | | | | | | |