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| --- | --- | --- |
| **Study Information** | | |
| Title of Study: |  | |
| IRB ID: |  |  |
| Principal Investigator (PI): |  | |
| If your research study includes the administration of a drug, biologic, or nutritional supplement, please fill in the required information in the table below *(add more rows, as needed).* | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| ***1. Drugs, Biologics, Dietary Supplements, and Food*** | | | | **IND\* Holder** | | | |
| **Substance Name**  **1 - Generic & Brand name, if applicable)**  **2 – Provide package insert(s)** | **Status**  **1 – IND approved/pending/Exempt**  **2 – Approved drug/Biologic** **for approved use**  **3 – Other (provide outline below):** | **Dosage** | **Route of Administration** | **IND Number from FDA** | **Sponsor** | **Investigator** | **Other (list)** |
|  |  |  |  |  | **Yes**  **No** | **Yes**  **No** |  |
|  |  |  |  |  | **Yes**  **No** | **Yes**  **No** |  |