Complete this form if you are conducting investigational treatment that involves administration of an approved drug for an unapproved use. (Do not include off label use of a drug as part of medical care - where the choice of drug, dose, timing or route is dictated by the protocol.

In some cases, use of an approved drug for an unapproved use may require an IND submission to the FDA. Your response to the following questions will help determine whether an IND submission is required. If using more than one drug, all of the questions in the table in section 1 will need to be answered for EACH drug (the table 2 below can be copied and pasted for each drug used).

|  |
| --- |
| **1**. Previous submission to the FDA |
| Has an IND application previously been submitted to the FDA for the off-label drug use in this investigational treatment? |
| [ ]  | **No.** Date submitted to the FDA: Insert date Date received by the FDA: Insert date |
| **Name of IND Requester** | Insert name of IND requester |
| Has the local PI contracted with the IND holder to perform any sponsor obligations? | yes or no - N/A if PI is the IND holder |
| Is the IND Holder also the local investigator?  | yes or no |

|  |  |
| --- | --- |
| [ ]  | **Yes.** *If yes,* ***select******one.***  |
| [ ]  | The FDA determined an IND is not required.  Stop. Do not complete the remainder of this form. Attach a copy of the FDA determination letter. |
| [ ]  | The FDA determined an IND is required.  Answer the questions below and provide documentation of the FDA assigned IND number. |
| **IND Number:** | Insert IND number | **Name of IND Holder** | Insert name of IND requester |
| Has the local PI contracted with the IND holder to perform any sponsor obligations? | yes or no - N/A if PI is the IND holder |
| Is the IND Holder also the local investigator?  | yes or no |