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| Drug Form  For Clinical Investigations |
| **Name of Drug:**Click or tap here to enter text.  Is there an IND? Yes  No  To determine whether the drug requires an IND, review this [FDA Guidance](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.fda.gov/media/79386/download)  If Yes:  IND Number:Click or tap here to enter text.  Holder of IND:Click or tap here to enter text.  Confirmation via:  Sponsor protocol imprinted with the IND  Written communication from sponsor  Written communication from FDA (i.e., this would be if the investigator is the holder of the IND)  If No, will drug be used as per approved indication?  Yes, confirmation via (select below):  Package Insert  Other  Brand name(s) of drug:  No, please **ATTACH** documentation of exemption from requirement for an IND submission. |
| **Source of Drug**  Sponsor Name:Click or tap here to enter text.  Non-sponsor Manufacturer, if applicable:Click or tap here to enter text.  Drug Form:Click or tap here to enter text.  Strength/Dose and Frequency:Click or tap here to enter text.  Route of Administration:Click or tap here to enter text. |
| **Additional Attachments**  Attach documentation of agreement from the QMC Research Pharmacy\*  Attach any Investigator Brochure associated with the drug  \*Please contact Kelly Watanabe, PharmD at [kewatanabe@queens.org](mailto:kewatanabe@queens.org) to request a review of your research to determine if resources are available to support your study. |
| **Authorized Prescribers (include any investigators listed on research):**  Click or tap here to enter text. |
| **In Case of Adverse Reaction, notify (list name and phone number):**  ***Principal Investigator:*** Click or tap here to enter text.  ***PI Designee:***Click or tap here to enter text.  ***Medical Director of Manufacturer:***Click or tap here to enter text. |