IBC
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Submission Form IBC B: Protocol Review

Date:
Protocol ID:
Project Title:

I. Protocol

		Yes	No
1a.	Has the protocol been granted a vaccine exemption under Appendix M-VI-A? ** If yes, please attach copy of the vaccine exemption correspondence received from NIH OBA.*	☐ *	☐
1b.	Has this protocol ever been reviewed by another IBC on behalf of this institution? **If yes, please explain:*	☐	☐
1c.	Date the IND application for this protocol went into effect: ☐ Pending *Please ask your sponsor, this related to compliance with annual NIH reporting requirements*		
1d.	Do you have a specific calendar requirement for opening enrollment? **If yes, date:* *Explanation:*	☐	☐

II. Principal Investigator Information

2a.	Name:	Degree(s):	Specialty:
2b.	Address:		
2c.	Phone:	Email:	

		Yes	No
2d.	Has the PI delegated reporting responsibilities (per NIH guidelines Appendix M-1-C) to another party, such as a corporate sponsor? **If yes, forward a copy of the delegation letter submitted to NIH OBA. Be aware delegation itself does not fulfill the NIH reporting requirement. If the sponsor does not report, the PI must.*	☐	☐
2e.	Has the PI ever been debarred or disqualified from participating in clinical research by any regulatory authority? **If yes, please attach a description of the circumstances and current status*	☐	☐
2f.	Are staff who prepare and administer the investigational agent qualified to do so under local and state laws? **If no, please explain:*	☐	☐

III. *PI Representative Information*

The PI representative is the person designated as the primary contact for IBC review.

3a.	PI Representative Name:	
3b.	Title:	
3c.	Address:	
3d.	Phone:	Email:

IV. Research Location

List all facilities where study agent will be present and where subjects received required post-dosing care.

4a.	Main Site, Name:		
4b.	Address:		
4c.	Phone:	Email:	
4d.	Type of facility:	☐ Outpatient medical office ☐ Other (specify):	☐ Hospital

4e.	What study activities will be done at this site? ☐ Agent receiving or shipping ☐ Agent Storing ☐ Agent Preparation ☐ Dosing ☐ Specimen collection ☐ Other subject medical care or follow-up ☐ Other (specify):
4f.	Additional Site Name:
4g.	Address:
4h.	Phone: Email:
4i.	Type of facility: ☐ Outpatient medical office ☐ Hospital ☐ Other (specify):
4j.	What study activities will be done at this site? ☐ Agent receiving or shipping ☐ Agent Storing ☐ Agent Preparation ☐ Dosing ☐ Specimen collection ☐ Other subject medical care or follow-up ☐ Other (specify): *To list more sites, please attach additional sheets*

V. Additional Contact Information

5a.	Sponsor Name:
5b.	Address:
5c.	Contact Name:
5d.	Phone: Email:
6a.	Medical Monitor Name:
6b.	Phone: Email:
7a.	CRO Name:
7b.	Address:
7c.	Phone: Email:
8a.	SMO Name:
8b.	Address:
8c.	Phone: Email:
9a.	IRB Name:
9b.	Address:
9c.	Phone: Email:

VI. Billing Information

10a.	Party to be billed:
10b.	Address:
10c.	Phone: Email:
10d.	Special instructions:

VII. Person Completing This Form

11a.	Name and Title:
11b.	Phone: