Appendix C: Use of Drugs Investigator Checklist

Protocol title:	
PI name:	Date:

Please complete and submit this checklist with your IRB protocol submission packet. This checklist serves as a guide to Sponsor-Investigators in determining and documenting information required by the IRB related to the use of an Investigational New Drug (IND) which falls under the FDA regulations (21 CFR312). (***Sponsor-Investigator* is the individual who initiates and also conducts the study/clinical investigation. Typically this is the Principal Investigator (PI). A sponsor-investigator must comply with regulatory requirements applicable to both sponsors and clinical investigators (21 CFR312.3)**

When a drug is being used in a research study, an IND may be required. Some studies may be exempt from requiring an IND (21 CFR 312.2) if certain criteria are met. Please consult the cited regulations for additional information on exemptions.

For guidance, this flowchart may be helpful in determining if an IND is required.

a.	**Drug name**_____(Investigations with multiple drugs must submit a separate form for each drug) **Please include drug/package insert or other documentation that describes the drug/usage/population/side effects, etc.**			HRPP USE ONLY: Confirm information for IRB review, (based on protocol submission and checklist) noting a check mark ✔.
b	Is the drug/biologic product lawfully marketed in the US?	☐ Yes	☐ No	
c	Is there any intent to report the findings of your investigation to the FDA as a well-controlled study in support of a new indication or any other significant change in the labeling of the drug?	☐ Yes	☐ No	
d	Is the study intended to support a significant change in the advertising of the drug?	☐ Yes	☐ No	
e	Will the investigation involve a change in <u>any</u> of the following factors:			
	• Dosage level (either raising or lowering dose, frequency or duration compared to approved label)	☐ Yes	☐ No	
	• Patient population	☐ Yes	☐ No	
	• Any other factor that significantly increases (or decreases the acceptability of the risk) risk associated with the use of the drug product (21 CFR 312.2(b) (1)(iii)).	☐ Yes	☐ No	
f	Is the Investigation intended to promote or commercialize the drug product (21 CFR part 312.7)?	☐ Yes	☐ No	
g	Is a waiver of documentation of informed consent being requested?	☐ Yes	☐ No	
	If ANY OF THE SHADED BOXES HAVE BEEN CHECKED, AN IND APPLICATION TO THE FDA IS LIKELY REQUIRED.			
h	If you have obtained an IND from the FDA please provide the IND #: _____			
i	If it has been determined that an IND is NOT required, please indicate if this determination was made by the PI or the FDA.	☐ PI	☐ FDA	

	• If the drug has not been evaluated by the FDA, the IRB may assess the drug's risks and make a determination of exemption from IND requirements. **Please provide/attach supporting documentation, e.g., letter from the FDA, package insert, or other information that may provide support for a determination that an IND is not required.**			
j	Please provide the plan to securely obtain store, dispense/use, and dispose of the drug. Attach a separate document that includes this information or note the location/section/page # where this information may be found in the protocol			
k	The informed consent process/document must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained **and the possibility that the FDA may inspect the records.** (21 CFR 50.25 (a) (5))			
l	Is the study an applicable clinical trial? *"Applicable clinical trials" generally include:* *(1)* Trials of Drugs and Biologics*: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;* *(2)* Trials of Devices*: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.* *Complete statutory definitions and more detailed information on the NIH's current thinking about the meaning of "applicable clinical trials" may be found here: "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial".* ***If "Yes" go to "p" .***	☐ Yes	☐ No	
m	Is the clinical trial registered on Clinicaltrials.gov?	☐ Yes	☐ No	
	• Under federal regulation 21 CFR 50.25(c) the following statement **must be** reproduced word-for-word in informed consent documents for applicable clinical trials that began after March 7, 2012: "*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time"*			