**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CPHS – DRUGS OR BIOLOGICS**

**(Note:** Please review the criteria for determining whether a project should be submitted to the D-HH IRB rather than the CPHS prior to beginning your application. The criteria are posted [here](https://med.dartmouth-hitchcock.org/research/irb-submission.html). )

**Please complete: CPHS# PI:**

 **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

Please fill out a separate copy of this form for each drug and biological agent that is not approved by the FDA for the specific indication for which it is used in this study and for which an IND# has not been obtained.

**Drug or Biologic Agent:**

 **Exemption from the requirement to file an IND:**

The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirement to file an IND application if all of the following criteria apply:

**Please indicate whether the following criteria apply to the proposed research:**

1) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use, nor intended to be used to support any other significant change in the labeling for the drug;[ ]  **No** [ ]  **Yes**

2) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;[ ]  **No** [ ]  **Yes**

3) The investigation does not involve a route of administration that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

[ ]  **No** [ ]  **Yes**

Explain:

4) The investigation does not involve a dosage level that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

 [ ]  **No** [ ]  **Yes**

Explain:

5) The investigation does not involve use in a subject population that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

[ ]  **No** [ ]  **Yes**

Explain:

6) The investigation does not involve any other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product

[ ]  **No** [ ]  **Yes**

Explain:

7) The investigation is conducted in compliance with the requirements for institutional review set forth in Part 56 and with the requirements for informed consent set forth in Part 50;

[ ]  **No** [ ]  **Yes**

8) The investigation is conducted in compliance with the requirements of 21 CFR 312.7. This section outlines promotion and charging requirements for investigational new drugs. Investigators and sponsors may not promote investigational new drugs as being safe and effective and they may not charge for, distribute or test market these drugs without FDA approval;

[ ]  **No** [ ]  **Yes**

\*The FDA requirements to qualify for an exemption status from filing an IND may be found in 21 CFR 312.2(b)

Note: The IRB may determine that an IND is required for this study.