**Investigator Checklist**

**Use of Drug or Biologic under REMS**

**Background:** A Risk Evaluation and Mitigation Strategy (REMS) is a safety strategy to manage a known or potential serious risk associated with a drug or biological product.

A REMS will be required if the Food and Drug Administration (FDA) determines that a REMS is necessary to ensure the benefits of the drug or biological product outweigh its risks. A REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use, and an implementation system. Click [here](https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm) for more information on REMS.

**For specific information about drugs or biologics under REMS, check** [**this**](https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm) **site.**

**Investigator:** *Please submit completed form to Margaret Huber at* *mhuber@emory.edu* *in the Office of Compliance for review of any research study using a drug or biologic that is under an FDA REMS.*

***NOTE****: Two or more drugs may be listed on one form if the answers to all questions will be the* ***same*** *for all drugs.*

IRB number:

PI Name:

Study Title:

Person completing this form:

**Q1. List the name of the drug or drugs (if more than one drug, answer provided must apply to all drugs). Include REMS information: a protocol reference, link to the REMS website or attach** “**REMS document” issued by FDA.**

**Q2. Does REMS include elements to assure safe use?**

No [ ]  Yes [ ]

**Q2a. If yes**

Prescriber training: No [ ]  Yes [ ]

Certification of prescriber, pharmacy, facility: No [ ]  Yes [ ]

If pharmacy certification required:

Protocol specifies that Specialty Pharmacy ships drug to IDS\*: No [ ]  Yes [ ]

Protocol specifies that Specialty Pharmacy ships drug to subject\*: No [ ]  Yes [ ]

 \*Unless protocol specifies otherwise, Specialty Pharmacy ships drug to subject

Patient registration: No [ ]  Yes [ ]

Patient Information Sheet or other materials: No [ ]  Yes [ ]  If yes, include in eIRB submission.

Review of lab test results: No [ ]  Yes [ ]  If yes, specify: Click or tap here to enter text.

Other: No [ ]  Yes [ ]  Specify: Click or tap here to enter text.

**Q3. Does the consent document describe REMS requirements for subjects?**

No [ ]  Yes [ ]

If no, consent document must describe REMS requirements for subjects before this checklist can be approved.

*Sample consent language:*

*In order to participate in this study, you must register into and follow the requirements of the \_\_\_\_\_\_ REMS® program.  This program provides education and counseling on the risks of \_\_\_\_\_ and need for \_\_\_\_ monitoring.  Before you consent to participating in this study, your study doctor will discuss with you the full requirements of the \_\_\_\_\_ REMS Program within the \_\_\_\_\_\_\_\_\_ (name of patient information sheet) that you have received and must agree to follow.*

**Q4. Does REMS apply to all study subjects?**

No [ ]  Yes [ ]

If no, specify: Click or tap here to enter text.

**Q5. Does REMS require specific testing other than pregnancy testing?**

No [ ]  Yes [ ] If yes, specify: Click or tap here to enter text.

**Q6. Does REMS require subject counseling?**

No [ ]  Yes [ ]

**Q6a. If yes, who provides counseling?** Click or tap here to enter text.

**Q6b. Are counselors required to be certified?** No [ ]  Yes [ ]

If yes, describe process or protocol citation: Click or tap here to enter text.

**Q6c. How is counseling certification documented? Click or tap here to enter text.**

**Q6d. Where is subject counseling documented?** Click or tap here to enter text.

**Q7. Does REMS address reproductive risks?**

No [ ]  Yes [ ]

**Q7a. If yes, is childbearing potential (CBP) defined in the protocol?**

No [ ]  Yes [ ]

If no, protocol must include definition of childbearing potential before this checklist can be approved.

**Q7b. If yes, is the CBP definition in agreement with the FDA “REMS Document”?**

No [ ]  Yes [ ]

If no, definition in the protocol must be in agreement before this checklist can be approved.

**Q7c. Where will CBP determination be documented for every subject enrolled for this study? e.g. medical record, CRF.**

Click or tap here to enter text.

**Q7d. Does REMS require subjects to use contraception?** No [ ]  Yes [ ]

If yes, where is contraception method documented for every subject enrolled in the study?

 Baseline: Click or tap here to enter text.

 Ongoing during study: Click or tap here to enter text.

**Q7e. Does REMS require pregnancy testing?** No [ ]  Yes [ ]

 **If yes, provide protocol citation for pregnancy testing requirements:** Click or tap here to enter text.

**Baseline** only: No [ ]  Yes [ ]

 **Baseline & ongoing during study**: No [ ]  Yes [ ]

**Who reviews test results?** Click or tap here to enter text.

**When are test results reviewed?** Click or tap here to enter text.

**Where are test results and review documented?** Click or tap here to enter text.