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## Request to Rely (R2R) Process Change for FCOI Review for Continuations

For R2R continuations submitted after July 19, 2019, study teams will be responsible for initiating the FCOI Review for continuation submissions when relying on an external IRB. It is recommended that the FCOI Review is complete prior to submission of the continuation to the external IRB. An incomplete continuation submitted to PPHS will be returned to the study team to complete the FCOI process.

### PURPOSE

1. Minimize additional submissions to an external IRB when a study requires review by the FCOI Committee at the time of continuation;
2. Decrease delays in the turnaround time of the release of the ISMMS PPHS acknowledgement of continuations with FCOIs disclosed, including updating InfoEd with continuation approval dates for study fund access;

### PROCESS

1. Six weeks prior to expiration, create the new Investigator Form (IF). *Note: FCOIR has three weeks to complete their review.*
2. An FCOI Review is required if:
  - a. The study has a COI Management Plan from the previous year and no personnel have a conflict disclosed on the new IF;
  - b. Any personnel have indicated YES to a financial conflict of interest or an institutional conflict of interest on the new IF (Screenshot below indicates where it will be indicated on the IF in Sinai Central).

Investigators	
Jennifer I Kucera (Jen, Jenny)	Role: Principal Investigator
Financial Conflict in Research	Status: SUBMITTED Fin. Interest? N Inst. Interest? N Submitted: 07/29/2019 Amended:
Suspension and Debarment	Status: SUBMITTED Issue N
COI Annual Forms	2018 Status: NOT APPLICABLE 2019 Status: NOT STARTED

3. Initiate the FCOI Review by emailing [FCOIR@mssm.edu](mailto:FCOIR@mssm.edu). If study is not in Ideate, attach the current protocol and informed consent to the email. *See examples for email content on Page 2.*
4. If the FCOIR issues a continued Management Plan from the previous year (i.e., there are no changes), submit a copy of the email from FCOIR with the continuation submission in Ideate.
5. If the FCOIR issues a new or revised Management Plan:
  - a. Obtain all required researcher signatures;

- b. Revise consent forms, as indicated in the COI Management Plan;
  - c. Submit the signed COI Management Plan and revised consent forms with the continuation to the external IRB.
6. When external IRB approval documents are received, confirm the following prior to submission in Ideate:
- a. Documented acknowledgement of the COI Management Plan on the approval letter
  - b. Approved consent forms contain COI language
  - c. If approval documents are incomplete, work with the external IRB to obtain revised documents prior to submission to PPHS.
7. When external IRB approval documents are complete, attach to continuation submission in Ideate. For non-Ideate studies, attach to continuation email.
- a. Continuation for a study enrolling subjects with a new COI Management Plan:
    - i. External IRB approval letter with documented approval of COI Management Plan and revised consent form(s)
    - ii. Approved consent form(s) with applicable COI language
    - iii. Signed COI Management Plan
  - b. Continuation for a study closed to enrollment with a new COI Management Plan:
    - i. External IRB approval letter with documented approval of COI Management Plan
    - ii. Signed COI Management Plan
  - c. Continuation with a continued COI Management Plan (i.e. no changes):
    - i. External IRB approval letter
    - ii. A copy of the email from FCOIR documenting the continued Management Plan.
8. An incomplete continuation submitted to PPHS will be returned to the study team to complete the FCOI process, which may require the submission of a modification to the external IRB.

**EXAMPLES OF EMAILS FOR IDEATE STUDIES**

1. If any personnel have a conflict disclosed on the new IF, email the following information:
- a. To: [FCOIR@mssm.edu](mailto:FCOIR@mssm.edu)
  - b. CC: PI and any other study contact that should be cc'd on the response from FCOIR.
  - c. Subject: FCOI Review for IRB#/GCO#
  - d. Body of the email:

The study below has an FCOI disclosed for an external IRB continuation.

Ideate#	
GCO#	
IF#	
PI	

2. If the study has a COI Management Plan from the previous year and no personnel have a conflict disclosed on the new IF, email the following information:
- e. To: [FCOIR@mssm.edu](mailto:FCOIR@mssm.edu)
  - f. CC: PI and any other study contact that should be cc'd on the response from FCOIR.
  - g. Subject: FCOI Review for IRB#/GCO#

- h. Attach: Current protocol and current approved ICF(s)
- i. Body of the email:  
The study below has an active COI Management Plan, but there are no FCOIs disclosed on the annual IF created for an external IRB continuation.

Ideate#	
GCO#	
IF#	
PI	

**EXAMPLES OF EMAILS FOR NON-IDEATE STUDIES**

- 3. If any personnel have a conflict disclosed on the new IF, email the following information:
  - j. To: [FCOIR@mssm.edu](mailto:FCOIR@mssm.edu)
  - k. CC: PI and any other study contact that should be cc'd on the response from FCOIR.
  - l. Subject: FCOI Review for GCO#
  - m. Attach: Current protocol and current approved ICF(s)
  - n. Body of the email:  
The study below has an FCOI disclosed for an external IRB continuation.

GCO#	
IF#	
PI	

- 4. If the study has a COI Management Plan from the previous year and no personnel have a conflict disclosed on the new IF, email the following information:
  - o. To: [FCOIR@mssm.edu](mailto:FCOIR@mssm.edu)
  - p. CC: PI and any other study contact that should be cc'd on the response from FCOIR.
  - q. Subject: FCOI Review for GCO#
  - r. Body of the email:  
The study below has an active COI Management Plan, but there are no FCOIs disclosed on the annual IF created for an external IRB continuation.

GCO#	
IF#	
PI	