

<b>SOP: Transferring Studies with SBER IRB</b>				
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HRP-016	11/09/2016	J. Morelli, C. Choy, and N. Mitra	J. Morelli, Health Sciences IRB	1 of 2

## 1 PURPOSE

- 1.1 This policy provides guidance about transferring studies between the Tufts Health Sciences IRB and Tufts Social, Behavioral & Educational Research (SBER) IRB and vice versa.
- 1.2 The process begins when a PI requests to transfer a study from one Tufts IRB to the other (Tufts Health Sciences IRB or SBER IRB).
- 1.3 The process ends when a determination is made as to whether it is acceptable to transfer a study from one Tufts IRB to the other.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 As a general rule, studies that have been reviewed by one Tufts IRB or are currently under review by one Tufts IRB will not be transferred to the other IRB. Active studies will not be transferred between Tufts IRB offices.
- 3.2 It is not acceptable to close out a study with one Tufts IRB to re-open the study with the other Tufts IRB.
- 3.3 In rare circumstances, it might be acceptable for a study that has multiple distinct components to close out one component and submit the subsequent component to the other Tufts IRB as a new study if the component requires the expertise of the other Tufts IRB. For example, if a study has an initial component consisting of preliminary research and development of a bigger project, then that initial distinct part could potentially be closed at one IRB and the new distinct study could be opened at the other IRB. This would not apply if the subjects enrolled in the initial component were also active subjects in the subsequent part of the study.  
Under this circumstance, the PI is to:
  - 3.3.1 Inform the current IRB about the plan and rationale to submit the subsequent component to the other Tufts IRB, and
  - 3.3.2 Inform the IRB that will now review the subsequent component about the history of IRB approval for the prior component so this is well documented in the IRB study file.
- 3.4 Prior to submitting a study to a Tufts IRB, the PI should refer to the [HSC-SBER IRB Flowsheet.pdf](#) in order to determine which Tufts IRB to submit to.

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 Provide guidance to Investigators and research teams in accordance with the above policy.
- 5.2 Forward requests to transfer studies between Tufts IRBs to the IRB Chair/Vice-Chair for a determination, as needed.
- 5.3 If the Tufts Health Sciences IRB or SBER IRB Chair/Vice-Chair determine a study can be closed out with the reviewing Tufts IRB, follow the standard close out procedures.
  - 5.3.1 For the Tufts Health Sciences IRB, the PI is to submit the [Study Close Out \(Cover Letter\)](#).
- 5.4 Communicate with the other Tufts IRB to discuss and agree upon an acceptable plan, as needed.

## 6 MATERIALS

- 6.1 [HSC-SBER IRB Flowsheet.pdf](#)
- 6.2 [Study Close Out \(Cover Letter\)](#)



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## **7 REFERENCES**

7.1 None