Nova Southeastern University – Institutional Review Board Standard Operating Procedures		
SOP #1-7 Version #1	TITLE: Generation, Use, and Revisions of Standard Operating Procedures (SOPs) and Policies	
Date First Effective: December 14, 2017	Revision Date: N/A	Page 1 of 3

OBJECTIVE

To describe the policies and procedures for developing, reviewing, revising, and distributing standard operating procedures (SOP) or policies for the Institutional Review Board (IRB)

GENERAL DESCRIPTION

The Nova Southeastern University (NSU) IRB maintains standard operating procedures and policies to ensure effective functioning of the NSU human research protection program. The IRB documents when procedures are initiated, revised, and disseminated to staff, IRB members, investigators, and research personnel.

The IRB Office may make minor changes to SOPs, which are reported to the next convened IRB. All other SOP changes can only be implemented or modified by a vote of the convened IRB. New and revised SOPs adopted by the IRB must also be approved by the Institutional Official. The IRB will disseminate all new and modified SOPs to the university community.

RESPONSIBILITY

Execution of SOP: IRB Office Staff, IRB Members, Institutional Official

PROCEDURES

A. Procedures for Writing Standard Operating Procedures

1. With advice from NSU researchers, IRB members, and the Institutional Official, the IRB Office determines when a new SOP needs to be written. The IRB Director will designate the IRB staff responsible for writing the SOPs.

2. All SOPs must comply with federal, state, and institutional regulations.

3. The IRB staff designated to write SOPs may consult with the IRB Chairs and members on IRB related issues in developing the SOPs.

4. As appropriate, the IRB Office Staff will distribute copies of newly drafted SOPs to IRB Chairs, IRB members, IRB staff members and/or other IRB stakeholders for review.

5. If the SOP involves coordination with another NSU administrative office, the IRB Office will cooperate with the administrative unit involved in drafting the SOP and route the SOP to the appropriate individual representing that office for review and comment prior to being presented to the convened IRB for final review and approval.

6. The IRB Office will present the new SOP to the convened IRB and any members who wish to attend for a final review and approval by majority vote.

7. Once a SOP has been approved by the convened IRB by a majority vote, it is forwarded to the Institutional Official for review and approval. Should the Institutional Official reject the SOP, the SOP will be returned to the convened IRB for additional review along with any comments/suggestions from the Institutional Official. The process is repeated until there is a majority vote for the revised SOP.

8. The IRB Office will ensure that each SOP designates the date on which it originally became effective, as well as the most recent revision date.

9. Each SOP contains a version number, which indicates how many times since its origination, the IRB Office has revised an SOP.

B. Revisions to Standard Operating Procedures

1. With advice from NSU researchers, IRB members, and the Institutional Official, the IRB Office determines when to revise an existing SOP.

2. The IRB Office may make minor administrative corrections without revising an SOP or presenting to the convened IRB. The IRB Office must notify the IRB Chair of any minor revisions to SOPs. Minor revisions may include but are not limited to grammatical/typographical corrections, changes in the titles of individuals listed, title changes to the names of policies or procedures, revisions to the layout of the policy as needed for formatting purposes, or minor changes to attached documents associated with a policy or the descriptions/references of those documents within a policy.

3. All SOP revisions must comply with federal, state, and institutional regulations.

4. Approval of revised SOPs follows the same procedure as writing new SOPs, except minor revisions may be implemented without review by the Institutional Official. The minor revision will be discussed between the IRB Office and the IRB Chair, and then presented to

the convened IRB. Minor changes will not change the version number for the SOP, but the change will be documented in the SOP Tracking System, as outlined in Section D of this policy.

C. Dissemination of Standard Operating Procedures

1. The IRB Office will disseminate all new and revised SOPs to all IRB Chairs and IRB members.

2. The IRB Office will maintain the most recent versions of all approved SOPs on the NSU IRB website.

D. Record Keeping

1. Each SOP will maintain a "SOP Tracking System" that will be kept as a record to document new SOPs. The IRB Director, IRB Chair, and Institutional Official will sign and date a SOP Tracking Form that will be kept in the SOP binder.

2. The IRB Office maintains copies of all current SOPs in both hard copy and electronic formats. The IRB Office will maintain copies of all the current versions of the SOPs in the SOP binder.

3. The IRB Office files the SOPs in the SOP binder, and places the electronic files into the SOP folder in the IRB shared drive. The IRB Office maintains copies of all original and subsequent revisions of all SOPs indefinitely.

REFERENCES

Not applicable.