

## STANDARD OPERATING PROCEDURE

### Reporting Mechanisms Between NF/SGVHS and the UF IRB-01

**1. PURPOSE:** To establish policy and procedures for reporting and communicating information between North Florida/South Georgia Veterans Health System (NF/SGVHS) and the University of Florida Institutional Review Board (UF IRB-01) regarding new regulations, directives or handbooks, audits, allegations of non-compliance, accreditations, inspections, misconduct pertaining to protocols, adverse events, complaints and other issues. There is an obligation to notify and supply copies of any new documents pertaining to new regulations concerning human subject protections to the IRB. Information may be sent by e-mail or other convenient and expedient methods.

**2. BACKGROUND:** In accordance with the Memorandum of Understanding (MOU) between NF/SGVHS and the University of Florida concerning the use of the University Institutional Review Board (IRB), communication of information between the two parties is essential as it pertains to effective functioning, monitoring and oversight of the Human Research Protection Program (HRPP).

**3. SCOPE:** The exchange of information and communication between the components of the HRPP are crucial to effective functioning and may affect compliance of the HRPP as it relates to an investigator who has an approved protocol at NF/SGVHS. It may also affect an oversight agency including the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), the Government Accounting Office (GAO), the Office of Research and Development (ORD), the Office of Research Oversight (ORO), or other agencies regarding HRPP. The exchange of information will occur between the Institutional Official NF/SGVHS and/or his designee(s).

- The point of contacts to provide information will be those positions as indicated in the responsibilities.
- The Medical Center Director's (MCD) Designee includes, but is not limited to the Chief of Staff, Associate Director, Associate Chief of Staff for Research (ACOS/Research), Deputy ACOS/R, Research Compliance Officer, Chair of the R&D Committee, and/or VA General Counsel.
- ACOS/Research designee's include, but are not limited to the Deputy ACOS/R, the Administrative Officer for Research, Chair of the R&D Committee, or the HRPP Administrator.

**4. RESPONSIBILITIES:** The responsibilities of both NF/SGVHS and UF are outlined in the MOU and in the section below. In addition to those outlined below, both parties agree to cooperate fully to the extent permitted by applicable law in the event that the University or the NF/SGVHS is subject to an accreditation visit, audit, inspection, or evaluation by any authorized oversight entity including, but not limited to, OHRP, ORO, FDA, GAO, ORD, and the VA approved agency for the accreditation of the Human Research Protection Program.

**NF/SGVHS is responsible for providing information to the UF IRB-01:**

1. **New or revised human subjects protection regulations, directives or handbooks.** Upon receipt or access to copies of any new documents, the ACOS/Research and/or the ACOS/Research designee will send by e-mail to the Assistant Director of IRBs, IRB Chair or other UF designee.
2. **Unanticipated Problems Involving Risks to Subjects or Others.** Members of the NF/SGVHS research community must report unanticipated problems involving risk to subjects or others to the IRB within 5 business days after becoming aware of the problem in accordance with NF/SGVHS and IRB policies and procedures.
3. **Serious Adverse Events (SAEs).** Members of the NF/SGVHS research community must report serious adverse events to the IRB within 5 business days after discovery in accordance with NF/SGVHS and IRB policies and procedures.
4. **Serious or Continuing Noncompliance.** Members of the NF/SGVHS research community must report apparent serious or continuing noncompliance with applicable human research protection requirements (e.g., 38 CFR 16, VHA Handbook 1200.05, FDA regulations) in accordance with NF/SGVHS and IRB policies and procedures. Allegations of non-compliance, research misconduct, complaints, problems and unanticipated problems pertaining to the HRPP is the responsibility of the Medical Center Director or his/her designee, e.g., the Chief of Staff, Research Compliance Officer, ACOS for Research. Reports will be provided to the IRB verbally and in writing as written documents are provided.
5. **Results of any internal NF/SGVHS compliance audits involving human research activities** will be reported to the IRB by the Research Compliance Officer as required by VHA Handbooks and local policies and procedures as applicable. These include required informed consent audits, regulatory audits or any for-cause audit results.
6. **Terminations or suspensions of NF/SGVHS approval of research projects** will be reported to the IRB by the MCD and/or designee.
7. **The results of any regulatory actions and/or inspections of the NF/SGVHS HRPP** conducted by ORO, OHRP, FDA, GAO or other authorized entities will be provided by the MCD or designee.

8. **HRPP Accreditation** The MCD or designee will provide UF and IRB-01 with complete and timely information needed for HRPP accreditation (scheduling the application submission, on-site survey, etc) and information on the outcome of the accreditation. Notification will be provided verbally and in writing as provided by the accrediting body.
9. **Modifications to or changes in the status of the NF/SGVHS Federal Wide Assurance (FWA)** will be reported by ACOS/R or designee.
10. **Updates on VA HRPP procedures, updates on structural or personnel changes, and updates on policy and/or procedures** will be provided through training, e-mail, and summaries (as decided between the parties) by the ACOS/R or designee.

**UF IRB-01 is responsible for providing information to NF/SGVHS:**

1. **New regulations, audits, allegations of non-compliance, accreditations, inspections, misconduct pertaining to protocols, adverse events, complaints and other issues.** Information will be made available to the NF/SGVHS MCD's Office and the Research Service office through the office of the Assistant Director, UF IRBs. Information may be sent by email or other convenient and expedient methods.
2. **IRB determinations of serious or continuing noncompliance or unanticipated problems involving risk to subjects or others** must be reported in accordance with NF/SGVHS policies and procedures and VHA Handbook 1058.01 to the MCD and copied to the ACOS/R and R&D Committee.
3. **Suspensions or terminations of IRB approval** must be reported in accordance with NF/SGVHS policies and procedures and VHA Handbook 1058.01 to the MCD and copied to the ACOS/R and R&D Committee.
4. **Notification of changes in IRB membership** must be provided as required by NF/SGVHS policies and procedures and VHA Handbook 1058.03 to the ACOS/R or designee.
5. **Modifications to or changes in the status of the UF Federal Wide Assurance (FWA)** will be reported by UF to the ACOS/R or designee.
6. **Draft minutes of IRB meetings** with 3 weeks of the convened IRB meeting date are made available through the IRB database to designated NF/SGVHS HRPP personnel.
7. **Information from IRB-01's database** for the purposes of tracking ongoing VA research activity is made available to designated NF/SGVHS HRPP personnel.

**REFERENCES**

MOU between NF/SGVHS and the University of Florida concerning the use of the IRB  
VHA Handbook 1058.01 *Requirements for Reporting Research Events to Facility Oversight Committees and the Office of Research Oversight*  
NF/SGVHS SOP *Procedures for the Protection of Human Subjects in Research*  
Institutional Review Board (IRB-01) Policies and Procedures:  
<http://irb.ufl.edu/docs/irb01ppmanual.doc>  
VHA Handbook 1200.05 *Requirements for the Protection of Human Subjects in Research*  
NF/SGVHS SOP *Research Compliance Reporting Requirements*

**FOLLOW-UP RESPONSIBILITY**

This SOP will be reviewed annually, and revised as needed by the ACOS of Research.

***Initial Approval:*** February 12, 2007  
***Revised:*** September 5, 2013