1. **PURPOSE**
   
   1.1. This procedure establishes the process by which the UF IRB-01 serves as the affiliate IRB for the North Florida South Georgia VA Medical Center.

2. **POLICY**

   2.1. For all research involving the North Florida / South Georgia Veterans Health System (NF/SG VHS) NFSG VHS UF IRB-01 will defer to current versions of the VHA Handbook 1200.05 (Requirements For The Protection of Human Subjects In Research) and the VHA Handbook 1058.01 (Research Compliance Reporting Requirements) to assure that study conduct and reporting guidelines are consistent with current Veteran Health Administration regulations.

   2.2. A memorandum of understanding (MOU) will be signed between the University of Florida and the NF/SG VHS to outline the roles of the IRB-01 and NF/SG VHS relating to the UF IRB-01 serving as the affiliate IRB.

3. **PROCEDURES**

   3.1. Reporting timeframes (all days are in work days):

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Time to report to IRB</th>
<th>Time IRB must review</th>
<th>Action Taken by IRB</th>
<th>Report to VA (Time and to Whom)</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Local Research Deaths that are unanticipated and related</td>
<td>5 days of PI becoming aware</td>
<td>Review by Chair or qualified designee within 5 days of receipt</td>
<td>Must be reviewed by Full Board at next convened meeting</td>
<td>By email or telephone ORO, VA Director and ACOS/R within 2 days. Written determination within 5 days</td>
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<tr>
<td>● Local Research Deaths</td>
<td>5 days of PI becoming aware</td>
<td>Review by Chair or qualified designee within 5 days of receipt</td>
<td>Must be reviewed by Full Board at next convened meeting</td>
<td>To ORO, VA Director and ACOS/R within 5 days of determination</td>
</tr>
<tr>
<td>● Local SAEs</td>
<td>5 days of PI becoming aware</td>
<td>Review by Chair or qualified designee within 5 days of receipt</td>
<td>Must be reviewed by Full Board at next convened meeting</td>
<td>To VA Director, ACOR/R, and RCO within 5 days of determination</td>
</tr>
<tr>
<td>● Serious Problems</td>
<td>5 days of PI becoming aware</td>
<td>Review by Chair or qualified designee within 5 days of receipt</td>
<td>Must be reviewed by Full Board at next convened meeting</td>
<td>To VA Director, ACOR/R, and RCO within 5 days of determination</td>
</tr>
<tr>
<td>● Apparent Serious or Continuing Noncompliance</td>
<td>5 days of PI becoming aware</td>
<td>Review by Chair or qualified designee within 5 days of receipt</td>
<td>Must be reviewed by Full Board at next convened meeting</td>
<td>To VA Director, ACOR/R, and RCO within 5 days of determination</td>
</tr>
<tr>
<td>● Suspensions or Terminations of VA Research</td>
<td>• Reviewed by Full Board at next convened meeting not to exceed 30 days</td>
<td>• Must be reviewed by Full Board at next convened meeting</td>
<td>To VA Director, ACOR/R, and RCO within 5 days of determination</td>
<td></td>
</tr>
</tbody>
</table>
3.2. Recruitment

3.2.1. A VA facility may not use the VA Facebook page as a method of advertising non-VA studies.

3.2.2. Telephone Recruitment

3.2.2.1. Initial Contact. During the recruitment process, members of the research team must make initial contact with potential subjects in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. **NOTE:** If a research repository from a previous study is used to identify subjects, there must be an IRB approved HIPAA waiver for this activity in the new protocol.

3.2.2.2. (1) Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research.

3.2.2.3. (2) If a contractor makes the initial contact by letter, the VA investigator must sign the letter.

**NOTE:** This paragraph does not apply to situations where a Veteran calls in response to an advertisement.

3.3. International Research

3.3.1. VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S.

3.3.2. Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html). **NOTE:** The VA medical facility Director must approve participation in the proposed international research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).

3.3.3. All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO.

3.4. Photography, Video and/or Audio Recording for Research Purposes.

3.4.1. The informed consent must include the UF IRB’s “Consent to be Photographed, Video and/or Audio Recorded” addendum for research involving any photographs, video, and/or audio recordings to be taken or obtained for research purposes.

4. REFERENCES

4.1. VHA Handbook 1200.05
4.2. VHA Handbook 1058.01