

<b>SOP: QA 901</b> <b>Version No:</b> <b>Effective Date: 01/10/07</b>	<b>QA/QC PROGRAM FOR THE IRB</b>	<b>Supercedes Document Dated:</b>
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## 1. POLICY

Quality assurance (QA) and quality control (QC) of the daily operations of the IRB ensures effective support of the Board's mandate. Therefore, the QA/QC program consists of three components:

- Regular review and assessment of standard operating procedures (SOP).
- Ensuring the IRB members and IRB staff have the required education, experience and training to perform their duties appropriately.
- Ongoing assessment of IRB operations and outputs.

The first component is addressed in detail in SOP GA 101 (Policies and Procedures Maintenance). The second component is addressed in detail in SOP GA 102 (Training and Education) and GA 103 (Management of IRB Personnel). This SOP addresses the third component.

### Specific Policies

- 1.1 Ongoing assessment of IRB operations and outputs is conducted through QC monitoring and QA auditing (internal and external). QC monitoring involves periodic, real time checks of specific IRB operations, documents and records. The IRB Administrator performs these QC steps on a routine basis.
- 1.2 Internal auditing is a retrospective assessment of IRB operations through document and record review. Internal audits may be horizontal, where a particular function is assessed across several studies (e.g., minute-taking); or they may be vertical, where a particular study is audited in whole or in part (e.g., high-risk research). The OROC Office has the authority to implement an internal audit, as requested. An independent auditor performs internal auditing, as requested.
- 1.3 Sponsors or other responsible agents (e.g., contract research organizations) periodically conduct an audit of their studies reviewed by the IRB. In addition, Food and Drug Administration inspections provide additional assessment of the quality of IRB operations (refer to QA 902, Audits by Regulatory Agencies). These audits are considered external audits.
- 1.4 IRB management (IRB Chair and IRB Administrator) has the authority to implement a QA/QC program and to act on identified deficiencies by implementing corrective and preventative action plans via revisions to the Standard Operating Policies and Procedures.

## 2. SCOPE

These policies and procedures apply to all aspects of the IRB.

## 3. RESPONSIBILITY

The IRB Administrator is responsible for implementation and oversight of the QA/QC program, and for reporting identified deficiencies to the Institutional Official and the IRB Chair.

All OROC staff and IRB members are responsible for contributing to the effectiveness of the QA/QC program.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards  
 FDA's A Self-Evaluation Checklist for IRBs

**5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

**6. ATTACHMENTS**

QA 901-A Self-Evaluation Checklist for IRBs (FDA)

**7. PROCESS OVERVIEW**

The OROC personnel will review the qualifications and educational needs of the members of the IRB on a periodic basis. Generally this will be done once per year. The OROC staff shall participate on a routine basis in national and regional meeting when they come available. These include, but may not be limited to NAIM, ARENA, PRIM&R and SRA annual meetings. The policies and procedures and other administrative aspect of research shall be reviewed on a yearly basis.

**8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

<b>Who</b>	<b>Task</b>	<b>Tool</b>
<i>OROC Staff</i>	Review IRB operations at least annually.	
<i>Institutional Official</i>	Select independent auditor to conduct internal audits and provide written report of audit results.	
<i>IRB Administrator</i>	Develop and implement quality improvements as indicated by periodic assessment.	