SOP 901.003

Title	Quality Assurance Inspections
SOP Code	901.003
Effective Date	08-Oct-2019

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
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1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for monitoring, evaluating and improving the effectiveness of the human research protection enterprise.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and the QA officer, if separate from the REB Office Personnel, are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of terms.

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5.1.6 The QA Officer reports the findings to the REB Chair or designee, and to the REB and/or to the appropriate Organizational Official as required;

5.1.7 The QA Officer works with the REB Chair or designee to implement improvements (e.g. new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

5.2 Researcher Quality Assurance Inspections

5.2.1 The QA Officer will develop a schedule for routine QA inspections and implement inspections in response to Researcher requests;

5.2.2 The QA Officer will work with the REB and the organization at which the research is being conducted to determine if and when a for-cause inspection of a Researcher is warranted;

5.2.3 The REB may direct the QA Officer to conduct for-cause inspections;

5.2.4

5.2.7 The QA Officer or designee will conduct the inspection using designated/ appropriate evaluation tools;

5.2.8 When the QA Officer conducts an inspection of the Researcher, the inspection may include some or all of the following (as applicable):

An assessment of the SOPs and compliance with applicable regulations and guidance,
A review of all regulatory binders including the REB approval documentation, REB approved consent documents, signed consent documents, correspondence between the Researcher and sponsor, etc.,
Interviews with the research staff and/or the Researcher,
A review of test article accountability,
A review of specimens and associated collection processes,
A review of computer hardware and/or software associated with the research,
A review of the consent form(s) and associated processes including eligibility requirements,
A review of the completed case report forms (CRFs) or other data collection mechanisms,
A review of appropriate source material (participant medical records),and
A review of other documentation, as relevant and available;

5.2.9 The REB or the QA Officer may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;

5.2.10

5.3 Corrective Action

5.3.1 The QA Officer may recommend corrective action based on the findings;

5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;

5.3.3 The QA Officer will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4 The QA Officer will follow-up with the Researcher in a timely manner to