SOP 902.003

Title	External Inspections or Audits
SOP Code	902.003
Effective Date	08-Oct-2019

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
Albert F Clark		06JAN2022
Jennifer Couture		06JAN2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures to be followed before, during and following an external inspection or audit.

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 mn600.4BDC q12 0 D 38>BDC q0.00x nBT/F1 12 Tf1 0 0 1 213.41 507.31 Tm0 g0 G[ )]TJETC

The US Food and Drug Administration (FDA) has the authority to audit Researcher sites involved in studies conducted under a US Investigated New Drug Application (IND) or Investigational Device Exemption (IDE) to assess compliance with relevant regulations

5.2 Participating in an Inspection or Audit

5.2.1 The REB Chair or designee will meet with the inspector/auditor as scheduled.

5.3.2 The REB Chair or designee and any other designated individuals will review any findings relevant to the REB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The response to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the Researcher);

5.3.3 The REB Chair or designee and any other designated individuals will institute any correction actions as applicable and revise the REB SOPs as needed;

5.3.4