GVHealth	**TITLE:**	**Clinical Trial Standard Operating Procedure 02: Investigator Responsibilities**	
Document Type:	Procedure	**Approved by:**	CMO & EDMS
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

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Name:	Dr John Elcock
Position:	Executive Director of Medical Services and Chief Medical Officer
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1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0

1. PURPOSE:

To define Investigator responsibilities and to provide instruction associated with undertaking a clinical trial in accordance with International Council for Harmonisation of Technical requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (and requirements of the Integrated Addendum to this Guideline published by the Therapeutics Goods Administration (TGA)) (ICH GCP E6 (R2)) responsibilities for Investigators in clinical trials and teletrials.

2. SCOPE:

This standard operating procedure (SOP) is applicable to all Goulburn Valley Health (GVH) Principal Investigators (PI), Associate Investigators (AI), Clinical Trial Coordinators, and other staff delegated trial-related activities by the PI for all phases of clinical investigation of medicinal products, medical devices, therapeutic interventions and diagnostics. The responsibilities described in this SOP are additional to and are to be read in conjunction with to all relevant local GVH policies, procedures and frameworks and Investigator responsibilities defined in all other National and/or National Mutual Acceptance (NMA) SOPs. All study personnel involved in the clinical study must operate within their scope of practice.

3. PROCEDURE:

3.1. Investigator Responsibilities

3.1.1. Before the Research Project Commences the Investigator must:

- At all times, fulfil Roles and Functions as defined in the National Clinical Trials Governance Framework (NCTGF).
- Declare in writing any conflicts of interest, or payments they will receive from other parties with any relationship to the study and notify the sponsor.
- Ensure any payment received for undertaking the trial is noted in the Participant Information Sheet and Consent form (PICF).
- Demonstrate that adequate participant recruitment is possible.
- Demonstrate adequate facilities and staffing levels to ensure success of the study at the site (including any Satellite Site/s).
- Be thoroughly familiar with the appropriate use of the investigational product as described in the protocol, in the current Investigator's Brochure (IB) for medicines or Product Information for devices and in other information sources provided by the Sponsor.
- Be provided with evidence of Human Research Ethics Committee (HREC) approval, Research Governance authorisation, and the registration number of the trial once it is registered on a publicly accessible World Health Organisation compliant clinical trials registry before the first participant is recruited to the study.
- Have written evidence of Good Clinical Practice (GCP) training. All core trial staff must maintain current GCP certification.

3.1.2. During the Course and at the Completion of the Research Project the Principal Investigator must:

- At all times, fulfil Roles and Functions as defined in the National Clinical Trial Governance Framework (NCTGF).

- Perform site evaluation of any Satellite Site deemed to be potentially able to recruit participants to the research project. For each trial, infrastructure and training requirements for Satellite Sites are the same for both the Primary and Satellite Sites, and a Satellite Site should have appropriately contracted, qualified and trained Investigator(s) and delegated staff to undertake delegated trial related activities including obtaining informed consent (if required).
- For teletrials, a detailed Supervision Plan is required, in addition to a Delegation Log required by ICH GCP E6 (R2) for all Satellite Sites, regardless of experience. The conduct of the trial is detailed under the 'head agreement' (Clinical Trial Research Agreement (CTRA) between the Sponsor and the PI's Institution) and a Sub-Contract between the Primary Site and the Satellite Site Institutions (see GVH_CT-SOP-Abbreviations and Terms). Trial participants may have trial visits at both the Primary and Satellite Sites, as determined by the Protocol and Supervision Plan.
- Delegated activities to be performed by a Satellite Site are trial and Satellite Site specific. The Primary Site must consider a Satellite Site's personnel and facilities in developing a Delegation Log and Supervision Plan suitable for a trial. The proposed delegation of duties and Supervision Plan must be agreed with the team and Sponsor at the time of site selection and must be documented before the study is initiated at each Satellite Site.
- Select and initiate the Satellite Site only when a potentially eligible participant population has been identified.
- Ensure all Primary Site and Satellite Site staff are trained on and adhere to these SOPs.
- Ensure study staff, including those at Satellite Sites, are trained in the Protocol, IB, study procedures, Adverse Event (AE)/Serious Adverse Event (SAE) reporting, and that a system for safety reporting duties is in place for all study staff.
- Disseminate all approved Protocol variations and ensure adequate training of all trial personnel in the reason for and implications of the new Protocol. Ensure all personnel are suitably trained to undertake the trial and deliver the trial intervention.
- Ensure that study related documentation files and procedures are established and maintained throughout the study at both the Primary and Satellite Sites (as relevant) in accordance with GVH_CT-SOP-07 The Study Master File, including procedures for managing the security of information and trial data and a process for managing data security or privacy breaches.
- Ensure study staff, including those at Satellite Sites, have a clear understanding of the process for securely and suitably storing and ensuring accountability for the Investigational Medicinal Product (IMP).
- Sign all trial related documentation during the course of the research project in a timely manner.
- Ensure audit/inspection readiness throughout the study, have oversight of any audit or inspection of their trial at both Primary and Satellite Sites,

and ensure any deficiencies identified through audit or inspection are actively managed to ensure continuous improvement:
    - Procedures must be in place to ensure that the Primary Site is made aware of any findings that arise from a Satellite Site audit or inspection.
    - The PI should follow Sponsor requirements to ensure that appropriate Corrective and Preventative Actions (CAPA) have been implemented and findings reported to the health service organisation and HREC.
- Inform relevant staff when recruitment has been completed and mark the Study Master File (SMF) as closed to recruitment.
- Sign all trial related documentation at the end of the research project, such as documents requiring an end date, indicating the research project is completed including but not limited to: Delegation Log, Training Log, Supervision Plan, agreements, progress reports, case report forms (CRF), SAE reports, etc.
- Ensure all trial related staff and third-party providers have been informed of research project closure, results, and publication plan.
- Inform participant's primary care physician (where participant has consented to do so) of research project closure, results and, if applicable, the treatment the participant was allocated for notation in the participant's medical record.
- Ensure appropriate ongoing care of participants throughout the trial, if a participant withdraws during the trial and/or if a trial is prematurely terminated.
- Record in the participant's medical record at the institution (which may be a Satellite Site) the treatment the participant was allocated (if applicable).
- Ensure a lay summary of the trial results (usually provided by the Sponsor) is disseminated to participants in accordance with the HREC application/trial Protocol and be prepared to respond to queries from participants in relation to the trial results.
- Document any deviation from the Protocol as per Sponsor's guide.
- Notify the Sponsor, HREC, and Research Governance Officer (RGO) if they leave the Institution, in writing with either their new place of employment and contact details or who their proposed replacement is with contact details for recording on all archiving related documentation.
- Ensure study related documents are archived according to GVH_CT-SOP 13-Site_Close_Out_and_Archiving (including at any Satellite Sites as relevant).

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An **audit** is a systematic and independent examination of trial activities to determine whether a trial is conducted in accordance with applicable requirements.

An **inspection** is similar to an audit in that it is an official review of trial related activities but is conducted by a regulatory authority that has rights conferred by regulation. External audits and regulatory inspections may be scheduled periodically at sites to confirm Protocol compliance and adherence to GCP and regulatory requirements.

It is recommended that procedures/work instructions covering specific responsibilities and activities for preparation and conduct of audits and inspections be developed; noting that regulatory inspections normally require more extensive planning and input from the organisation than routinely conducted trial audits.

ABBREVIATIONS AND TERMS:
Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY ALIGNED DOCUMENTS:
GV Health Procedures:
- GVH_CT-SOP-07 The Study Master File
- GVH_CT-SOP 13-Site Close Out and Archiving

REFERENCES:
ICH GCP E6 (R2)

NCTGF and User Guide

Contributors to the document

	Name	Position	Department
Document Owner:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Document Author:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Contributor:	Dr Md Rafiqul Islam	Director of Research	Research and Ethics
Committee:	Executive Committee – Safety, Quality & Performance		
	Dr John Elcock, Chief Medical Officer/ Executive Director, Medical Services		