Procedure Name: Research Team Communications/Interactions with IRB	**Number:** SOP 4 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure for providing Institutional Review Board ("IRB") with: (1) adequate information to permit an informed decision regarding whether to approve, defer, disapprove or require modifications to a proposed clinical study; and (2) updated information regarding previously approved clinical research.

SCOPE:

This SOP applies to all research team members responsible for communicating/interacting with the GWU IRB regarding clinical research conducted at the MFA

RESPONSIBILITY:

This procedure sets forth the responsibilities for research team members involved with communicating/interacting with the IRB regarding clinical research conducted at the MFA. The Principal Investigator ("PI") remains responsible for all communications/interactions with the IRB unless the investigator has expressly delegated this duty to a research team member and the delegation is documented on a study specific *Delegation of Authority* Log.

PROCEDURES:

1. Document IRB Compliance

    a. Confirm that the IRB is duly constituted and compliant with applicable federal and district regulations.
    b. As needed, request a copy of the IRB membership roster and the IRB Federal Wide Assurance (FWA) number.

2. Communicate with IRB at Study Start-Up

    a. Complete the *IRB Submission Form* for the appropriate IRB.
    b. Include all attachments as directed.
    c. Submit the package as per the IRB.

Procedure Name: Research Team Communications/Interactions with IRB	**Number:** SOP 4 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

d. Obtain an IRB approval letter for the protocol/investigational plan and the submitted documents, as appropriate.
e. Send a copy of approval documents to sponsor, as applicable.
f. Maintain all documents/copies of documents in appropriate study file.

3. Communicate with the IRB While the Study is Ongoing

   a. Promptly notify the IRB of any changes to the protocol/investigational plan, ICF, recruitment materials, etc. and of any new information provided by the sponsor.
   b. Submit continuing review (CR) forms/information in accordance with the IRB. Send a copy of IRB re-approval letter to the sponsor, as applicable.
   c. A study will be administratively terminated if the CR information is not submitted prior to the study expiration date. If the study expires, the PI must submit a new IRB submission package for approval. During the lapse in IRB approval period, the PI is prohibited from engaging in any study related activities.
   d. Obtain documentation of IRB approval of amendments to study-related documents prior to implementation, except when needing to manage an emergent subject safety issue. Send a copy to sponsor, as applicable.
   e. In accordance with the IRB Promptly Reportable Information Policy, notify the IRB of all promptly reportable events occurring during the approval period of a study. Send a copy of the acknowledgement of receipt by the IRB to sponsor, as applicable.
   f. In accordance with the IRB Promptly Reportable Information Policy, submit to the IRB all required IND Safety Reports received from the sponsor. Send a copy of the acknowledgement of receipt by the IRB to sponsor, as applicable.
   g. Maintain all documents or copies or documents in the appropriate study files.

4. Communicate with the IRB at time of study close-out/termination

   a. At the end of a study, submit a *Study Closure/Study Closure Report* form to the IRB.
   b. If a sponsor terminates a study for any reason, notify the IRB of such termination using the *Promptly Reportable Information* submission form in accordance with the IRB Policy.

Procedure Name: Research Team Communications/Interactions with IRB	**Number:** SOP 4 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

5. The current forms should always be used for submission to the IRB.
    1. GWU IRB forms are located: OHR Website
    2. WIRB forms are located: WIRB Website
    3. Advarra Reliance Template: Attachments

Review and Revision

This procedure shall be reviewed every 2 years. This procedure may be reviewed more frequently if it does not reflect current operations.

Attachments

Advarra Reliance Agreement Template

REFERENCES:

21 CFR 56.103	Circumstances in which IRB review is required.
21 CFR 56.104	Exemptions from IRB requirement.
21 CFR 312.32	IND safety regulations and monitors.
21 CFR 312.53	Selecting investigators and monitors.
21 CFR 312.54	Emergency research under 50.24 of this chapter.
21 CFR 312.66	Assurance of IRB review.
21 CFR 812.40	General responsibilities of sponsors.
21 CFR 812.42	FDA and IRB approval.
21 CFR 812.47	Emergency research under 50.24 of this chapter.
21 CFR 812.110	Specific responsibilities of investigators.

Procedure Name: Research Team Communications/Interactions with IRB	**Number:** SOP 4 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

21 CFR 812.140	Records.
21 CFR 812.150	Reports.
MFA SOPs	SOP 3- Regulatory Binder and Study File Maintenance SOP 8- Reporting Events Guidance Document- Study Close-Out/Termination
OHRP Guidance, NOV 2010	Continuing Review Guidance
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
WIRB Guide Rev 1.7 Dec 23 2, 2021	A Guide for Researchers http://www.wirb.com/Documents/Guide%20for%20Researchers.pdf#home
GWU, OHR Investigator Guidance Documents and IRB policies/SOPs	Investigator Guidance Documents and IRB policies/SOPs

Name of Institution or Organization Providing IRB Review (*Institution/Organization A):*
Advarra, Inc. ("Advarra IRB")

Advarra IRB Registration #: IRB00000971

Advarra IRB FederalWide Assurance (FWA) #: FWA00023875

Name of Institution Relying on the Designated IRB (*Institution B*): _____

FWA #: _____

(check one):
☐ Institution B has an FWA.

☐ Institution B does not have an FWA.

The Officials signing below agree that (*Institution B):*_____ may rely on the designated IRB for review and continuing oversight of its human subjects research described below:
(*check one*)

☐ This agreement applies to all human subjects research covered by Institution B's FWA.

☐ This agreement is limited to the following specific protocol(s):

Name of Research Project: _____

Protocol Number: _____

Name of Principal Investigator: _____

Sponsor or Funding Agency: _____ Award Number, if any: _____

☐ Other (*describe*): _____

The review performed by Advarra IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. Advarra IRB will follow written procedures for reporting their findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (*Advarra IRB):*

_____ Date: _____

Print Full Name: _____ Institutional Title: _____

Signature of Signatory Official (Institution B): _____

_____ Date: _____

Print Full Name*:* Institutional Title*:*