POLICY: Release of Regulatory Inspection Documents

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-1003	Executive Director, IRB Office Northwestern University	05/01/2025	Page 1 of 1

1 PURPOSE

1.1 This policy exists to assist human research Investigators and their study teams in responding to sponsor requests for documents related to institutional and investigator Regulatory Inspections.

2 PREVIOUS VERSION

2.1 Revised from the previous version dated: 11/01/2024

3 BACKGROUND

3.1 The Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), and other regulatory agencies routinely inspect Northwestern University's Institutional Review Board (IRB) and individual Principal Investigators. The Northwestern University IRB Office recognizes that, on occasion, research sponsors or their designee Clinical Research Organization (CROs) may ask for documents related to Regulatory Inspections occurring at Northwestern University. Sponsor requests typically focus on inspections of the University's IRB or individual investigators. Documents commonly requested include the FDA Form 483, responses to the Form 483, or the Establishment Inspection Report (EIR).

4 POLICY

4.1 Northwestern University will not provide Institutional or investigator-related inspectional information to sponsors or their designees (e.g., Clinical Research Organizations).

4.2 Sponsors/designees may request information from federal agencies related to inspections through the Freedom of Information Act.

4.3 An individual investigator may choose to provide to other parties, documents related to regulatory inspection reports (e.g., Form 483, EIR, and their responses to the FDA) **only for those inspections where they were the sole investigator under inspection**, except as described below:

4.3.1 Contracts with industry sponsors frequently provide that all information provided to Northwestern University by the sponsor constitutes the sponsor's confidential, proprietary information, which may not be disclosed except to individuals who have a need to know in order to conduct the study. Therefore, prior to releasing information about regulatory inspections, the investigator should review and appropriately redact the 483 document and any other document(s) provided by the regulatory agency to ensure the released information complies with executed contracts and confidentiality agreements under which the inspected study(ies) were conducted.

4.3.1.1 Common elements for redaction include: protocol information such as study title, investigational product, IND/IDE numbers, the condition under investigation, and eligibility criteria.

4.3.1.2 The investigator is responsible for reviewing documents to ensure that no other protected information is released.