



POLICY: eIRB+ and IRB Electronic Signature Policy

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

- 1.1 This policy establishes the validity of electronic communications sent through the Northwestern University Institutional Review Board (IRB) Office's electronic IRB system (eIRB+).
- 1.2 This policy establishes the validity of electronic signatures as equivalent to hand-written signatures for means of obtaining Informed Consent

2 PREVIOUS VERSION

- 2.1 Revised from the previous version dated 6/27/2022.

3 POLICY

- 3.1 The Northwestern University Institutional Review Board (IRB) Office does not provide a signature on IRB correspondence generated through its electronic IRB system (eIRB+). Only authorized individuals disseminate correspondence via eIRB+, and all eIRB+ electronic communications are official communications from the IRB Office.
- 3.2 The Northwestern University IRB Office considers written consent that is documented through an electronic signature (scanned, digital image or typed name logically associated with the consent, executed, or adopted by a person with the intent to sign the record) as the binding equivalent of traditional hand-written signatures, subject to applicable University policies.
 - 3.2.1 When the human research study is FDA-Regulated, the platform used to capture electronic signatures for consent must be secure and compliant with part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11).