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 previous version dated 4/30/2015.

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 or is obtaining HIPAA authorization, 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).