

Memo To File

To: C-53 V1.0

Subject: CONFORM study -Use of Electronic Informed Consent (eConsent)

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This memo outlines the option for using Electronic Informed Consent (eConsent) as an alternative to traditional written/paper informed consent form (ICF).

CONFORM clinical sites are permitted by CONFORMAL to utilize an eConsent process in accordance with site institutional IRB regulatory requirements and SOPs.

The eConsent process and platform utilized must comply with:

- 21 CFR Part 11 (Electronic Records, Electronic Signatures)
- ICH E6(R2) Good Clinical Practice (GCP)
- Institutional IRB regulatory requirements and SOPs

All subject ICFs whether performed via eConsent or paper version must be filed in the site study file.