

## Memo To File

**To:** C-51 V1.0

**Subject:** CONFORM study -Verbal Informed Consent

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**Date:** 5 December 2025

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This memo outlines the process for obtaining verbal consent from patients to allow **de-identified** historical images, e.g. CT or TEE, to be provided to the sponsor of the CONFORM pivotal study for preliminary eligibility screening. Images will be provided to Conformal Medical through the study EDC platform.

Verbal consent applies **ONLY** to the collection of historical imaging data, e.g. CT or TEE, for initial eligibility screening.

This process has been validated with WCG Institutional Review Board (IRB) and is compliant with FDAs guidance document-FDA Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, August 2023

Document the verbal consent in each subject's medical chart via a progress note.

Example of a progress note:

The following is an example of a note to be included in a subject's medical chart by the Research Assistant documenting the consent process:

*[PERSONNEL NAME] spoke with XXX [subject name] by phone on [Date] at [Time] regarding the Conformal Pivotal Study (CONFORM). [PERSONNEL NAME] discussed that verbal consent was being requested solely to provide de-identified historical imaging (CT or TEE) to the sponsor for preliminary eligibility review. The subject appeared to understand and provided consent on [Date] at [Time].*

Important Notes:

- Verbal consent may only be used for the limited purpose of historical imaging data transfer to the Sponsor.
- Site staff must ensure this process complies with all local IRB policies (as applicable) and site institutional SOPs.
- Documentation of verbal consent is required to be included in the subject's record.
  - IRB approved informed consent must be completed in-person or electronically before any study-related procedures can occur.