Informed consent forms (ICFs) and practices vary widely across CTSA institutions. A recent survey identifies both Collecting and Disseminating Best Practices and Template Broad Consent Documents as priorities among CTSAs [1]. Our CTSA hub has developed the Informed Consent Navigator, a novel tool that addresses these priorities and advances health equity.

The navigator guides researchers through creating an ICF by answering questions about their study. The navigator uses those responses to produce a clear and compliant ICF, displaying a live preview of the final form as content is added. Versions and edits are tracked to facilitate shared editing by the research team and communication with the institutional review board.

The output is a printable ICF document formatted in accordance with plain language templates developed by the UAMS Center for Health Literacy [2,3]. Richly structured representations of the form’s contents in the navigator’s database have been aligned with terms from the Informed Consent Ontology (ICO) [4] to support future use of generated ICFs to collect, integrate, and query consent data.

This tool addresses both ends of the consent equation by helping to guide the creation of study specific language, while ensuring compliance with regulatory requirements, and producing an ICF that is easy to understand and read.

The navigator application is configurable and includes ninety questions managed by survey logic that dynamically adjusts to include only those questions pertinent to each study. For example, the section on research involving biospecimens is automatically skipped for a researcher who indicates early in the survey that their study does not involve collection of biospecimens.

References