PROFESSIONAL Services

Informed Consent Form Writing

Capabilities and Services Menu

Obtaining the effective informed consent of individuals participating in a clinical trial is paramount to ethical research. Translating information from a protocol document into an understandable informed consent form (ICF), compliant with federal regulations applicable to clinical trials, is critical. The ICF will inform potential research participants of important aspects of the trial, relevant to their decision to participate, which ultimately impacts site enrollment. Oftentimes, potential participants struggle to understand the ICF, complicating their decision on whether or not they want to participate. Ensure your clinical trial documentation is compliant and easily understandable by utilizing Advarra Services for ICF writing, making your study activation process more efficient.

Resources and Expertise

Utilizing relevant study-related documentation, Advarra professional services applies federal regulations, ethical standards/guidelines, and Advarra IRB best practices to develop a comprehensive ICF template(s). Institutions can further customize these templates to reflect each site's individual requirements, as applicable. Appropriate firewalls have been established between professional services and the IRB to ensure independent and unbiased IRB reviews of any document created under this service. Requesting ICF development prior to or as part of the IRB submission process minimizes IRB-requested changes, streamlining study activation timelines, and allowing your staff to focus on other critical research-related activities.

SERVICES MENU

1. Translate the protocol document into necessary consent templates meeting federal regulations, ethical standards, and Advarra IRB best practices.
2. Generate parental permission, minor assent, screening, or sub-study consent documents as necessary.
3. Store and apply customer-specific ICF language and information to streamline
4. Access to Advarra domain experts assisting with accurate and understandable risk section creation.