University of Nebraska Medical Center

IRB Newsletter

Consent Form Readability

Providing easy-to-understand health information is a fundamental part of patient-centered research and an important ethical, compliance, and safety concern. Recent changes to the Federal Regulations governing human subject research (the “Common Rule”) have included a focus on improving the readability of consent forms and include regulations requiring understandable language, and organization and presentation of information that facilitates understanding.

In response to these requirements, beginning later this year, consent forms must satisfy minimum readability standards.

Though we expect to extend the standard to other sections of the consent, initially only the readability of the invitation and summary section will be assessed.

The summary section must have Flesch Kincaid reading level ≤8 and Flesch Reading Ease ≥ 60. Readability may be scored within the RSS application by
clicking on the “Readability” button. In addition, RSS will provide an area where the writer can work with consent form language and receive immediate feedback on readability, and then cut-and-paste that language in the summary.

Consent forms not meeting these minimum readability measures will be returned to the investigator for modification.

To assist investigators and their staff in developing necessary skills to write effective consent forms, the PI and the Lead Coordinator, or person responsible for writing the consent form, must complete online training through PRISM (Program for Readability in Science and Medicine, https://prism.kpwashingtonresearch.org). The hour-long training covers health literacy and readability, plain language strategies and examples, and interactive editing examples and exercises.

RSS Feature Spotlight: The Message Portal

The Message portal is a new update feature to keep communication about a study transparent and easy to find. Remember to communicate about your study with IRB administrators through the portal.

IRB Process Update: Institutional Approval

In an effort to better understand IRB approval timelines, we have moved to separate IRB from institutional requirements. You will be notified when IRB requirements are complete and provided a list of institutional requirements to be completed. The research cannot begin until you are notified of final release by the Office of Regulatory Affairs (ORA).

FAQs: Single IRB

What is Single IRB?

The single IRB (sIRB) policy is an NIH policy that applies to most grants and contracts submitted to NIH on or after January 25, 2018, especially those that
involve multi-site non-exempt human subjects research. The policy requires the use of a single IRB to accomplish IRB review and approval for all domestic sites.

**What are the options for awardees to comply with the single IRB policy?**

An NIH award recipient has several possible options for complying with the NIH single IRB policy including having the IRB at one of the participating sites agree to serve as the single IRB, using an independent IRB, including the IRB of a non-participating site, or using the IRB as required in the Funding Opportunity Announcement (FOA) or Request for Proposal (RFP) (for example, certain cancer clinical trials funded by the National Cancer Institute (NCI) are required to use the NCI Central IRB (CIRB)).

**How do I request UNMC serve as the Single IRB for my study?**

UNMC IRB provides Reliance Consultation services to help investigators initiate a SIRB model for their multisite studies. This meeting is the first step in setting up a SIRB process at the UNMC. Even if you aren't sure about your funding or only want to get a better feel for what the UNMC IRB can offer, this meeting can get you started.

Once you submit a reliance request (available on the UNMC IRB website) You will be contacted to set up a meeting by phone or in-person. Note that this meeting should include at least one investigator on the study, as well as any key study personnel (coordinating center staff) involved in the regulatory process.

This meeting will help determine if UNMC IRB is a good fit for the study and provide you with guidance on your roles and responsibilities when using the SIRB model.

For more information on the background, policy, or FAQs, visit [https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5167](https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5167). To request UNMC serve as the sIRB visit [https://www.unmc.edu/irb/reliance/sirb.html](https://www.unmc.edu/irb/reliance/sirb.html)