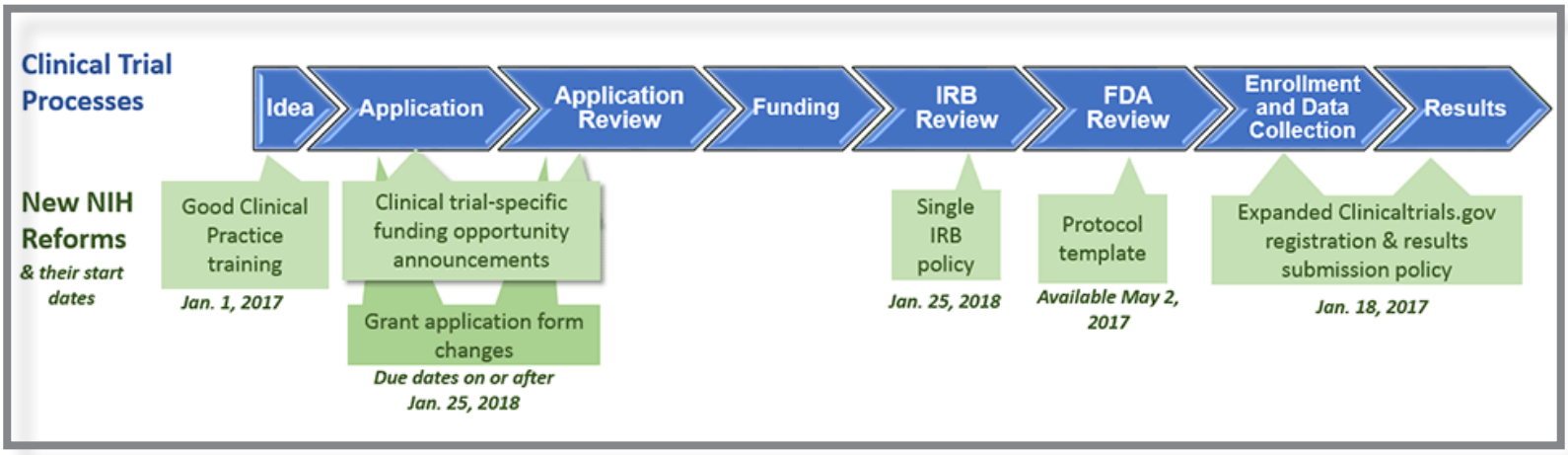
Clinical Trial Requirements Got You Down?



Our Clinical Research Support Program (CRSP) team can help!

Study Design & Implementation: Is your protocol feasible? Will your outcomes match your aims? Our CRSP team works closely with CCTS Biostatistics, Epidemiology, and Research Design (BERD) experts to ensure your study's **methodology** is rigorous, reproducible, and will meet all federal clinical trial requirements. BERD also offers expert guidance on **clinical data management.** CRSP can also connect you to the CCTS Informatics team to test hypotheses and identify potential cohorts via our i2b2 tool to ensure your meet your **recruitment** targets.

Study Registration & Reporting: Does your human subjects study qualify as a clinical trial according to the NIH definition? For this and other questions about registering and/or reporting the results from your study or trial in the **ClinicalTrials.gov Protocol Registration and Results System** (PRS) or for help with the new **FORMS-E**, CRSP offers one-on-one technical consults.

A Rapidly Changing Clinical Trial Landscape:

January 2017—all clinical trial grant applications and contract proposals, whether funded in whole or in part by NIH and that meet the definition of an NIH clinical trial, **must be registered within 21 days.** Further, registration must take place prior to patient enrollment as a condition for consideration of publication by many journals. All NH-funded clinical trials must also enter their results in ClinicalTrials.gov **within one year of trial completion.**

May 2017—**multisite studies are required to use a single IRB of record** for the review of non-exempt human subjects research studies.

January 2018—**NIH applicants must use the new FORMS-E**, which includes up to 12 new attachments.

July 2018—the **International Committee of Medical Journal Editors (ICMJE) requires a data sharing statement for all manuscripts submitted** to one of the 1,000+ ICMJE journals.

January 1, 2019—**data sharing plans will be required by NIH** as part of the ClinicalTrials.gov registration process.

NIH National Institutes of Health

ICMJE International Committee of Medical Journal Editors

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