Reducing Burden: The Value of a Research Consent Writer Team

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Background

Each year, thousands of patients participate in clinical trials at MD Anderson Cancer Center.

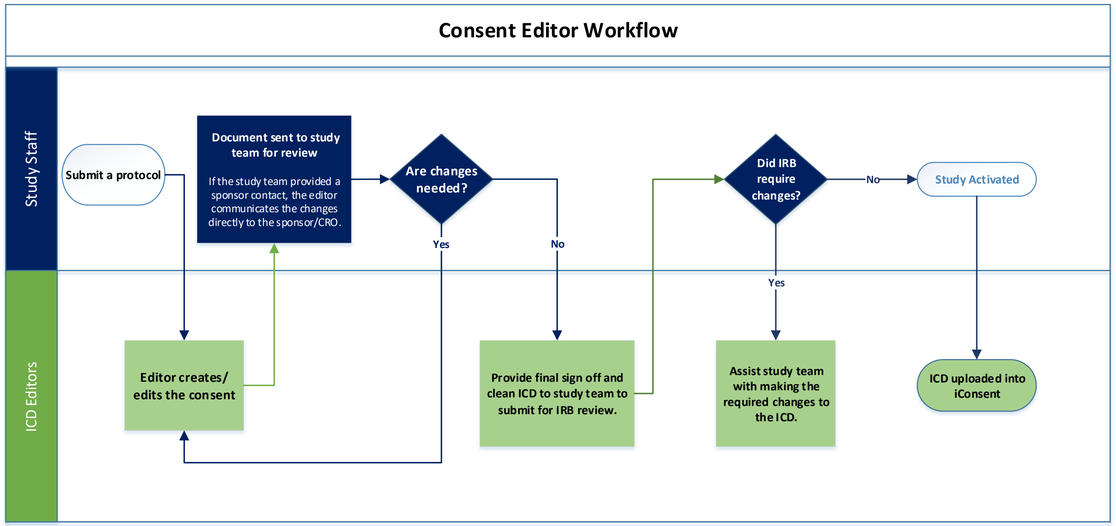
In 2022 alone, 10,074 patients participated in 1,680 research trials.

Each of these trials requires principal investigators and research teams to present the potential subjects with an informed consent document that is comprehensive, meets the required elements of Federal Regulations and Good Clinical Practice Guidelines, and is understandable to the potential trial subjects, parents, and/or legally authorized representatives.

Creating and modifying informed consent documents accurately and adequately can be a regulatory burden to research staff, industry sponsors, and reviewers.

Clinical Trial Participation

Based on FY 2022 Data



Solutions and Methods

MD Anderson has developed a team of Clinical Research Consent Writers with goals to:

- Enhance the services offered by a central clinical research office through expertise in research regulations and health literacy.
- Remove burden from research departments by preparing new consent documents and modifying existing ones for submission to the Institutional Review Board (IRB).
- Use plain language to make the clinical research process more coherent and accessible to patients and potential subjects.
- Facilitate translations of consent documents when necessary.
- Work with Information Technology partners to code and upload electronic consents.

The consent writing team has created template documents and checklists to guide consent drafting. The team follows a multi-step standard operating procedure to ensure consents contain information that is accurate, adequate, and appropriate.

For investigator-initiated trials, the consent writing team begins the process by drafting a consent form utilizing the protocol and collaborating with the research team.

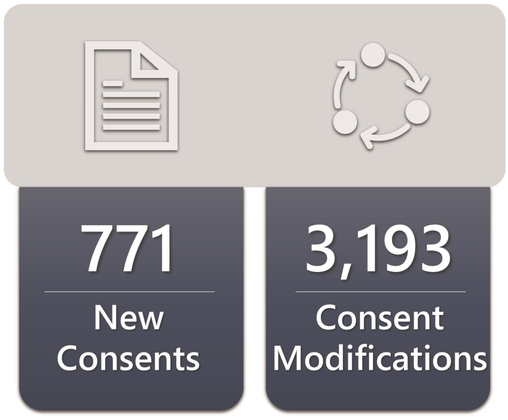
For industry sponsored trials, the consent writers use the consent document provided by sponsors and make edits to meet institutional requirements while negotiating language with appropriate stakeholders and completing a quality assurance process. This allows the team to ensure the submitted consent meets federal standards and is comprehensible to potential trial participants.

Outcome

In Fiscal Year 2022, the consent team assisted the research community by developing 771 new consent documents and providing reviews of 3,193 consent modifications.

Through this process, the burden on the central office and on researchers was lessened by having a dedicated team to address the consent requirements. Furthermore, potential participant understanding is improved through a consent document that is more coherent and comprehensible. In addition, feedback received from study teams regarding the consent services has been positive.

Consent Assistance



Based on FY 2022 Data

Conclusions

It has been challenging and time-consuming to navigate the extent of modifications and communication regarding requested modifications between sponsors, study teams, and IRBs in terms of the content of the informed consent document. This back and forth communication process can lead to delays in initial approval and continuing review.

Future directions include working with research teams to identify minimum standards that must be in place within protocols to begin drafting an initial consent, collaborating with IRBs to identify common consent document changes needed, and working jointly with sponsors to identify common trends that delay consent reviews.