

## **Key Concerns with the Proposed Rule for Clinical Trials Registration and Results Submission**

### **Broad Concerns**

- The proposed regulations extend beyond statutory requirements, introducing inefficiencies without adding value for users of ClinicalTrials.gov.
- The timeframes for reporting are overly stringent and inconsistent with the logistics and realities of research conducted at academic institutions, making it difficult to fully comply in a timely manner. Greater frequency of reporting is costly to institutions and the public, with little tangible benefit to users.
- The greater the volume of data requested, the less time scientists can dedicate to conducting research. Additional requirements are at the expense of research activity and progress.

### **Timelines for Reporting**

#### Timeline for Results Reporting

The drafters of the Food and Drug Administration Amendments Act (FDAAA) understood that results reporting might not be realistic within 12 months and specifically gave the FDA authority to increase the results reporting time-frame from 12 months to 18 months. The Notice of Proposed Rulemaking, issued in November of 2014, did not propose to exercise this option.

Providing the extra 6 months legislators allowed for would recognize the complexity of university-based research and improve compliance without compromising scientific advances and public understanding.

**Recommendation:** The FDAA specifically allows for the regulations to increase the time period for submitting results information to 18 months. We strongly recommend that §11.44 (a) be modified to allow 18 (rather than 12) months after the primary completion date to report results.

#### Reporting Windows for Updates and Corrections

Many of the proposed data element timelines require updates within 15-30 calendar days per §11.64(b). However, the statute does not require updates of less than 30 days for any fields. Shorter time-frames do not consider the time necessary to communicate pertinent data and update the study record, the widening scope of data elements that will be required, or the complexity of some data. Further, a mixture of 30-day and 15-day windows increases the complexity of understanding and complying with reporting and updating requirements with little corresponding benefit to the public. We would also like to note that the NPRM added several categories of 30 day update requirements for information that may not be available to academic researchers.

The ClinicalTrials.gov Protocol Registration and Results System also currently requires updates based on shorter timeframes than required by statute. These requirements are significantly more stringent than the requirements for updating the IRB and do not correspond with the current regulations for annual updates for continuing review and approval of human research studies.

**Recommendation:** We request streamlining to two sets of timeframes: 30 day reporting timeframes should remain restricted to correcting errors in the record and changes to overall recruitment status and completion, and all other necessary updates restricted to 12 month reporting requirements. Shorter windows do not provide sufficient increased benefit to information seekers relative to the increased compliance burden and risk. These timeframes (i.e., 30 days and 12 months) are sanctioned in statute and can be more readily implemented by institutions and researchers in an efficient and compliant manner particularly when they harmonize with other existing requirements, including updates to the IRB.

### **Scope of Reporting**

#### Expanding the Scope

If the final regulation were to further expand registration or results reporting requirements (e.g., reporting for unapproved products) and add requirements for lay or technical summaries, which is contemplated in the preamble to the regulations but not articulated in the NPRM, the added regulatory effort would be disproportionate to the public benefit. As it currently stands, results reporting often takes three or more submissions to be accepted by the clinicaltrials.gov quality assurance review process. Requirements of this nature would result in additional, lengthy, corrections and further add to researcher's time spent administering to reporting requirements. Already Federal estimates of results reporting work have increased from 25 hours, to 40 hours, to the present estimate of 50 hours. That is more than a work week, and researchers may have more than one clinical trial underway in a given period. This represents a significant challenge for researchers with many competing demands for their time, and a loss of time devoted to clinical research. Additional requirements should dramatically advance public knowledge to justify their inclusion.

**Recommendation:** The regulations should not exercise the option to include results reporting for unapproved products and should not add additional requirements to upload protocols or create lay summaries or detailed scientific summaries.

### **Regulatory Burden**

Members of Congress have consistently expressed concern with the amount of time and funding that is spent on administrative processes required for the conduct of federally funded research. In just the last two months, the [National Academies](#) and the [Government Accountability Office](#) have released reports, at the request of Congress, detailing federal regulatory burden and

providing recommendations for reducing that burden. In May of 2014, the [National Science Board](#) published a similar report which resulted in a congressional hearing on this topic.

Members of Congress have made clear their desire to balance the need for oversight and transparency with facilitating research. Expanding the window for results and other reporting is consistent with statute and the goal of streamlining administrative requirements for federally funded research.

While for the purpose of this meeting we have focused on the proposed regulations, consistent with OIRA's role, we do wish to note that further expansion of scope introduced by the NIH policy (e.g., the inclusion of social and behavioral research and exploratory studies, or studies that could not be completed due to poor enrollment, and requirements to use clinicaltrials.gov's extensive and rigid reporting formats even for studies that have published with peer review) and some of the challenging interface issues of the clinicaltrials.gov system add successive layers of inefficiency. These inefficiencies result in significant increases in the amount of time researchers must dedicate to complying with this rule without meaningful benefit to the public.

### **Conclusions**

In summary, the following changes to the proposed regulation would facilitate timely reporting, and advance data sharing and public understanding:

- An 18 month results reporting time-frame as allowed by law;
- 30 day reporting timeframes should remain restricted to correcting errors in the record and changes to overall recruitment status and completion, and all other necessary updates restricted to 12 month reporting requirements as allowed by law;
- The final regulation should not further expand registration or results reporting requirements as contemplated in the preamble to the regulations, but not articulated in the NPRM.
- Maintain the current distinction between results reporting which is required for trials of FDA-approved drugs and devices but is not required for drugs and devices that are not FDA approved (for any purpose or population), as allowed by law.

These suggestions would greatly facilitate compliance and more efficiently focus government and academic effort on meaningful outcomes.