If you are an investigator conducting human research studies, you may need to comply with ClinicalTrials.gov regulations. The responsibility for compliance with the FDAAA and NIH requirements for ClinicalTrials.gov rests with the entity or individual determined to be the Responsible Party. The Responsible Party is considered to be the study sponsor (IND holder, initiator of the study, or the grantee for NIH-funded trials). For investigator-initiated trials, the principal investigator is considered to be the sponsor, and thus the Responsible Party for ClinicalTrials.gov requirements. For industry-sponsored trials, the sponsor is considered the Responsible Party, and will ensure compliance to the ClinicalTrials.gov regulations.

This is part 1 of a three-part informative series on the new rules and regulations surrounding ClinicalTrials.gov.

ClinicalTrials.gov is a publically-available database that was developed to make information about clinical trials widely available to the public and scientific community. There are two distinct stages of submitting information into the ClinicalTrials.gov database:

1) Initial registration of study design and protocol information
2) Results reporting of subject participation, final outcome measures and safety events.

The type of clinical trial, funding source, and publication goals all play a factor in the scope or extent to which registration and results reporting are required in the ClinicalTrials.gov database, as follows:

- The Final Rule to the Food and Drug Administration Amendments Act (FDAAA) was recently published, which solidified the ClinicalTrials.gov requirements for studies of FDA-regulated products.
- A National Institutes of Health (NIH) policy was published which requires ClinicalTrials.gov registration and results reporting for all fully-funded and partially-funded NIH clinical trials, regardless of study phase or intervention type.
- The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical trials in a public database (such as ClinicalTrials.gov) as a prerequisite for publication in any of their associated medical journals.

The table below provides a summary for these various requirements.

<table>
<thead>
<tr>
<th></th>
<th>FDAAA Final Rule</th>
<th>NIH Policy</th>
<th>ICMJE Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>All except Phase 1 Studies</td>
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<td>All Phase Studies</td>
</tr>
<tr>
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<tr>
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<tr>
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<td>Registration only</td>
</tr>
<tr>
<td>Enforcement</td>
<td>Criminal Proceedings and Civil Penalties up to $10,000/day; Loss of HHS Funding</td>
<td>Loss of NIH Funding</td>
<td>Refusal to Publish</td>
</tr>
</tbody>
</table>
The new FDAAA Final Rule and the NIH Policy take effect **January 18, 2017**. Clinical trials initiated after this date will be expected to comply with these new FDA and NIH requirements. Currently ongoing studies with expected completion after January 18, 2017 will follow the original requirements for registration, but will be expected to comply with the new requirements for results reporting.

**Questions?** Scott Low is tasked with assisting Internal Medicine investigators with compliance to the regulations for ClinicalTrials.gov. If you have any questions, or would like assistance in the registration, information updates, or results reporting in the ClinicalTrials.gov database, please contact:

**Scott J. Low, MBA, CCRP**
Clinical Research Compliance Manager
University of Utah, Department of Internal Medicine
801-585-1380
scott.low@hsc.utah.edu

Stay tuned for Parts 2 and 3 of this ClinicalTrials.gov Update and Summary, which will cover the initial study registration and results reporting in more detail.

**Research Reproducibility Conference, November 14-15**

The reproducibility of research is critical to the advancement of science. Utah’s first **Research Reproducibility Conference** will bring together researchers, students, and administrators to start a frank discussion on open science, open data, transparency, good research practices and how institutions can help support research reproducibility. [Click Here for the Conference Schedule.](#)

The conference will be held Monday November, 14 at the S. J. Quinney College of Law. The conference is free for participants, but **registration is required by October 31**. [Click Here to Register](#).

In addition, the **Center for Open Science** will be hosting a Post-Conference Workshop on Tuesday, November 15. The workshop will include training on open and reproducible tools, methodologies, and workflows ([Click here for more information](#)). The workshop is free, and requires separate registration: [Click Here to Register](#).

**Upcoming NIH Video Briefings on Fellowship and R01 Grant Peer Review Process**

The NIH Center for Scientific Review (CSR) will host online video briefings for NIH grant applicants, their mentors, and reviewers. The first two briefings (November 2 and December 1) will provide fellowship and R01 grant applicants key information to navigate the NIH peer review process. The third briefing (December 2) will focus on proposing and reviewing basic research.

The three opportunities are:

**Nov. 2, 2016 - 8 Ways to Successfully Navigate NIH Peer Review and Get a Fellowship Grant**
This briefing will cover the key things applicants need to know about the submission and review of their fellowship applications.
Dec. 1, 2016 - 8 Ways to Successfully Navigate NIH Peer Review and Get an R01 Grant
This briefing will cover the key things applicants need to know about the submission and review of their R01 applications.

Dec. 2, 2016 - NIH Peer Review Briefing for Basic Research Applicants and Reviewers
The NIH Director and other NIH/CSR official will reaffirm NIH's commitment to basic research and help applicants and reviewers do their part in proposing and reviewing basic research.

Registration for the briefings is available on the CSR site.

NIH Announces Electronic Submission for Prior Approval Requests for Direct Costs > $500K

Are you planning to submit a NIH grant with direct costs of $500K or more for a single budget year? If so, prior approval is needed. NIH has developed a way to provide you with an option to electronically submit these prior approval requests through eRA Commons. Effective Sept. 15, this option is a reality.

Here is how it works:

**The Invite to Initiate a $500K Request**
The PI will reach out via email or phone to the Program Official at the Institute/Center (IC) with whom they have been working concerning the $500K request, per current practice. The PO can then choose to invite the PI to initiate the prior approval request through eRA Commons. The initiation of the request will trigger an email notification to the PI and to the email address listed for receiving the Notice of Award (NoA) on the Institutional Profile screen.

**PI Action**
Upon being notified, the PI will go into eRA Commons and go to the Prior Approval tab along the top navigation menu. The PI will find two options and should click *List my Requests*. The PI will find the $500K Request under the column Request Type, with a status of “In Progress PI,” and should click the “Modify” link.

The Prior Approval Request $500K screen will open. The screen is pretty straightforward with a few required fields, such as Project Title, FOA number, and Anticipated Submission Date. The PI will need to provide a short justification (just 500 characters) for the request, with up to 10 supporting documents allowed. Depending on the business processes of the institution, the PI can route the request to the SO for review, or submit directly to NIH.

**SO Action**
Since the notice to submit the prior approval request is sent to the NoA address as well, the SO should login to eRA Commons and go to the Prior Approval tab. SOs should use the *Search for Requests* button and select the $500K Request under the Request Type drop down. The SO has the ability to view the request, or if they choose, recall it, thus giving them the ability to modify it and submit it.

**Next Steps**
If the request is approved by the Program Official at the IC, the PI will receive an email from the Program Official. When the error free application is received by NIH, this application will be matched with the $500k approval from the IC and the application will move through the normal process.
For the moment, this is an option for the submission of $500K requests. However, as we continue to move from all paper processes to a formal electronic environment, this option may become a requirement as we seek solutions that provide accountability, transparency and improved reporting capabilities.

For more information, please see Guide Notice NOT-OD-17-005.

Meet your Research Administration Team - Staff Spotlight

Sarah Elliott  
Research Manager & Career Development Specialist  
sarah.elliott@hsc.utah.edu  
801-581-3694  

Bio: Sarah grew up in Indiana, and lived in Steamboat Springs, CO for approximately 9 years before moving to Utah. Sarah has been with the University of Utah for 3 years and has a background in Business Administration. In her spare time, Sarah runs Spartan Races and works heavily with non-profits.

Responsibilities: Sarah primarily focuses on grant submissions, especially with new/early faculty. She also oversees Clinical Trial contract/budget negotiations and billing and manages Intergovernmental Personnel Agreements (IPAs). Sarah also assists with post-award grant management for Gastroenterology, Genetic Epidemiology, Infectious Disease and Oncology.

Contact Sarah for questions about: Any of the above! In particular, if you are new or early career faculty members with questions on processes, submissions, or any general questions related to research, do not hesitate to contact Sarah.

Sarah’s tip for researchers: Contact your research administrator as early as possible in the grant submission process!

IM Research Administration Contacts

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<tr>
<th>Name</th>
<th>Title</th>
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<th>Phone</th>
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