Research and Compliance Meeting (RACM): January 10, 2018

Presented by Office of Research and Innovation
Agenda Items

• SF424 FORMS-E
• No really…What’s a “Clinical Trial?”
• VCU’s position on NIH-observing vs. non-NIH observing sponsors
• CT.gov reporting (NIH and FDA applicable, ability to publish)
• ICMJE Definition and Interpretation
• Handy “Is it a Clinical Trial” Decision Tree
• Choosing the right Program Announcement (PA) for an NIH Clinical Trial application
• Single IRB (“sIRB”) and IRB Reliance
• Certificates of Confidentiality
Federal-wide Forms

• Standard Forms 424 ("SF424") form families are the government-wide standard data sets and forms for grant application packages. They are used by all federal agencies and applicants for submissions to Grants.gov. The Office of Management and Budget (OMB) approves all forms in use.

• Periodically there are updates to the forms which result in a new version. We colloquially refer to “SF424 FORMS-A”, “SF424 FORMS-D, etc. and on January 25, 2018, Grants.gov (and therefore all of us) are transitioning to “SF424 FORMS-E”
Federal-wide Forms

- VCU’s RAMS-SPOT is both a database of information but also allows VCU “system-to-system” (“S2S”) capability for most of our federal grant applications. RAMS-SPOT submits to Grants.gov
- Having S2S capability saves us time because a lot of information is pre-populated into the forms and validated.
- Currently there are both SF424 FORMS-D and SF424 FORMS-E applications available for selection in RAMS-SPOT. Choose which form set you need based on the application’s due date.
Federal-wide Forms

• Due dates on or before January 24, 2018 should utilize SF424 FORMS-D in RAMS-SPOT, with the following exceptions clarified in NOT-OD-17-062:

These FOAs will expire on February 25, 2018 giving applicants one month to complete their initiated FORMS-D applications.

<table>
<thead>
<tr>
<th>FOA#</th>
<th>FOA Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA-16-285</td>
<td>Change of Grantee Organization (Type 7 Parent)</td>
<td></td>
</tr>
<tr>
<td>PA-16-286</td>
<td>Successor-in-Interest (Type 6 Parent)</td>
<td></td>
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<tr>
<td>PA-16-287</td>
<td>Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp)</td>
<td></td>
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<tr>
<td>PA-16-288</td>
<td>Research Supplements to Promote Diversity in Health-Related Research (Admin Supp)</td>
<td></td>
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<tr>
<td>PA-16-289</td>
<td>Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp)</td>
<td></td>
</tr>
</tbody>
</table>

• Due dates on or after January 25, 2018 should utilize SF424 FORMS-E in RAMS-SPOT.
FORMS-D vs. FORMS-E: Where to look in RAMS-SPOT

Funding Proposal Smart form:

Federal Grant Information

1. Enter an opportunity ID below, then click Find. From the list returned, select an opportunity, then click Continue.

<table>
<thead>
<tr>
<th>Opportunity ID (PA or RFA Number):</th>
<th>Find...</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFDA Number:</td>
<td></td>
</tr>
<tr>
<td>Competition ID:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunity Id</th>
<th>Opportunity Title</th>
<th>Opening Date</th>
<th>Closing Date</th>
<th>CFDA Number</th>
<th>Competition ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA-HL-17-015</td>
<td>Bold New Bioengineering Methods and Approaches for Heart, Lung, Blood and Sleep Disorders and Diseases (R21)</td>
<td>11/14/2017</td>
<td>9/7/2018</td>
<td></td>
<td>FORMS-D</td>
</tr>
<tr>
<td>RFA-HL-17-015</td>
<td>Bold New Bioengineering Methods and Approaches for Heart, Lung, Blood and Sleep Disorders and Diseases (R21)</td>
<td>6/13/2016</td>
<td>1/24/2018</td>
<td></td>
<td>FORMS-E</td>
</tr>
</tbody>
</table>

- The form set is displayed as the “Competition ID”
- The Opportunity ID, aka Program Announcement selection drives which FORMS package is created
- You can update your Opportunity ID selection in RAMS-SPOT up until you execute the “Create-Update SF424” activity
- If you realize you have selected the wrong opportunity after you have executed the “Create-Update SF424”, you must create a new FP
FORMS-E: What’s different for NIH?

- The standard forms must be utilized by the federal agencies. There can also be agency-specific forms used in combination with the standard forms. (Example: both SF424 Face Page and PHS 398 forms are part of an NIH application.)

NIH has issued numerous notices over the last year announcing the changes about to take effect.
- **NOT-OD-18-009**: “FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2018”

  Focus of changes:
  - Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
  - Expansion and use of discrete form fields for clinical trial information to
    - provide the level of information needed for peer review;
    - lead applicants through clinical trial information collection requirements;
    - present key information to reviewers and agency staff in a consistent format; and
    - align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
  - Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms
FORMS-E: What’s different for NIH?

NIH “High Level Summary of Form Changes in FORMS-E Application Packages”

• These forms “Updated OMB Expiration Date to 03/31/2020”: PHS 398 Career Development Award Supplemental Form, Cover Page Supplement, Modular Budget, Research Plan, Research Training Program Plan, Training Budget, Training Subaward Budget Attachment, Additional Indirect Costs, Assignment Request Form, Fellowship Supplemental Form

• PHS Human Subjects and Clinical Trials Information Form (new)

• PHS Inclusion Enrollment Report (decommissioned)
Purpose of Human Subjects Reforms & Policy Changes

In 2016, NIH announced initiatives targeted to enhance and improve:

**Efficiency**
Enhance the efficiency of how research studies involving human participants are conducted

**Transparency**
Promote a culture of transparency in research in order to advance public health

**Accountability**
Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship

**Timely Reporting**
Decrease the time it takes investigators to publicly report study results

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New Application Packages (FORMS-E)

Due Dates on or after January 25, 2018, FORMS-E Application Packages is **REQUIRED** (including new Human Subjects and Clinical Trials form)

✓ **Consolidates** human subjects, inclusion enrollment, and clinical trial information into one form
✓ Collects information at the **study-level**
✓ Uses **discrete form fields** to capture clinical trial information and provide the level of detail needed for peer review
✓ Presents key information to reviewers and staff in a **consistent format**
✓ **Aligns** with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov

Resources for the Human Subjects & Clinical Trials Information Form

✓ Explore the new Annotated Form Set for FORMS-E
✓ Take a video tour of the new Human Subjects and Clinical Trial Information form

https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvkBJeHcb4yai7_fDnFZFPEmQK&index=1
Forms-E & Changes to the Appendix Policy

**NOT-OD-17-098**: Updated Appendix Policy Eliminates Clinical Trial-Related Materials for NIH/AHRQ/NIOSH Applications Submitted to Due Dates on or after January 25, 2018

Since the new Human Subjects and Clinical Trials Information form collects key elements from the protocol, the optional protocol submission will be removed from the Appendix Policy.

No really…What’s a “Clinical Trial?”
What is a Clinical Trial?

Key factors for making a determination

• Use NIH definition to answer the 4 questions
• Consider how your study is funded – specific requirements for NIH
• Where will results be published? ICMJE journals?
• Industry vs. NIH assessment (health related)
## NIH Clinical Trial Definition

A research study¹ in which one or more human subjects² are prospectively assigned³ to one or more interventions⁴ (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.⁵

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¹See Common Rule definition of research at 45 CFR 46.102(d).

²See Common Rule definition of human subject at 45 CFR 46.102(f).

³The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

⁴An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

⁵Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

NIH Decision Tree

Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?

- YES
- NO

Are participants prospectively assigned to an intervention?

- YES
- NO

Is the study designed to evaluate the effect of the intervention on the participants?

- YES
- NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?

- YES
- NO

This study is a clinical trial.

The study is NOT a clinical trial.
NIH Definition of a Clinical Trial

https://grants.nih.gov/policy/clinical-trials/definition.htm

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if...

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention
NIH’s Expanded Interpretation of “Health-Related”

• “all NIH-funded research investigating biomedical or behavioral outcomes is considered to be health-related. Hence, if the outcome is biomedical or behavioral, the study may be a clinical trial (if the answers to the other three questions are “yes”). Many clinical trials are “mechanistic” or “exploratory” falling outside the realm of efficacy or effectiveness trials.”

https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5244
Wait... What’s a “Mechanistic Clinical Trial”? 

**Definition:** a study designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention

- “health-related” encompasses more than clinical endpoints
- additional clarification can be found through Notices, Parent Announcements, and FOAs
- look at individual FOA to see if mechanistic studies allowed/required

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Mechanistic Clinical Trials

Examples of mechanistic clinical trials include but are not limited to, studies that:

• use a manipulation (physiological or behavioral) to answer basic science questions about normal functions.
• use an experimental manipulation in order to understand normal functioning or the pathophysiology of a disease or disorder, but do not aim to demonstrate clinical improvement.
• involve the prospective use of efficacious interventions where the intent is to obtain and analyze biospecimens to identify genetic risk associations, novel biomarkers, examine the disease process, or characterize mechanisms of therapeutic response.
• in which an intervention with demonstrated efficacy for a population is being studied to understand mechanisms of response, non-response, or risk of adverse effects of the efficacious intervention.

Example of NIH Mechanistic Clinical Trial

https://grants.nih.gov/policy/clinical-trials/case-studies.htm#case1

General Case Studies (Updated 1/4/18)

Case #1: The study involves the recruitment of research participants who are randomized to receive one of two approved drugs. It is designed to compare the effects of the drugs on the blood level of a protein.

- **Does the study involve human participants?** Yes, the study involves human participants.
- **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to receive an intervention, one of two drugs.
- **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to evaluate the effect of the drugs on the level of the protein in the participants' blood.
- **Is the effect being evaluated a health-related biomedical or behavioral outcome?** Yes, the effect being evaluated, the level of a protein, is a health-related biomedical outcome.

✓ This study is a clinical trial.
What ISN’T a clinical trial?

- Observational studies
  - No prospective assignment

- Registry studies
  - No intervention

- Certain device studies
  - No health outcome
  - Studying the device, not the person
  - Example: NIH Case Study #7a

(These studies are clinical research.)
VCU’s position on NIH-observing vs. non-NIH observing sponsors
How VCU is handling

• The NIH definition and “interpretation” which includes “mechanistic” studies will be applied to studies funded in whole or in part by NIH and NIH-observing sponsors.
• Mechanistic studies funded by other sponsors will not be considered clinical trials.
CT.gov registration & reporting (NIH and FDA applicable, ability to publish)
Studies meeting the ICMJE clinical trial definition below must be registered on ClinicalTrials.gov. FDA Applicable Clinical Trials and clinical trials supported in whole or in part by NIH also require results reporting.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Clinical Trials Definition</th>
<th>ClinicalTrials.gov Obligation</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICMJE</td>
<td>any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome</td>
<td>Registration prior to first enrollment</td>
<td>Publication: Manuscripts that are not prospectively registered will not be published by ICMJE journals</td>
</tr>
<tr>
<td>NIH</td>
<td>a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Note: NIH considers mechanistic studies designed to explore or understand biological or behavioral processes to be clinical trials.</td>
<td>Registration within 21 days of first enrollment, but ICMJE &amp; VCU require prospective registration (initiated on/after Jan 18th 2017)</td>
<td>Funding: Loss of grant funding; Future grant funding may be affected</td>
</tr>
<tr>
<td>FDA</td>
<td>Applicable Clinical Trial Drugs &amp; biologics: controlled clinical investigations, other than phase 1, of products subject to FDA regulation Devices: 1) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies 2) pediatric postmarket surveillance as required by FDA</td>
<td>Registration within 21 days of first enrollment, but ICMJE &amp; VCU require prospective registration</td>
<td>Results Reporting no later than 12 months after primary completion date</td>
</tr>
</tbody>
</table>

To register or report results, log into the Protocol Registrations and Results System (PRS): [https://register.clinicaltrials.gov](https://register.clinicaltrials.gov)

PRS Organization: VirginiaCU
ClinicalTrials.gov Registration

• All FDA Applicable Clinical Trials must be registered (2007)
• All NIH-funded studies must be registered (2017)
  – “funded in whole or in part”
• All ICMJE studies must be registered (2007)
  – ICMJE uses a broad interpretation of the definition of a clinical trial
  – Aligns with NIH definition/interpretation
  – Registration protects ability to publish
ClinicalTrials.gov Results Reporting

• FDA Applicable Clinical Trials & NIH Clinical Trials
  – Optional for other studies (non FDA IIT, ICMJE only)
  – If you report, all reporting elements must be complete
• Protocol & Statistical Analysis Plan required as component of results reporting
• “IRB Approved” Protocol
  – Submit protocol with initial IRB submission
  – Use “See protocol” within RAMS-IRB (rather than duplicating info in smart form)
  – Amended protocol submitted to IRB as needed
  – Potential revisions to RAMS-IRB smart form TBD
ICMJE Definition and Interpretation
Definition: International Committee of Medical Journal Editors (ICMJE)

ICMJE Definition

• “The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events”

ICMJE Interpretation

Excerpt of email from Darren Taichman, MD, PhD, Secretary, ICMJE on 11/28/17
Handy “Is it a Clinical Trial” Decision Tree
DRAFT Decision Tree

Does the study involve one or more human subjects? 

No

Yes

Are participants prospectively assigned to an intervention? 

No

Yes

Is the study designed to evaluate the effect of the intervention on the participants? 

No

Yes

Is the study a mechanistic clinical trial??

Not sure

Yes

Is the study supported in whole or in part by NIH funding?

No

Yes

Do you intend to publish in an ICMJE journal?

No

Yes

This study is an NIH mechanistic clinical trial and must fulfill all additional clinical trials requirements for NIH and VCU

This study may be considered a clinical trial by ICMJE. VCU recommends registering your study on ClinicalTrials.gov to protect your ability to publish your findings in an ICMJE member journal.

The study is NOT a clinical trial.

Does the study qualify as clinical research by meeting any one of the following general criteria?

- Patient-oriented
- Epidemiological or behavioral
- Outcomes research or health services research

The study is clinical research

*Mechanistic clinical trials meet the other clinical trial criteria and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention.
Takeaways

• What kind of study is this?
  • Make determination sooner, not later
  • NIH Program Officer
  • Funding source matters

• Even if your study isn’t NIH funded, you may have additional clinical trials obligations
  • GCP
  • coverage analysis
  • OnCore
  • ClinicalTrials.gov

• VCU interpretation (non-NIH) is not changing
  • revised guidance documents under development

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Choosing the right Program Announcement (PA) for an NIH Clinical Trial application due after January 25, 2018
Funding Opportunity Announcements (FOAs) for Clinical Trials

Effective for due dates on/after January 25, 2018 – All grant applications & contract proposals involving one or more clinical trials must be submitted through an FOA or Request for Proposal (RFP) specifically designated for clinical trials

Clinical Trial-specific FOAs allow NIH to:

✓ identify proposed clinical trials
✓ ensure that key pieces of clinical trial-specific information are submitted with each application
✓ uniformly apply clinical trial-specific review criteria

Important: Adding a clinical trial to a non-clinical trial application is no longer permitted via the prior approval process. Grantees must submit competitive renewal.
Identifying the Right Funding Opportunity Announcement (FOA) is Key

Due Dates on or after January 25, 2018
All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

**How to determine if an FOA accepts clinical trials?**

1. Refer to Section II. Award Information in the Program Announcement
2. Indicated in FOA title (new FOAs only)

**Tip:** Check your FOA at least 30 days before the due date for any updates
Title of the Opportunity clarifies if Clinical Trial is (1) Required; (2) Optional; or (3) Not Allowed
Weekly NIH Funding Opportunities and Notices
NIH Guide for Grants and Contracts
November 24, 2017
Table of Contents (TOC)

Notices
• (none)

Requests for Applications
• Innovative Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R21 - Clinical Trial Not Allowed)
  National Cancer Institute
  Application Receipt Date(s): February 28, 2018; May 29, 2018; September 28, 2018; by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

• Advanced Development and Validation of Emerging Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R33 - Clinical Trial Not Allowed)
  National Cancer Institute
  Application Receipt Date(s): February 28, 2018; May 29, 2018; September 28, 2018; by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

• Innovative Biospecimen Science Technologies for Basic and Clinical Cancer Research (R21 - Clinical Trial Not Allowed)
  National Cancer Institute
  Application Receipt Date(s): February 28, 2018; May 29, 2018; September 28, 2018; by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

• Advanced Development and Validation of Emerging Biospecimen Science Technologies for Basic and Clinical Cancer Research (R33 - Clinical Trial Not Allowed)
  National Cancer Institute
  Application Receipt Date(s): February 28, 2018; May 29, 2018; September 28, 2018; by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

• Elucidating HIV and HIV-treatment Associated Metabolic/Endocrine Dysfunction (R01 Clinical Trial Optional)
  National Institute of Diabetes and Digestive and Kidney Diseases
  Application Receipt Date(s): November 13, 2018; by 5:00 PM local time of applicant organization. All types of applications allowed for this funding opportunity announcement are due on these dates.

• The Role of the Microbiome in the Developmental Origins of Health and Disease (DOHaD) (R01 Clinical Trial Not Allowed)
  National Institute of Environmental Health Sciences

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What type of clinical trial can be included?

- Look in the FOA and in Notices for Parent Announcements

**TYPE OF TRIALS SUPPORTED BY THIS FOA**

Trials proposed must meet the NIH definition of a clinical trial (see NOT-DD-15-015) and should contribute to the advancement of evidence-based medicine/practice and the sciences that support it. Applicants may propose to conduct an early phase trial by itself, or in combination with other non-clinical trial research aims as appropriate. The FOA will support the conduct of investigator-initiated oncologic intervention research at all early stages, from early mechanistic research and intervention development (e.g., stage 0 and/or I) through implementation and cost-effectiveness research. NCI funds may be used to support single-site, multi-site, hypothesis-driven, pathway-related, exploratory/feasibility and pragmatic trials (as defined below) designed to improve the management of care for patients with cancer. The trial design should be appropriate for the hypothesis to be tested. This FOA also

<table>
<thead>
<tr>
<th>Funding Opportunity Title</th>
<th>NIH Research Project Grant (Parent R01 Clinical Trial Required)</th>
</tr>
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<tbody>
<tr>
<td>Activity Code</td>
<td>R01 Research Project Grant</td>
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<tr>
<td>Announcement Type</td>
<td>New</td>
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</tbody>
</table>

**Related Notices**

- NOT-AR-18-008 NIAAMS Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements
- NOT-HL-17-546 NHLBI Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for the NIH Parent R01 Clinical Trial Required Announcement
- NOT-AT-18-001 NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials
- NOT-MH-18-004 NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements
Single IRB ("sIRB") and IRB Reliance
NIH Requirement


- **Effective for due dates on/after January 25, 2018** – NIH expects that all multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a *single Institutional Review Board (sIRB)* to conduct the ethical review required for the protection of human subjects

- **sIRB policy aims to:**
  - ✓ Streamline IRB review process to enhance research efficiency
  - ✓ Reduce unnecessary administrative burdens and inefficiencies

When does this apply

sIRB DOES apply:
- Collaborative/multi site study
- Funding proposal RECEIPT date is on or after Jan 25th, 2018, or the contract solicitation is issued on or after Jan 25th 2018 AND
- Sites follow the same protocol (same study questions and research design)

sIRB DOES NOT apply
- Foreign sites
- Career development (K), research training (T), or fellowship (F) awards
- Ongoing, non-competing awards, UNTIL grantee submits a competing continuation after January 25th, 2018
- FDA regulated research where local review is REQUIRED by the FDA
- Sites where local review is required by federal, tribal or state laws
sIRB Implications for Proposal Submission

• The sIRB plan is uploaded as an attachment to Question 3.2 of the new FORMS-E Human Subjects and Clinical Trials Information Form.
• sIRB plan must include:
  – Statement that awardee(s) will comply with NIH requirement
  – Name of the IRB serving as the reviewing IRB
  – Indicate that all sites agree to rely AND that any sites added after award will also comply
  – Provide an overview of the communication plan (see SMART IRB template)
  – Indicate that all sites will sign an IAA (Institutional Authorization Agreement)
  – Identify which institution will maintain records of IAAs and communication plans (VCU will always maintain records of both)
• Do not include copies of the IAA or Communication plan with your grant application
• NIH does not require letters of support, however VCU believes this is best practice. A LoS will be required for most reliance requests.
sIRB Budgeting Implications for Proposal Submission

• NIH expects that the entity serving as the sIRB will charge fees to review other sites. The fees are the responsibility of the lead site and should be included in the grant budget. *This is a new responsibility.*

• When VCU is relying on another sIRB, remember to include associated fees of the sIRB in the grant budget.

• When VCU is serving as the sIRB, we will be charging for review for other engaged sites, as allowable by the new NIH requirement. Cost structure coming soon.

• NIH guidance on sIRB and costing is available in [NOT-OD-16-109](#).
Requesting Reliance

• Early communication is key!
  – Involve irbreliance@vcu.edu in reliance discussions early to prevent delays later

• Submit request for VCU to rely on another institution, or serve as the sIRB through REDcap form
  – Will be available on the Reliance page on the VCU website
  – Requires contact information for reviewing/participating site IRB, and overview of the research
  – Submit request at least two weeks before final draft is due to OSP.
IRB Master Agreements

• Master agreements document the reliance agreement between institutions for any study (not study specific). Therefore:
  – Do not require study specific IAA
  – Can request reliance through email to irbreliance@vcu.edu

• VCU currently has master agreements in place with:
  – Western IRB
  – NCI Central IRB
  – Schulman IRB
Other Agreements

• **SMART IRB**
  – Request at: [https://smartirb.org/reliance/](https://smartirb.org/reliance/)
  – Or through the VCU Reliance Request REDcap form

• **IRBChoice**
  – Request at: [https://www.irbchoice.org/p/register-study/](https://www.irbchoice.org/p/register-study/)
  – Or through the VCU Reliance Request REDcap form
Questions...

• Please visit the reliance website at https://research.vcu.edu/human_research/reliance.htm

• Contact IRBreliance@vcu.edu for questions
Certificates of Confidentiality
Updated Certificates of Confidentiality (CoC) Policy

Effective October 1, 2017 - CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016

✓ Eliminates the need for NIH funded investigators to apply for a CoC
✓ Enhances the privacy protections of individuals participating in NIH-funded research
✓ Requires investigators to only disclose information under specific circumstances
✓ Applies to NIH awards funded wholly, or in part, by NIH
✓ Disclosure restrictions also apply to anyone who receives a copy of identifiable sensitive information protected by the policy, even if they are not funded by NIH
✓ CoC is issued as a term and condition of award (no physical certificate)

Learn more at https://humansubjects.nih.gov/coc/index
Certificates of Confidentiality

• Determining Applicability of NIH COC Policy – If the research began on or after 12/13/16

1. Is the research conducted or funded by NIH? ☐ Yes ☐ No
2. Is the activity biomedical, behavioral, clinical, or other research? ☐ Yes ☐ No
   – If the answer to either of these questions is No, then the activity is not issued a CoC and the policy does not apply. If the answer to both is Yes, answer the following questions:
     • 1. Does the research involve human subjects as defined by 45 CFR Part 46? ☐ Yes ☐ No
     • 2. Are you collecting or using information or biospecimens that are identifiable to an individual as part of the research? ☐ Yes ☐ No
     • 3. If collecting or using information or biospecimens as part of the research, is there a small risk that some combination of the information or biospecimen, a request for the information or biospecimen, and other available data sources could be used to deduce the identity of an individual? ☐ Yes ☐ No
     • 4. Does the research involve the generation of individual level, human genomic data? ☐ Yes ☐ No
   • If the answer to any one of these questions is Yes, then a CoC is automatically issued and the policy applies.
CoCs for Research Not Funded by NIH

• Research Supported by CDC, HRSA, or SAMHSA, or under the authority of FDA:
  – These agencies issue their own certificates of confidentiality. Contact the Certificate Coordinator at the funding agency to determine how to obtain a CoC.

• Other Non-DHHS, Federally Funded Research and Non-Federally Funded Research:
  – Health-related research that is not federally funded may request a CoC using the online application system hosted by NIH. The proposed informed consent form must be submitted as part of the CoC application. Direct a CoC request to the NIH Institute or Center (IC) that supports similar research. NIH recommends verifying this VCU guidance document available here.
Research and Compliance Meeting (RACM): January 10, 2018

SPOT Update
SPOT Patches

• Last patch occurred 12/11/17
• Next patch scheduled for 5/18/18
  – Deadline for new requests – 4/1/18
SPOT Patch 12/11/17

• Implemented Forms-E

Federal Grant Information

1. Enter an opportunity ID below, then click Find. From the list returned, select an opportunity, then click Continue.

* Opportunity ID (PA or RFA Number): RFA-HL-17-015

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<th>Opportunity ID</th>
<th>Opportunity Title</th>
<th>Opening Date</th>
<th>Closing Date</th>
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<td>11/14/2017</td>
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<td>Bold New Bioengineering Methods and Approaches for Heart, Lung, Blood and Sleep Disorders and Diseases (R21)</td>
<td>9/13/2016</td>
<td>1/24/2018</td>
<td>FORMS-D</td>
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SPOT Patch 12/11/17 (cont.)

• Updated notifications from the FP
  – Includes text of comment in the email received

• Revised CP (continuation proposal/supplement) process
  – Will autofill significant information when created
    • Reduce data entry
    • Assist with processing changes as Administrative Actions
SPOT Patch 12/11/17 (cont.)

• New Closeout Process
  – Submit AA
  – E-closeout forms are eliminated
  – Submission of AA will transition AW to “Closeout In Progress”
SPOT Patch 12/11/17 (cont.)

• Updated security to the Award
  – If the FAU was different in the FP than the AW, this led to difficulties in processing AW actions (AAs, CPs, and subaward actions)
  – This has been corrected so that all those in the Access list for the FAU of the AW should have all of these rights.

• Allow access list to be changed for inactive units
• Finalized subaward process
  – All functionality fully functioning
  – All subaward forms have been eliminated

• Revised MTA process
  – Submit Document for Review
  – Eliminated all MTA forms
  – Integrated DocuSign technology into SPOT