Kathy Kawamura
Assistant Director

July 13, 2017

Topics

- NIH Good Clinical Practice
- ClinicalTrials.gov
- F&A Rate Application
- TIF Rate
- NIH Notice Updates

NIH Good Clinical Practice

As presented at previous RAF (January 12, 2017), NIH issued NOT-OD-16-148 which outlines the NIH policy on Good Clinical Practice training for NIH awardees involved in NIH-fund clinical trials.

- "This policy establishes the expectation **that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)**"
- Training may be achieved through a class or course, academic training program, or certification by other sources.
- GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines.

NIH Good Clinical Practice

UCLA Process:

- PI is responsible for ensuring that NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials are up to date with GCP training.
  - New Awards: OCGA will confirm GCP training completion with department/PI
- Existing/ongoing NIH clinical trials – remind PIs to complete their training and ensure relevant staff complete training.
  - Upcoming: OCGA to follow-up for completion of GCP training certification
- If previously completed training from source other than CITI; will be required to provide evidence of completion
- ePass - OCGA will review sponsor & program type based upon NIH definitions

NIH Good Clinical Practice

NIH Good Clinical Practice

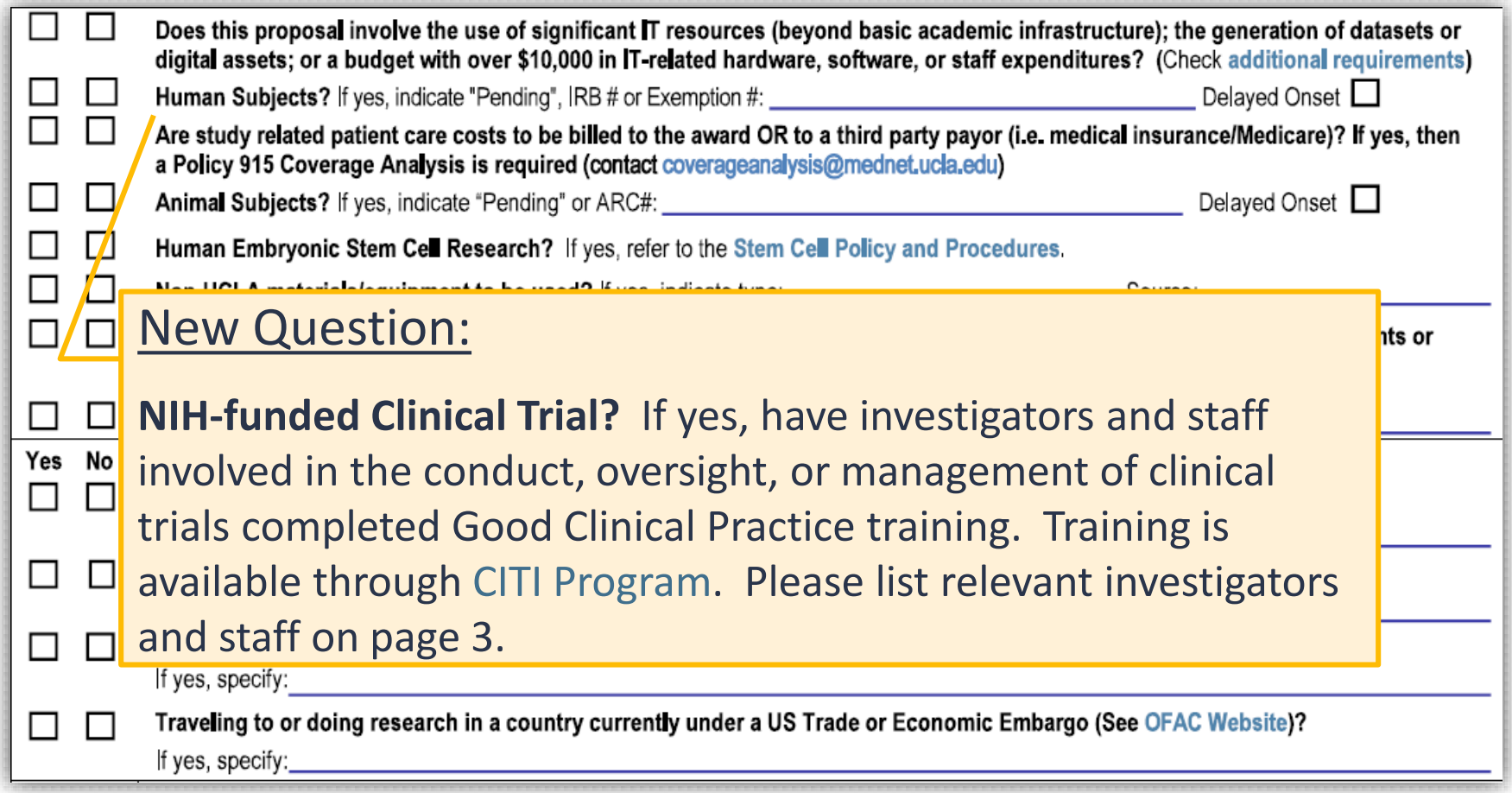
Last Name	First Name	DEPARTMENT	DEPT	Learner Group or Course Taken	Completion Date	Expiration Date	Type of Course
Bruin	Joseph	CLINICAL RESEARCH CENTER	1790	Good Clinical Practice (OPTIONAL)	4/8/2013	4/7/2016	GCP
Bruin	Josephine	MEDCTR-VOLUNTEERS	2808	Good Clinical Practice (OPTIONAL)	12/11/2009	12/10/2012	GCP
Conte	Lee	MEDICINE-HEMATOLOGY-ONCOLOGY	1559	Good Clinical Practice (OPTIONAL)	6/10/2013	6/9/2016	GCP
Don	Glen	CANCER PREVENTION & CNTRL RESEARCH	1916	Good Clinical Practice (OPTIONAL)	10/27/2015	10/26/2018	GCP
Ley	Gay	MEDICINE-HEMATOLOGY-ONCOLOGY	1559	Good Clinical Practice (OPTIONAL)	11/18/2013	11/17/2016	GCP
Shire	Will	MEDCTR-JULES STEIN EYE INSTITUTE	2892	Good Clinical Practice (OPTIONAL)	6/16/2017	6/15/2020	GCP

Compliant

Non-Compliant

Pending Epass Changes (NIH Good Clinical Practice)

EPASS Section 6



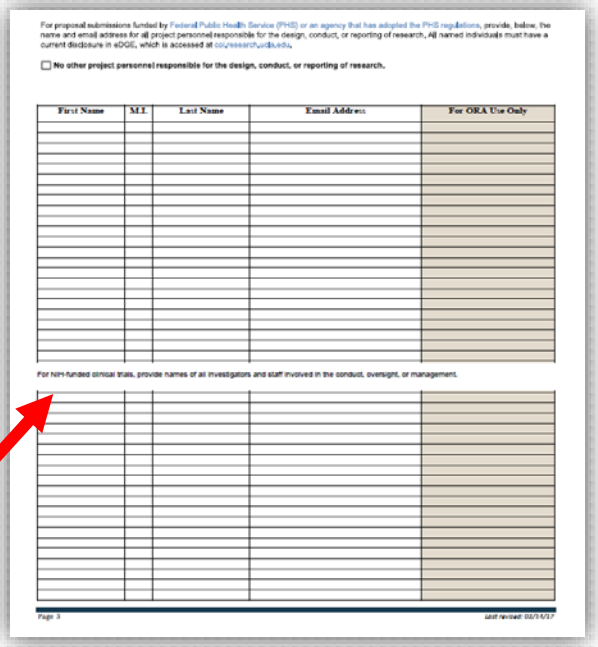
New Question:

NIH-funded Clinical Trial? If yes, have investigators and staff involved in the conduct, oversight, or management of clinical trials completed Good Clinical Practice training. Training is available through CITI Program. Please list relevant investigators and staff on page 3.

Pending Epass Changes (NIH Good Clinical Practice)

EPASS Page 3

List all of the “NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP)”



For proposal submissions funded by Federal Public Health Service (PHS) or an agency that has adopted the PHS regulations, provide, below, the name and email address for all project personnel responsible for the design, conduct, or reporting of research. All named individuals must have a current disclosure in eDGE, which is accessed at coi.research.ucla.edu.

☐ No other project personnel responsible for the design, conduct, or reporting of research.

First Name	M.I.	Last Name	Email Address	For ORA Use Only

For NIH-funded clinical trials, provide names of all investigators and staff involved in the conduct, oversight, or management.

Page 3 Last revised: 02/14/17

For NIH-funded clinical trials, provide names of all investigators and staff involved in the conduct, oversight, or management.

ClinicalTrials.gov

Compliance with FDAAA 801 Requirements (Final Rule)

- "ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world"
- Based upon FDAAA 801 Requirements (Final Rule), it "requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov."
- FDAAA 801 applies to any clinical study that meets the definition of an Applicable Clinical Trial and that was initiated after September 27, 2007, or that was initiated on or before that date and was still ongoing as of December 26, 2007.
- Definition of Applicable Clinical Trial under FDAAA

ClinicalTrials.gov FAQs

ClinicalTrials.gov
(NIH requirement)

Compliance with FDAAA 801 Requirements (Final Rule)

- Per the Deans, Directors, Department Chairs, and Administrative Officers memo issued by Interim Vice Chancellor Karagozian and Vice Chancellor Mazziotta dated June 2, 2017 (*appendix*) National Institutes of Health *Policy on the Dissemination of NIH-Funded Clinical Trial Information* (NOT-OD-16-149) went into effect on January 17, 2017.
- It requires registering and submitting results information to ClinicalTrials.gov for all studies funded wholly or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to FDAAA Section 801. See: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html.

ClinicalTrials.gov

Compliance with FDAAA 801 Requirements (Final Rule)

- ***Cancer Studies**:* The Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center: jcccorc@mednet.ucla.edu. The process of registering trials and results reporting is managed by the JCCC in collaboration and consultation with the investigator, using investigator-supplied information and documentation**.** Investigators *do not* need to maintain individual user accounts for cancer studies.

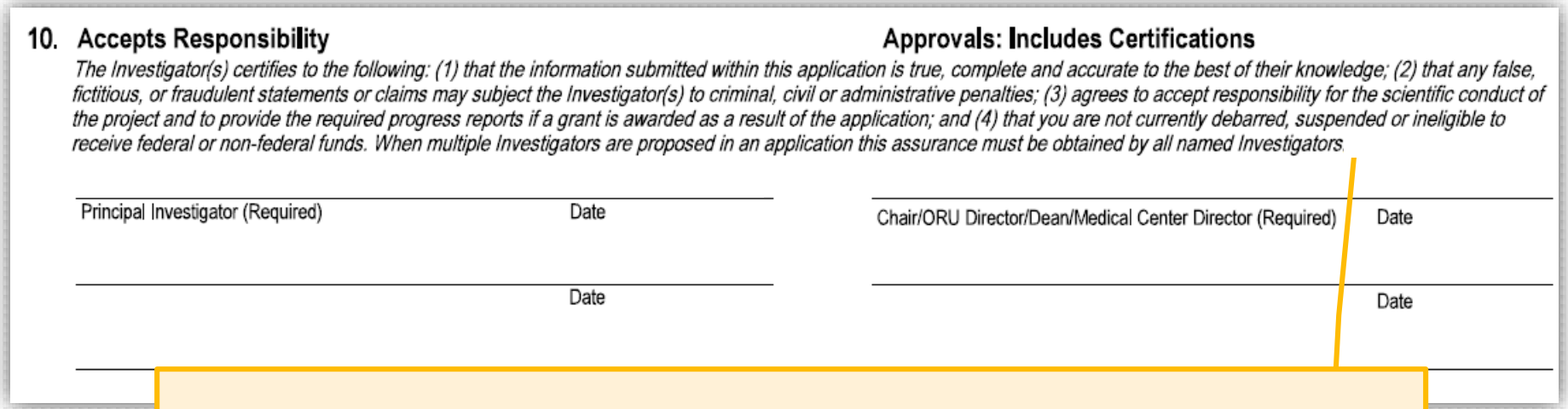
- ***Non-Cancer Studies**:* The Office of Regulatory Affairs, Clinical and Translational Science Institute (CTSI): ctsiora@mednet.ucla.edu. Each Investigator receives a user account under the "UCaliforniaLA" organization name to be able to log in to register and maintain their own studies. CTSI staff can view and edit all records in the organizational account and can provide guidance on registration and results-reporting requirements and the Protocol Registration System (PRS) data entry process. Study support staff and co-investigators may be given access to view and edit a study record, but only the Responsible Party can release the record to ClinicalTrials.gov.

- Per NIH (https://grants.nih.gov/clinicaltrials_fdaaa/certify-compliance.htm), AOR's signature on a competing application or RPPR assures compliance with FDAAA.

Pending Epass Changes

(ClinicalTrials.Gov)

PI Certifications



10. **Accepts Responsibility** **Approvals: Includes Certifications**

The Investigator(s) certifies to the following: (1) that the information submitted within this application is true, complete and accurate to the best of their knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Investigator(s) to criminal, civil or administrative penalties; (3) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application; and (4) that you are not currently debarred, suspended or ineligible to receive federal or non-federal funds. When multiple Investigators are proposed in an application this assurance must be obtained by all named Investigators.

Principal Investigator (Required) Date

Date

Chair/ORU Director/Dean/Medical Center Director (Required) Date

Date

INSERT:

(5) all Clinical Trials based upon FDAAA 801 , will be registered in ClinicalTrials.gov.

Technology Infrastructure Fee (TIF)

https://www.it.ucla.edu/support-training/campus-billing-help/2017-2018-billing-rates-announcement

- FY 18 TIF Rate: **$41.22**
- Effective July 1, 2017
- TIF based upon paid FTE

TIF Fee FAQs

https://www.it.ucla.edu/support-training/campus-billing-help/general-billing-faqs/technology-infrastructure-fee-faqs

F&A Rate

Sponsored Activity	Effective Period		
	FY 2017 July 1, 2016 To June 30, 2017	FY 2018 July 1, 2017 To June 30, 2018	FY 2019 July 1, 2018 To June 30, 2019*
Organized Research	54%	55%	56%
Other Sponsored Activities	35%	38%	38%
Instruction	37%	40%	40%
Off-Campus (all functions)	26%	26%	26%
Intergovernmental Personnel Agreement (IPA)	8%	8%	8%

UCLA F&A Rate Agreement

http://www.research.ucla.edu/ocga/Documents/F_A_Rate_Agreement_5-3-17.pdf

Split F&A Rates

Budget Period 1: 1/01/18 – 12/31/18

Total Direct 275,000
Total Exclusion 75,000

1/1/18– 6/30/18 **(6 months)** UCLA F&A Rate **55%**		7/1/18 – 12/31/18 **(6 months)** UCLA F&A Rate **56%**	
Total Direct	137,500	Total Direct	137,500
exclusions	37,500	exclusions	37,500
Base	100,000	Base	100,000
Indirect	55,000	Indirect	56,000
Total Cost	192,500	Total Cost	193,500

NIH Notice Updates

NOT-OD-17-048

NIH Continuing Resolution

- Non-competing awards issued ~90%

Update

NOT-OD-17-086

FY17 passed May 5, 2017

$2B increase from FY16 budget ($34.3b)

"*in general* reductions will be fully restored"

NIH Notice Update

NOT-OD-17-084

- NRSA Predoc Increased Stipend Levels FY17
- NRSA awards with PreDocs will be amended if issued from FY17 funds
- Amended Appointment Forms must be updated via Xtrain (eCommons)
  - Reminder: Stipends noted on Statement of Appointment Forms must match Stipends paid

NOT-OD-17-003 *(Postdoc NRSA FY17 Levels)*

NIH Updates

NOT-OD-17-062

New NIH “FORMS-E”

For proposal due dates on or after 1/25/18

Forms-E to be released ~October 2017

- Consolidate Human Subjects Information
- Expand Clinical Trial Information
  - Align with ClinicalTrials.gov

MASTER TRAINING

http://ora.research.ucla.edu/OCGA/Pages/Training-Resources/training-calendar.aspx

JULY

Post Submission Pre-Award

Wednesday, July 26, 2017

New Location

10889 Wilshire Blvd., Conf Room 820-20

9:30am-11:00 am

UCLA Office of Contract & Grant Administration is the central point of contact for all pre-award actions related to sponsored projects to be funded upon receipt of satisfactory compliance. This session will focus on NIH Just-in-Time (JIT), DOD pre-award process, Reps and Certs, other authorizations (Federal, State, County) and sponsor requests.

MASTER TRAINING

http://ora.research.ucla.edu/OCGA/Pages/Training-Resources/training-calendar.aspx

August

NSF FastLane and Research.gov

September

What Constitutes a Complete Proposal Package?

Questions

Appendix: NIH Definition of Clinical Trial

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

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

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

The 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 the clinical trial.

*Source: https://grants.nih.gov/grants/glossary.htm#ClinicalTrial

Appendix: NIH Definition of Clinical Trial

An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies.

A *health-related biomedical or behavioral outcome* is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life.

Appendix: NIH Definition of Clinical Trial

Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.

Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

UCLA

Health Sciences
Office of the Vice Chancellor for Research

Deans, Directors, Department Chairs, and Administrative Officers

Dear Colleagues:

This guidance is issued to remind the campus clinical research community of the longstanding requirements to register and report results of clinical trials on the Federal database, www.ClinicalTrials.gov. It supplants campus guidance distributed in 2008.

Several changes to relevant federal regulations took effect in January 2017. They are:

The *Final Rule for Clinical Trial Registration and Results Information Submission* (42 CFR Part 11) went into effect on January 18, 2017. The Final Rule clarifies and expands the requirements of the Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) registration and reporting requirements. Studies subject to the registration and results submission requirements described in FDAAA 801 are known as Applicable Clinical Trials (ACTS). See: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission.

National Institutes of Health *Policy on the Dissemination of NIH-Funded Clinical Trial Information* (NOT-OD-16-149) went into effect on January 17, 2017. It requires registering and submitting results information to ClinicalTrials.gov for all studies funded wholly or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to FDAAA Section 801. See: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html.

Additionally, the *International Committee of Medical Journal Editors* (ICMJE) requires prospective registration in ClinicalTrials.gov as a precondition of consideration for publication of research results generated by a Clinical Trial in their journals (http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

Under the FDA regulations and NIH policy, the entity or individual responsible for registering a clinical investigation and submitting Clinical Trial information to ClinicalTrials.gov is known as the Responsible Party.

UCLA has established two institutional accounts in the Protocol Registration and Results System (PRS) for ClinicalTrials.gov to support UCLA investigators who serve as the Responsible Party on a clinical trial:

For cancer studies: The Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center: jcccorc@mednet.ucla.edu. **The process of registering trials and results reporting is managed by the JCCC in collaboration and consultation with the investigator, using investigator-supplied information and documentation.** Investigators *do not* need to maintain individual user accounts for cancer studies.

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Complying with the regulations is mandatory. Please forward this information to relevant individuals in your units. We urge all investigators to avail themselves of the support provided by the CTSI and JCCC to make reporting and registration easier, and to reduce the risk of monetary penalties that can be imposed by the FDA and/or the NIH for failure to comply.

For additional information see: http://researchgo.ucla.edu/clinicaltrialsgov.

Sincerely,

Ann Karagozian, Ph.D.
Interim Vice Chancellor for Research

John Mazziotta, M.D., Ph.D.
Vice Chancellor of UCLA Health Sciences

Identifying an "Applicable Clinical Trial" under FDAAA

- This flowchart presents basic guidance on determining if a trial is considered an "applicable clinical trial" under FDAAA. It maps out the guidance provided in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial", and is also available as an interactive flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm
- This flow chart may not address every situation. The grantee's sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.