

How To Register A Protocol

ClinicalTrials.gov

Getting Started

- ClinicalTrials.gov account:
 - Establish an account
 - Connect With CT.gov Administrator
 - Blazer ID, Email, Phone Number
- CT.gov Website:
 - <https://clinicaltrials.gov/>
 - <https://register.clinicaltrials.gov/>

CT.gov Public Website

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore **327,786** research studies in all 50 states and in 209 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Status ⓘ

Recruiting and not yet recruiting studies

All studies

Condition or disease ⓘ (For example: breast cancer)

X

Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

Country ⓘ

X

[Advanced Search](#)

CT.gov Registration Website

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB NO: 0925-0588
EXPIRATION DATE: 02/29/2020
[Burden Statement](#)

Organization:

One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:

[Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.

[Send email to ClinicalTrials.gov PRS Administration](#)

Registering A New Record

Quick Links

New Record

[Admin Quick Reference](#)

[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Email: dhmckenz@uab.edu [[Update](#)]

Help us improve: [PRS Survey](#)

Record List

All Records (693) Problem Records (49) Custom Filter

Showing: 1-49 of 49 records 50 records per page

Search: [Show/Hide Columns](#)

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Primary Completion Date	Record Status	Last Update	Record Owner	Responsible Party	
Open	IRB-300001132	NCT03497195	Achieving Tuberculosis (TB) Control In Zambia	05/01/2020	Public	04/06/2018 03:44	twilson	Stewart Reid sereid@uab.edu	• Record Has 1 I
Open	IRB-300001201	NCT03488472	Radiosurgery Plus NovoTTF-200A for Metastatic Small Cell Lung Cancer to the Brain (RAD 1704)	04/2021	Entry Completed	05/04/2018 14:43	kkwebb	Drexell Hunter Boggs dhboggs@uab.edu	• Ready for Revi • Update Not Re
Open	R17-077	NCT03451123	FET-PET/MRI for Surgical Assessment of Pediatric Brain Tumors	02/2021	Entry Completed	05/08/2018 11:12	mvetrano	Jonathan E McConathy jmconathy@uabmc.edu	• Ready for Revi • Update Not Re
Open  	1135815	NCT03446690	MI Varnish for the Prevention of White Spot Lesions	11/01/2015	Released	04/24/2018 15:08	ckau	Chung How Kau ckau@uab.edu	• Late Results -
Open	IRB-300000471	NCT03342989	Speed of Processing Training for Cognitive Deficits After Delirium in Older Adults	09/2022	Public	03/14/2018 15:26	rkennedy	Richard Kennedy rekenned@uab.edu	• Record Has 1 I
Open	IRB-300000596	NCT03340025	Single-Use Negative Pressure Wound Therapy for Free Flap Donor	05/2019	In Progress	05/01/2018 13:00	dklowman	Brian Hughley bhughley@uabmc.edu	• Entry Not Com • Update Not Re

IRB – Clinical Trial Definition

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? Yes No

**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. For more information, see the full definition of clinical trial [here](#).*

If Yes, you will need to fulfill the following requirements (regardless of funding):

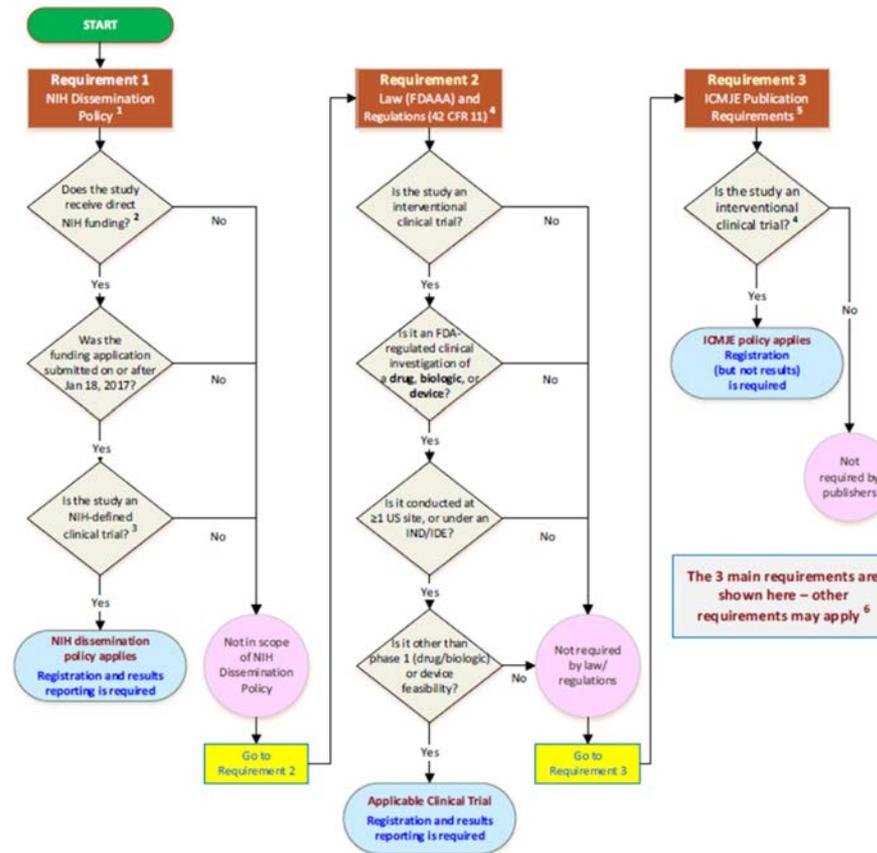
Determining Registration

- Who is funding the study?
- Interventional Study?
- Are there plans to publish?
- Have you checked with your contract officer or sponsor?
- If studies include Medicare patients, an NCT number is needed for billing purposes.

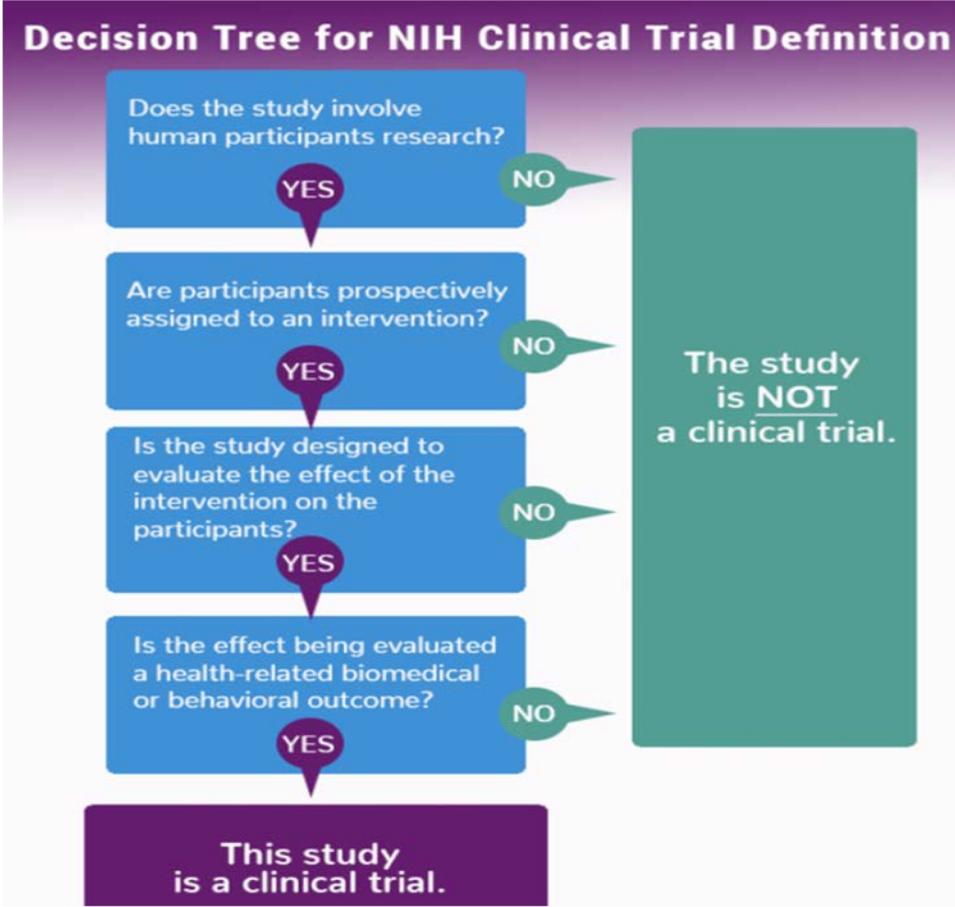
Registering & Reporting Requirements

When Does a Study Have to be Registered on ClinicalTrials.gov?

(Evaluate all requirements)



Decision Tree for NIH Clinical Trial Definition



NIH Interventions

- An 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.

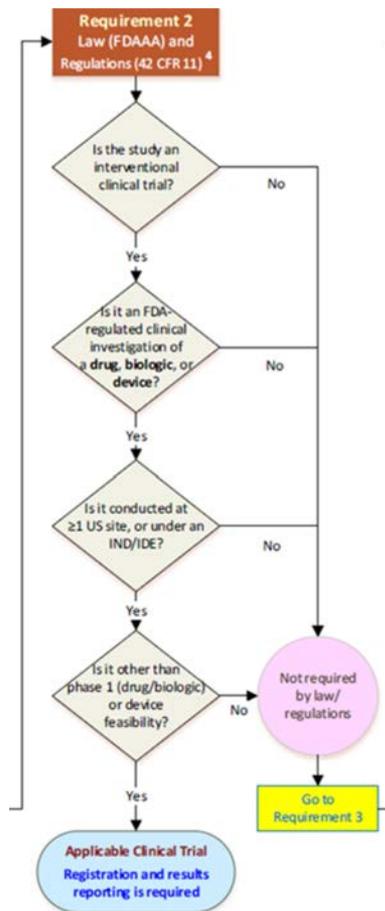
NIH Health-Related Biomedical or Behavioral Outcome

- Health-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 Non-Clinical Trials

- Studies that involve secondary research with biological specimens or health information, or studies that are intended solely to refine measures are not considered clinical trials.
- Review extensive list of “***Case Studies***”
- NIH advises to consult with your program officer should your research fall into a gray area

FDAAA 801 Registering & Reporting?



- Is the study an interventional clinical trial?
- Is it an FDA-regulated clinical investigation of a drug, biologic, or device?
- One or more sites?
- Is it conducted under an IND/IDE?
- Is it other than a phase 1 or device feasibility?

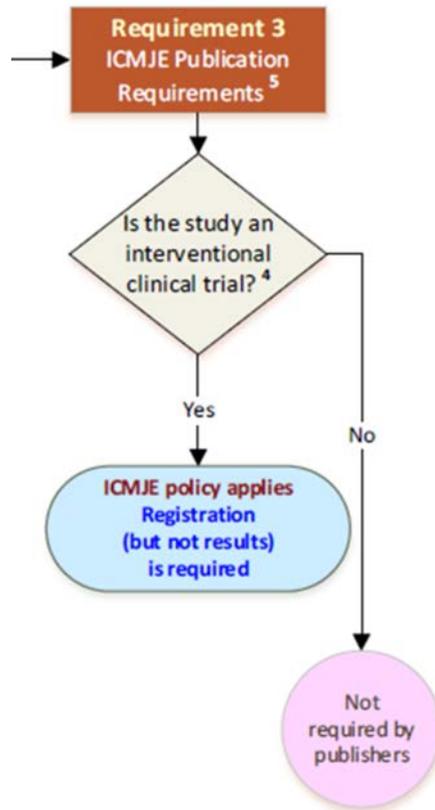
FDAAA & Other Regulations (42 CFR 11)

- Inclusions:
- Trials of drugs and biologics – All controlled clinical investigations, other than phase 1 (all Interventional Studies that meet established criteria).
- One or more sites, IND, involves a drug, biologic, or device
- Trials of devices – Controlled trials with health outcomes of devices, other than small feasibility studies and 2) pediatric post-market surveillance required by the FDA

FDAAA & Other Regulations (42 CFR 11)

- Exclusions:
- Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
- Phase 1 drug trials, including studies in which investigational drugs are used as research tools
- Non-interventional (observational) clinical research (such as cohort or case-control studies)
- Small clinical trials to determine the feasibility of a device, where the primary outcome measure relates to feasibility and not to health outcomes

ICMJE Registering & Reporting?

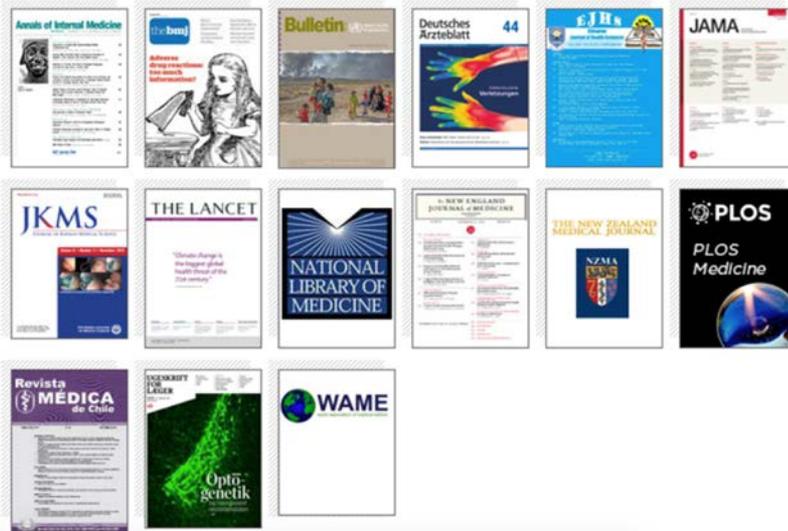


- Prospectively assigns individuals to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.
- Includes drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

International Committee of Medical Journal Editors (ICMJE)

- The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry “**at or before the time of first patient enrollment as a condition of consideration for publication.**”

Member Publications & Organizations



New Record

Quick Links

[New Record](#)

[Admin Quick Reference](#)

[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Email: dhmckenz@uab.edu [[Update](#)]

Help us improve: [PRS Survey](#)

Record List

All Records (618)

Problem Records (41)

▶ Custom Filter

No records to show (filtered from 41 records) 100 ▾ records per page

Search:

Show/Hide Columns

Protocol ID	ClinicalTrials.gov ID	Brief Title	Primary Completion Date	Record Status	Last Update	Record Owner	Responsible Party	Problems
No matching records found								

No records to show (filtered from 41 records) 100 ▾ records per page

Page ▾ of 0

KEY: R Results DR Delayed Results PR PRS Review

U XML Upload NP No longer public PR PRS Review Comments

Download...

Title Page

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:	<input type="text" value="F00123456"/>
* Brief Title:	<input type="text" value="Efficacy of Drug X vs Drug Y in Non-Small Lung Cell Lung Cancer"/>
	Special Characters
[*] Acronym: (if any)	<input type="text" value="NSCLC"/> If specified, will be included at end of Brief Title in parentheses.
* Study Type:	<input checked="" type="radio"/> Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol <input type="radio"/> Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care <input type="radio"/> Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Continue

Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Agenda of Information

Organization's Unique Protocol ID: F001032456

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Interventions
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK

Official Title

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:	<input type="text" value="F00123456"/>
* Brief Title:	<input type="text" value="Efficacy of Drug X/Y vs Drug Y in Non-Small Cell Lung Cancer"/>
[*] Acronym: (if any)	<input type="text" value="NSCLC"/> <small>If specified, will be included at end of Brief Title in parentheses.</small>
* § Official Title:	<input type="text" value="Evaluating the Efficacy and Safety of a New Novel Drug Combination Against the Standard Treatment for Non-Small Cell Lung Cancer"/> ⚠ WARNING: Official Title has not been entered.
[*] Secondary IDs: (if any)	<input type="button" value="+ Add Secondary ID"/>

Continue

Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

CT.gov View

Quick Links

- [New Record](#)
- [Admin Quick Reference](#)
- [Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Email: dhmcken@uab.edu [\[Update\]](#)

Help us improve: [PRS Survey](#)

Record List

All Records (526) Problem Records (51) Custom Filter

Showing: 1-3 of 3 records (filtered from 51 records) 100 records per page

Search:

Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open	F160920009		The Topic Trial - Study to Determine the Safety and Efficacy of Ivacaftor	In Progress	03/07/2017 12:01	ewestfal	Mark Dransfield, MD mdransfield@uabmc.edu	<ul style="list-style-type: none"> • PRS Review Comments • Entry Not Completed
Open	X141114004		Evaluating the Efficacy and Compatibility of Efinaconazole 10% Solution (Jublia) for the Treatment of Toenail Onychomycosis in Patients Wearing Toenail Polish Compared to Those Without Polish	In Progress	01/12/2017 14:08	cwang	Boni Elewski, MD belewski@uab.edu	<ul style="list-style-type: none"> • PRS Review Comments • Entry Not Completed
Open	F00123456		Efficacy of Drug X/Y vs Drug Y in Non-Small Cell Lung Cancer (NSCLC)	In Progress	03/10/2017 17:08	dhmcken	[Sponsor]	<ul style="list-style-type: none"> • Entry Not Completed • Never Released

Study Dates & Recruitment Completed

[Help](#) [Definitions](#)

* Record Verification Date:

Month: Year:

* Overall Recruitment Status:

Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date:

Month: Day: Year: Type:

Beginning of participant enrollment.

* Primary Completion Date:

Month: Day: Year: Type:

Final data collection date for primary outcome measure.

* § Study Completion Date:

Month: Day: Year: Type:

Final data collection date for study.

Continue

Back

Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Study Dates - ERROR

Edit Study Status

[Help](#) [Definitions](#)

* Record Verification Date: Month: Year:

* Overall Recruitment Status:
Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: Day: Year: Type:
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

 **WARNING:** Start Date October 2017 should not be in the past for a study that is Not yet recruiting.
 **ERROR:** Anticipated Start Date cannot be in the past.

* Primary Completion Date: Month: Day: Year: Type:
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: Day: Year: Type:
Final data collection date for study.

Sponsor/Collaborators

[Help](#) [Definitions](#)

* Responsible Party:

Sponsor

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

* Sponsor:

University of Alabama at Birmingham

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators:

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)
Enter **only the organization name**.

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Sponsor/Collaborators Completed

[Help](#) [Definitions](#)

* Responsible Party:

Principal Investigator ▼

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

Investigator Information

Investigator Name [Username]: Elaine C. Moreland [emoreland] ▼

Select the investigator's PRS account.

The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.

[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title: Primary Investigator

Investigator Affiliation: University of Alabama at Birmingham

* Sponsor:

University of Alabama at Birmingham

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators:

World Health Organization (WHO)

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)
Enter only the organization name.

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Oversight

[Help](#) [Definitions](#)

* § U.S. FDA-regulated Drug:	--Select-- ▾ Studying one or more U.S. FDA-regulated drug or biologic products?
* § U.S. FDA-regulated Device:	--Select-- ▾ Studying one or more U.S. FDA-regulated device products?
* U.S. FDA IND/IDE Study: (Not public)	--Select-- ▾ Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
* Human Subjects Protection Review:	Board Status: --Select-- ▾
Data Monitoring Committee:	--Select-- ▾
Plan to Share IPD:	--Select-- ▾ Indicate if there is a plan to make individual participant data (IPD) available to other researchers.
FDA Regulated Intervention:	--Select-- ▾

Continue

Back

Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Oversight Completed

Edit Oversight	
Help Definitions	
* § U.S. FDA-regulated Drug:	<input type="text" value="Yes"/> Studying one or more U.S. FDA-regulated drug or biologic products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF) .
* § U.S. FDA-regulated Device:	<input type="text" value="No"/> Studying one or more U.S. FDA-regulated device products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF) .
* U.S. FDA IND/IDE: (Not public)	<input type="text" value="No"/> Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
[*] Product Exported from U.S.:	<input type="text" value="Yes"/> Studying a drug or device product that is manufactured in and exported from the U.S.?
* Human Subjects Protection Review:	Board Status: <input type="text" value="Submitted, pending"/> The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.] Board Name: <input type="text" value="Institutional Review Board for Human Use"/> Board Affiliation: <input type="text" value="University of Alabama at Birmingham"/> Board Contact: Phone: <input type="text" value="205-934-3789"/> Extension: <input type="text"/> Email: <input type="text" value="irb@uab.edu"/> Address: <input type="text" value="Administration Building, Room 470"/> 701 South 20th Street Birmingham, AL 35294-0104
Data Monitoring Committee:	<input type="text" value="Yes"/>
FDA Regulated Intervention:	<input type="text" value="No"/>

* Required
§ Required if Study Start Date is on or after January 18, 2017

Study Description Completed

[Help](#) [Definitions](#)

* Brief Summary:

This study is being done to determine the overall progression-free survival (PFS) in patients with advanced or metastatic (Stage IIIB - pleural effusion/IV), non-squamous histology NSCLC treated with standard chemotherapy treatment vs combination chemotherapy.

[Special Characters](#)

Detailed Description:

Subjects will be treated with chemotherapy with Drug X and Drug Y weekly for 3 out of 4 weeks. Treatment with chemotherapy will be expressed as a 4-week cycle. Tumor response to treatment will be evaluated every 8 weeks.

Treatment with chemotherapy will continue for a total of 6 cycles unless there is evidence of disease progression, intolerable toxicity, or withdrawal of consent. Maintenance therapy will then continue until disease progression, intolerable toxicity or withdrawal of consent.

Potential biologic parameters to monitor anti-tumor activity of metronomic chemotherapy will be evaluated in 10 subjects. These biomarkers include: sequential determination of blood levels of VEGF, VEGFR2, thrombospondin-1, E-selectin, ICAM-1, and circulating endothelial cells and endothelial precursor cells.

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

Continue

Back

Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Conditions

Edit Conditions

[Help](#) [Definitions](#)

* Conditions or Focus of Study:

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.

If there are no conditions under study, enter brief description of focus of study instead.

Keywords:

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Conditions Complete

[Help](#) [Definitions](#)

* Conditions or Focus of Study:

Carcinoma, Non-Small-Cell Lung	<input type="button" value="x Delete"/>
Search MeSH , the National Library of Medicine's Medical Subject Headings, for valid condition terms.	
<input type="button" value="+ Add Condition"/>	

Keywords:

Non-Small Cell Lung	<input type="button" value="x Delete"/>
NSCLC	<input type="button" value="x Delete"/>
Drug X	<input type="button" value="x Delete"/>
Drug Y	<input type="button" value="x Delete"/>
<input type="button" value="+ Add Keyword"/>	

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Medical Subject Headings

 U.S. National Library of Medicine





Medical Subject Headings 2017

The files are updated each week day Monday-Friday by 8AM EST

FullWord ▾ **Exact** All Any

All Terms

- Main Heading (Descriptor) Terms
- Qualifier Terms
- Supplementary Concept Record Terms

MeSH Unique ID

Search in all Supplementary Concept Record Fields

- Heading Mapped To
- Indexing Information

Pharmacological Action

Search Related Registry and CAS Registry/EC Number/UNII Code (RN)

- Related Registry Search
- CAS Registry/EC Number/UNII Code (RN)

Search in all Free Text Fields

- Annotation
- ScopeNote

Sort by:

Relevance ▾

Results per Page:

20 ▾

Keywords Used For Search

[Help](#) [Definitions](#)

* Conditions or Focus of Study:

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.

Keywords:

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Interventional Study Design

[Help](#) [Definitions](#)

* Study Type:	Interventional
* § Primary Purpose:	--Select--
* Study Phase:	--Select-- <small>Use "N/A" for trials that do not involve drug or biologic products.</small>
* § Interventional Study Model:	--Select--
Model Description:	<input type="text"/>
* § Number of Arms:	<input type="text"/>
* § Masking:	<input type="checkbox"/> Participant <input type="checkbox"/> Care Provider <input type="checkbox"/> Investigator <input type="checkbox"/> Outcomes Assessor <input type="checkbox"/> No Masking <small>Check all roles that are masked or check No Masking.</small>
Masking Description:	<input type="text"/>
* § Allocation:	--Select-- <small>Select N/A for single-arm studies.</small>
* § Enrollment:	Number of Subjects: <input type="text"/> Type: --Select--

Continue

Back

Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Interventional Study Design Completed

[Help](#) [Definitions](#)

* Study Type: Interventional

* § Primary Purpose:

* Study Phase:

Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model:

Model Description:

* § Number of Arms:

* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor
- No Masking

Check all roles that are masked or check No Masking.

Masking Description:

* § Allocation:

Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type:

[Continue](#)

[Back](#)

[Quit](#)

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Arms

[Help](#) [Definitions](#)

+ Add Arm

Continue

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Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Arms Defined

[Help](#) [Definitions](#)

Arms:

* Arm Title:

Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

* Arm Type:

[*] Arm Description:

Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

* Arm Title:

* Arm Type:

[*] Arm Description:

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Interventions

[Help](#) [Definitions](#)

Arms: [No Arms have been specified.]

Interventions:

* Intervention Type:

* Intervention Name:

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

[*] Other Names:
(if any)

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

* § Intervention Description:

Do not repeat information already included in arm/group descriptions.

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Intervention Defined

[Help](#) [Definitions](#)

Arms: Experimental: Docetaxel & Bevacizumab
Active Comparator: Docetaxel

Interventions:

* Intervention Type:	Drug	
* Intervention Name:	Docetaxel & Bevacizumab	
	For a drug, use generic name if established. Use the same name as in the associated Arm/Group Description(s).	
[*] Other Names: (if any)	Avastin (Bevacizumab)	<input type="button" value="x Delete"/>
	Taxotere (Docetaxel)	<input type="button" value="x Delete"/>
	<input type="button" value="+ Add Other Name"/>	
	Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.	
* § Intervention Description:	A novel new combination treatment...	<input type="button" value="x Delete Intervention"/>
	Do not repeat information already included in arm/group descriptions.	
* Intervention Type:	Drug	
* Intervention Name:	Docetaxel	
[*] Other Names: (if any)	Taxotere (Docetaxel)	<input type="button" value="x Delete"/>
	<input type="button" value="+ Add Other Name"/>	
* § Intervention Description:	Standard Treatment...	<input type="button" value="x Delete Intervention"/>
<input type="button" value="+ Add Intervention"/>		

Arms & Interventions

[Edit](#)

Arms

Arm: Experimental: Docetaxel & Bevacizumab
Describe treatment for Drug X (Docetaxel) & Drug Y (Beverizumab)

Arm: Active Comparator: Docetaxel
Describe treatment for (Docetaxel)

[Edit](#)

Interventions

Intervention: Drug: Docetaxel & Bevacizumab
Other Names:
Avastin (Beverizumab)
Taxotere (Docetaxel)
A novel new combination treatment...

Intervention: Drug: Docetaxel
Other Names:
Taxotere (Docetaxel)
Standard Treatment...

[Edit](#)

Cross-Reference

Arms	Interventions	
	Drug: Docetaxel & Bevacizumab	Drug: Docetaxel
Experimental: Docetaxel & Bevacizumab Describe treatment for Drug X (Docetaxel) & Drug Y (Beverizumab)	✓	
Active Comparator: Docetaxel Describe treatment for (Docetaxel)		✓

✓ - Intervention is administered to patients in this Arm.

Outcome Measures

[Help](#) [Definitions](#)

* Primary Outcome Measure:

Outcome 1

Title:

Description:

Time Frame:

[*] Secondary Outcome Measures:
(if any)

Other Pre-specified Outcomes:

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Outcome Measures

Edit Outcome Measures

[Help](#) [Definitions](#)

* Primary Outcome Measure:

Outcome 1

Title:

Description:

Time Frame:

[*] Secondary Outcome Measures:
(if any)

Outcome 2

Title:

Description:

Time Frame:

Major & Advisory Issues

- Problems are now addressed by:
- Advisory – are suggestions to improve the clarity of the record
- Major Issues have to be addressed
- Priority for the participants to understand the language

Advisory Issues:

The Investigator's information in the Responsible Party data element is not properly formatted. Please provide the investigator's Official Title (e.g., Director, Head of Otolaryngology, Principal Investigator, Clinical Professor).

Major Issues:

1) The Time Frame does not appear to be specific and/or in the correct format.

The Time Frame "1 most" is not specific. Measures of change should specify two or more time points in the Time Frame to indicate the time points over which the change is assessed (e.g., baseline and 6 months).

Outcome Measure – Major Issue

7. TBS adjustment of FRAX scores for an enhanced fracture risk probability in pre and post-menopausal women undergoing bariatric surgery (Roux en Y vs. Gastric Sleeve). ▼ hide

The Trabecular Bone Score (TBS) is derived from the texture of the DXA image and has been shown to be related to fracture risk. Trabecular Bone Score (TBS) software will be used to adjust FRAX scores for an enhanced 10-year fracture risk probability (in %). FRAX adjusted for TBS is an algorithm derived from WHO FRAX calculation tool to adjust probability of fracture from clinical risk factors and BMD to account for TBS. The calculated probabilities of fracture have been shown to be more accurate when computed including TBS. TBS scores (in gradient of risk) ranges from 1.1% -1.9% coefficient of variation (C.V.)

[Time Frame: Baseline]

Comments [1]

Major Issues:

1) The Time Frame appears to be inconsistent with information provided here or in other parts of the record.

The Time Frame appears to be inconsistent with information provided in the Measure Description. Please review and revise as appropriate.

2) The Primary Outcome Measure Time Frame includes more than one time point, each of which appears to describe a separate measure.

The Primary Outcome Measure Title includes more than one time point. Each Outcome Measure should typically only specify a single time point of assessment. A common exception to this is a measure assessing change between two time points (e.g., "Change from Baseline Systolic Blood Pressure at 6 months"). If the Outcome Measure(s) are assessing a change, please revise the Outcome Measure Title(s) to specify that "change" is being assessed. If not assessing change, please revise and enter additional Outcome Measures so that there is only one Time Frame per Outcome Measure.

Eligibility: Inclusion & Exclusion

Edit Eligibility

[Help](#) [Definitions](#)

* Sex:

Biological sex of eligible participants.

[*] Gender Based:

If applicable, indicate if participant eligibility is based on self-representation of gender identity.

* Age Limits: Minimum: Maximum:

* § Accepts Healthy Volunteers:

* Eligibility Criteria:

Inclusion Criteria:

-

Exclusion Criteria:

-

[Special Characters](#)

Overall Contacts

[Help](#) [Definitions](#)

[Edit](#)

Overall Contacts

Central Contact Person:

Central Contact Backup:

Overall Study Officials:

[Copy locations...](#) from a master list, extracted from this organization's records.

[+ Add Location](#)

Information is required

[Continue](#)

[Back](#)

[Quit](#)

Overall Contacts

Edit Overall Contacts

[Help](#) [Definitions](#)

* Central Contact Person: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Central Contact Backup: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Overall Study Officials:

Study Location

Edit Location

[Help](#) [Definitions](#)

* Facility: Name:
City:
State/Province: ZIP/Postal Code:
Country:

* Site Recruitment Status:
Recruitment status for this individual location.

* Facility Contact: First Name: MI: Last Name: Degree:
Phone: Ext: Email:
Facility Contact Backup: First Name: MI: Last Name: Degree:
Phone: Ext: Email:
Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Investigators:

Study References

Edit References

[Help](#) [Definitions](#)

Citations:

+ Add Citation

Links:

+ Add Link

Available Study Data/Documents:

+ Add Data/Document

References

Citations

Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

PubMed Identifier

Definition: PMID for the citation in MEDLINE

Citation

Definition: bibliographic reference in NLM's MEDLINE format

Limit: 2000 characters.

Results Reference

Definition: Indicate if the reference provided reports on results from this clinical study.

Links

Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

URL

Definition: complete URL, including `http://` or `https://`

Limit: 3999 characters.

Description

Definition: title or brief description of the linked page.

Limit: 254 characters.

Study Data/Documents

Available Study Data/Documents

Definition: Study data sets and documents that are being shared. Provide the following information for each:

Type

Definition: The type of data set or document being shared.

- Individual Participant Data Set
- Study Protocol
- Statistical Analysis Plan
- Informed Consent Form
- Clinical Study Report
- Analytic Code
- Other (specify)

URL

Definition: The Web address used to request or access the data set or document.

Limit: 3999 characters.

Identifier

Definition: The unique identifier used by a data repository for the data set or document.

Limit: 30 characters.

Comments

Definition: Additional information including the name of the data repository or other location where the data set or document is available. Provide any additional explanations about the data set or document and instructions for obtaining access, particularly if a URL is not provided.

Limit: 1000 characters.

Record Summary

Record Summary

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → **Public**

[Reset to In-Progress...](#)

Next Step: Correct Error(s)

Record Owner: mvetrano

Last Update: 10/02/2017 11:19 by mvetrano

Initial Release: 09/13/2017

Last Release: 10/02/2017 [Receipt \(PDF\)](#)

Results Expected: No later than December 2021

Access List: [jomalley] [Edit](#)

Upload: Allowed [Edit](#)

PRS Review: [Review History](#)

Public Site: Last Public Release: 10/02/2017 [View on ClinicalTrials.gov](#)

FDAAA: ACT

[Spelling](#) [Preview](#) [Draft Receipt \(PDF\)](#) [RTF](#) [Download XML](#) Admin Only: [Copy Protocol](#) [Change Owner](#)

Open Protocol Section

Identifiers: NCT03303469 Unique Protocol ID: F170519002

Brief Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation: [18F]Fluoromisonidazole (FMISO) Imaging

Module Status:

- Study Identification: ✓ 1 Note
- Study Status: 1 Error 1 Note
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓
- Study Design: ✓
- Arms and Interventions: ✓ 5 Notes
- Outcome Measures: ✓ 1 Note
- Eligibility: ✓
- Contacts/Locations: ✓

Protocol Section

Open

Protocol Section

Identifiers: NCT03303469 Unique Protocol ID: F170519002

Brief Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation: [18F] Fluoromisonidazole (FMISO) Imaging

Module Status:

Study Identification: ✓ 1 Note

Study Status: 1 Error 1 Note

Sponsor/Collaborators: ✓

Oversight: ✓

Study Description: ✓

Conditions: ✓

Study Design: ✓

Arms and Interventions: ✓ 5 Notes

Outcome Measures: ✓ 1 Note

Eligibility: ✓

Contacts/Locations: ✓

IPD Sharing Statement:

References:

Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID: F170519002

Brief Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation. [18F] Fluoromisonidazole (FMISO) Imaging
 ◆ NOTE: Brief Title should have no more than 120 characters.

Official Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation. [18F] Fluoromisonidazole (FMISO) Imaging

Secondary IDs:

[Edit](#) **Study Status**

Record Verification: October 2017

Overall Status: Recruiting

Study Start: October 30, 2017 [Anticipated]
 ◆ NOTE: Study Start Date should be updated and changed to Actual once the first participant is enrolled.
 ❌ ERROR: Anticipated Start Date cannot be in the past.

Primary Completion: December 2020 [Anticipated]

Study Completion: December 2021 [Anticipated]

[Edit](#) **Sponsor/Collaborators**

Sponsor: University of Alabama at Birmingham

Responsible Party: Principal Investigator
 Investigator: Janis P. O'Malley [jomalley]
 Official Title: Principal Investigator, Professor of Radiology
 Affiliation: University of Alabama at Birmingham

Collaborators:

[Edit](#) **Oversight**

U.S. FDA-regulated Drug: Yes

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: Yes

IND/IDE Information: FDA Center: CDER
 IND/IDE Number: 136281
 IND Serial Number:
 Has Expanded Access: No

Human Subjects Review Board Status: Approved Approval Number: 170519002
 Board Name: University of Alabama at Birmingham IRB

[Edit](#) **Study Design**

Study Type: Interventional [Change...]

Primary Purpose: Diagnostic

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 20 [Anticipated]

[Open](#) **Arms and Interventions**

Arms	Assigned Interventions
Experimental: FMISO PET imaging post TACE and SBRT FMISO imaging at baseline, post-TACE and post-SBRT	Drug: FMISO FMISO PET/CT imaging at baseline Drug: FMISO FMISO PET/CT post TACE Drug: FMISO FMISO PET/CT post SBRT

◆ NOTE: Intervention Other Names have not been specified
 ◆ NOTE: Intervention Other Names have not been specified
 ◆ NOTE: Intervention Other Names have not been specified
 ◆ NOTE: More than one Intervention has the name 'FMISO'
 ◆ NOTE: More than one Intervention has the name 'FMISO'

[Edit](#) **Outcome Measures**

Primary Outcome Measure:

- Quantitate HCC tumor hypoxia at baseline using FMISO PET.
 Perform PET/CT imaging using FMISO at baseline to measure tumor hypoxia
 [Time Frame: At baseline]
- Measure changes in HCC tumor hypoxia and blood flow after TACE, prior to radiotherapy.
 Perform PET/CT imaging using FMISO post-TACE and prior to SBRT to determine tumor hypoxia
 [Time Frame: 1 month post-TACE procedures and prior to SBRT]
- Measure changes in treated HCC tumor hypoxia following TACE and radiotherapy
 Perform PET/CT imaging using FMISO post-SBRT to determine tumor hypoxia
 [Time Frame: 1 month post-SBRT]

◆ NOTE: Normally only one Primary Outcome Measure is specified.

Results Section

[Open](#)

Document Section

Documents that may be uploaded include:

- Study Protocol and Statistical Analysis Plan - only required with results information for studies with a Primary Completion Date on or after January 18, 2017
- Informed Consent Form - optional under 42 CFR Part 11, but may be required by funder, including if study is conducted or supported by a Common Rule (45 CFR 46) department or agency

Uploaded PDF/A Documents:

Results Section

[Enter Results](#) Results submission is required by FDAAA 801 for certain [applicable clinical trials](#) of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

[Delay Results](#) For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: [When Do I Need to Register and Submit Results?](#)

Need help with Results? [Contact ClinicalTrials.gov PRS](#) to request one-on-one assistance from one of our experts.

Results Section

[Open](#)

Document Section

Only certain studies need to have study documents uploaded.

- Full study protocol and statistical analysis plan -- required with results information submission for studies with a Primary Completion Date on or after January 18, 2017
- Informed consent forms - optional for all studies

Uploaded PDF/A Documents:

[Open](#)

Results Section

Module Status:

- Participant Flow: ✓
- Baseline Characteristics: ✓
- Outcome Measures: ✓
- Adverse Events: ✓ 1 Note
- Certain Agreements: ✓
- Limitations and Caveats:
- Results Point of Contact: ✓

Registration Updates

- Required annually (12months)
- “Record Verification” indicates the study data is correct and current.

Edit Study Status

[Help](#) [Definitions](#)

* Record Verification Date:

Month: Year:

* Overall Recruitment Status:

Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Registration Updates

- Responsible Parties should update their records within **30 days of a change** to any of the following:
- **Recruitment Status** and **Overall Recruitment Status** data elements on ClinicalTrials.gov
- **Completion Date** (See **Primary Completion Date** data element on ClinicalTrials.gov)

Study Status

Record Verification: October 2017

Overall Status: Not yet recruiting

Study Start: October 2017 [Anticipated]

⚠ WARNING: Start Date October 2017 should not be in the past for a study that is Not yet recruiting.

❌ ERROR: Anticipated Start Date cannot be in the past.

Primary Completion: November 2021 [Anticipated]

Study Completion: November 2021 [Anticipated]

Recent & Upcoming Changes

- ICMJE data sharing plan requirements:
 - *Include a **data sharing statement** in all manuscripts submitted to member journals as of 7/1/18, and
 - *Include a **data sharing plan** in all trial registrations (on ClinicalTrials.gov) for trials enrolling participants on or after 1/1/19

New ICMJE Policy

Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*		Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes				
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.		Plan to Share IPD:		
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code				
When will data be available (start and end dates)?	Immediately following publication. No end date.		IPD Sharing:		
With whom?	Anyone who wishes to access the data.				
For what types of analyses?	Any purpose.				
By what mechanism will data be made available?	Data are available indefinitely at (Link to be included).				

Edit IPD Sharing Statement

[Help](#) [Definitions](#)

Plan to Share IPD: Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Plan Description: Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

Supporting Information: Check all types of supporting information that will be shared.

- Study Protocol
- Statistical Analysis Plan (SAP)
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Analytic Code

Time Frame: Describe when the data will become available and for how long.

Access Criteria:

URL: Web address (if any) with additional information about the plan to share IPD.

* Required
 § Required if Study Start Date is on or after January 18, 2017
 [*] Conditionally required (see Definitions)

* These examples are meant to illustrate a range of, but not all, possible data sharing statements.

IPD Sharing Statements

- Required in manuscripts starting in July 2018
- Required in the CTgov Registration for studies than begin enrolling on/after January 1, 2019
- Point to ICMJE link (above) for types of entries ICMJE expects
- **Why it matters to investigators who want to publish – “editors may take into consideration data sharing statements when making editorial decisions”**
- Once education material is ready, we will send it to the investigators we have been tracking, and ask them to review their entries and update as necessary
- We will continue sending education material for the near term as entries are made in this module
- We don't intend to do this indefinitely, but the publication issue is important enough to investigators that we plan to keep with it for at least the near future

Common Rule

- Effective date of the revised Common Rule is January 19, 2019
- First time since it was issued in 1991
- Effort started in 2011 with 2 primary goals:
- Modernize and enhance the protections for human research participants
- Reduce the unnecessary burden/ambiguity for researchers

Common Rule

- Single Institutional Review Board (IRB) for multi-institutional research studies
- Improved consent forms and the process of obtaining consent:
- Begin with a “Concise & Focused” presentation of this key information that will most likely help someone make a decision about whether to participate in a study.
- Provide potential research subjects with a better understanding of a project’s scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.
- One version of the consent form used to enroll participants in federally funded clinical trials will be posted on a public website (CT.gov).

Common Rule

- For studies on stored identifiable data or biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- Establishment of new exempt categories of research based on the level of risk they pose to participants (allows IRBs to focus their attention on higher risk studies).
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such reviews do very little to protect subjects.

FDAAA Noncompliance

[New] Tracking FDAAA Noncompliance: AllTrials Calls on FDA to Levy Fines 19 February 2018

The international initiative AllTrials on Monday unveiled a new tracking tool to highlight clinical trial sponsors who fail to publish results as required by the FDA Amendments Act of 2007 (FDAAA). [\[Read More...\]](#)

- https://www.raps.org/news-and-articles/news-articles/2018/2/tracking-fdaaa-noncompliance-alltrials-calls-on-f?utm_source=Email&utm_medium=Informz&utm_campaign=Informz-Emails&zs=kQ0jK1&zl=vhMJ4

FDAAA TrialsTracker



Single trials

Ranked sponsors

FAQ

Blog

Fund this work!

@FDAAATracker

Who's sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively comes into force from Feb 2018. The FDA are not publicly tracking compliance. So we are, here.



Filter trials by status:

Overdue Ongoing Reported Reported (late)

Search

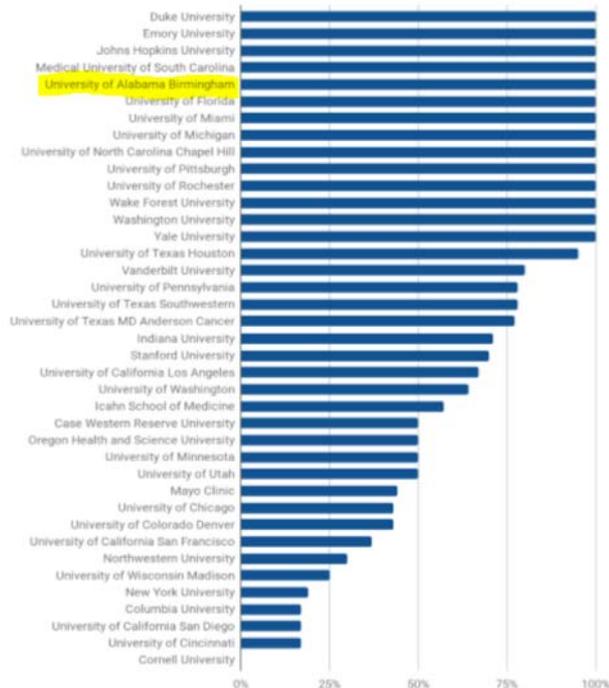
Showing 1 to 100 of 216 entries

Status	Sponsor	Trial ID	Title	Completion date	Days overdue
overdue	Alcresta Therapeutics, Inc.	NCT02750501	Absorption and Safety With Sustained Use of Relizorb Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding [pACT]	2017-03-30	31

Reporting Results - 2019

Legal Compliance by US Universities

Chart 1: Summary results posted for due clinical trials subject to FDAAA, % by university



Reporting Results Since 2017

- 14 universities achieved a reporting rate of 10%
- 31% of those trials are still missing results
- Violators:
 - MD Anderson – 77%
 - Mayo – 42%
 - UC SF -37%
 - New York – 21%

Reporting Results - 2019

Continued... “Sharing Results Should Not Be Optional”

OPINION POLICY-ISH

Academic Medical Centers Get An F In Sharing Research Results

February 23, 2016 - 1:59 PM ET

HARLAN KRUMHOLTZ



Who will check the study results if they aren't made public?
@mrs @ash@carle

“Not reporting results violates the basic principle of the scientific method. It hurts patients, society and science. It dishonors the people who gave their consent and bore the risk of participating...”

The holding back of the results impedes progress toward scientific breakthroughs, corrupts the medical literature and wastes research funding.”

Registering/Reporting

- 3 Key Facts To Remember:
 - Register
 - Update
 - Report
-
- Policy specifies that "the registration/reporting of all interventional trials is a **scientific, ethical and moral responsibility.**"

Need Assistance??

- We are always available, please call if in doubt:
- Denise McKenzie, dhmckenzie@uabmc.edu
Phone: 934-9360
- Dorothy Shaw, dshaw@peds.uab.edu
Phone: 996-7832
- Hina Amanullah, hamanullah@uabmc.edu
Phone: 934-3796