

Stem Cell Research Oversight (SCRO)

Regulatory Services for Clinical Trials

ClinicalTrials.gov, FDA INDs and IDEs

Elizabeth Massey Gendel, PhD

Director, Research Compliance

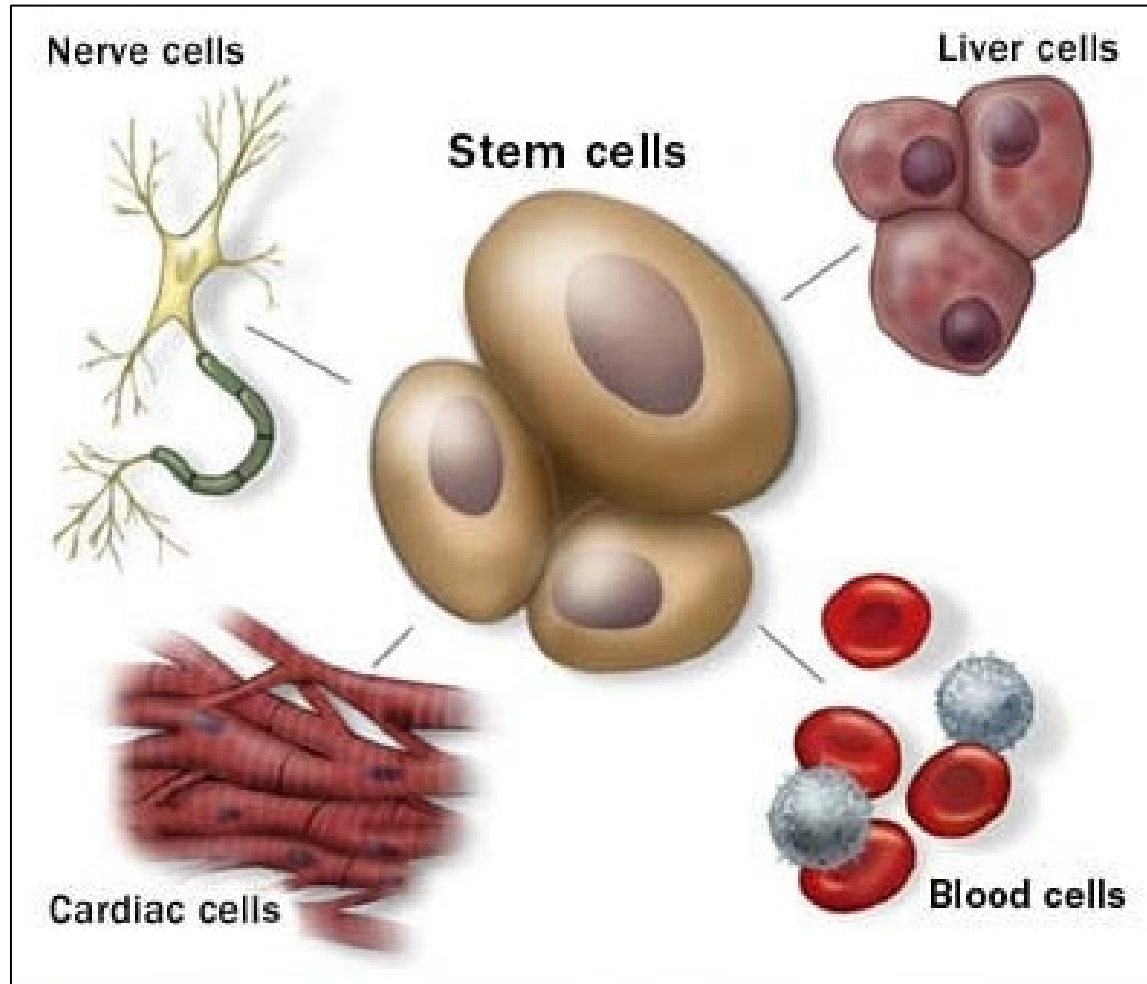
Vice Chair, Stem Cell Research Oversight Committee (SCRO)

Clinical Trials Resource Center (CTRC)

The University of Texas Health Science Center at Houston

Stem Cell Research Oversight (SCRO)

Stem cells are the body's raw materials — they are cells from which all other cells with specialized functions are generated



There are many different types of stem cells.

SCRO Committee review is only required for certain human stem cell types.

HOOP 200 – Review of Research

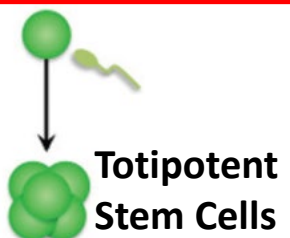
H. Human Stem Cell Research Oversight (SCRO) Committee

All research involving **human embryonic stem cells (hESCs)** or **human induced pluripotent stem cells (hiPSCs)** conducted at the university by its employees and/or involving use of its facilities or resources must be reviewed and approved by the Human Stem Cell Research Oversight (SCRO) Committee before it is initiated. Some research involving hESCs or hiPSCs may require additional approval by the AWC, IBC and/or CPHS. For more information on the application process, please contact the SCRO office at scro@uth.tmc.edu.

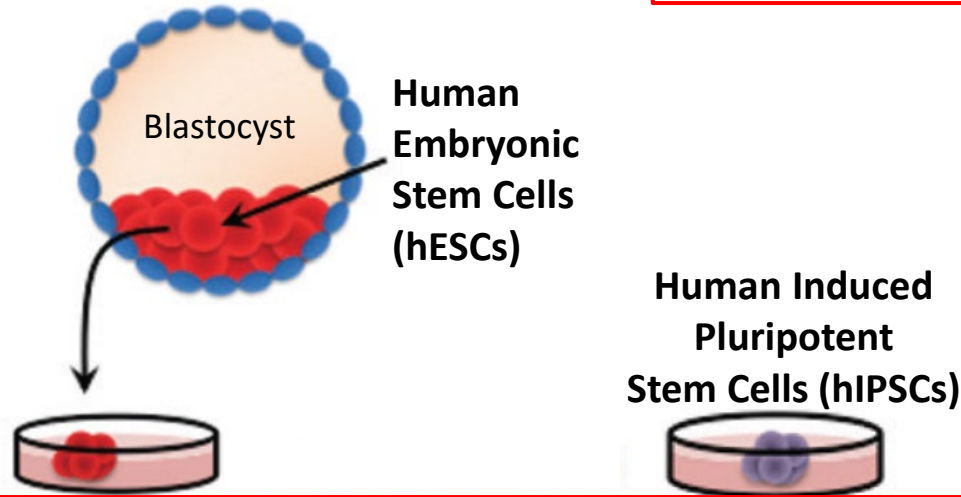
The *SOURCE* and *POTENCY* of the Stem Cell Line Determine Whether SCRO Review is Required

SCRO review is required for research involving:
human gametes
human embryos
human totipotent stem cells
human pluripotent stem cells (hESCs or hiPSCs)

Totipotent



Pluripotent

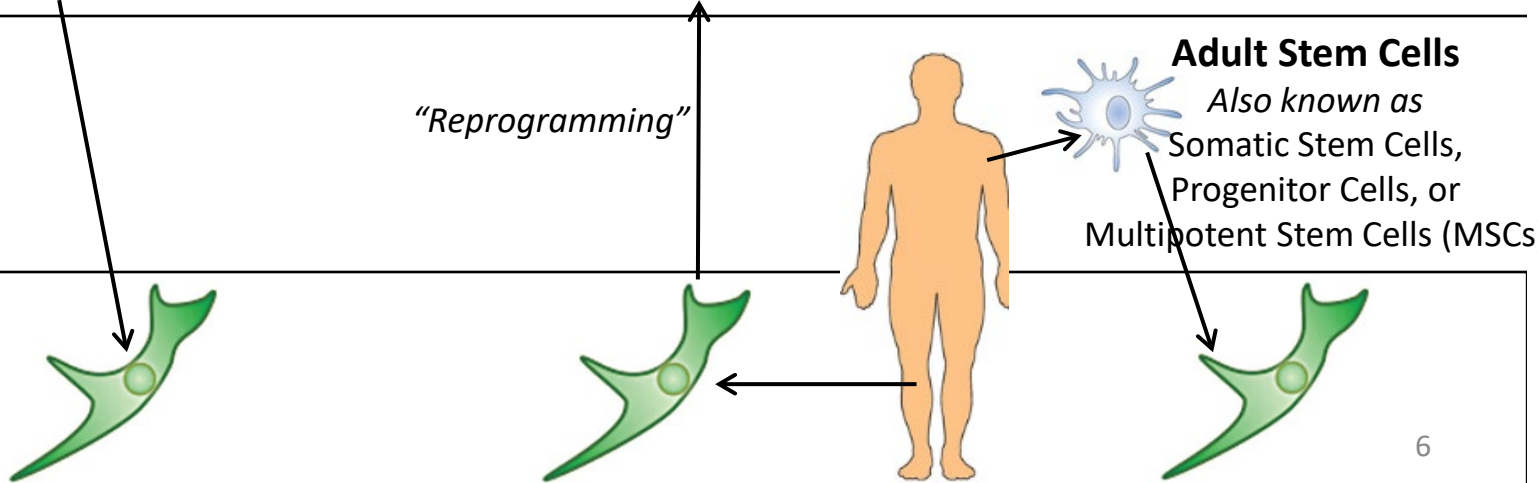


Multipotent

Oligopotent

Unipotent

Specialized Cells



SCRO Review is Required for Research Involving the Following (or their Derivatives)

	Generation for Research Purposes	Research Use
human embryonic stem cells (hESCs)	YES	YES
human induced pluripotent stem cells (hiPSCs)	<i>No</i>	YES
human totipotent stem cells	YES	YES
human gametes	YES	YES
human embryos	YES	YES
human adult stem cells (non-neural)	<i>N/A</i>	<i>No</i>
human neural stem cells, of any source	<i>depends on source</i>	YES

Reach out to Elizabeth Gendel to discuss whether SCRO review is required for your project.

Elizabeth.M.Gendel@uth.tmc.edu

To Avoid Delays in Release of Grant Funds:

- Ensure Review and Approval (R&A) Form Submitted to SPA Correctly Indicates Stem Cell Involvement and Correctly Indicates Stem Cell Types
- Ensure Project is Submitted to SCRO Well Before Grant Funding is Received

R&A Form within UTSTART

INSTITUTIONAL COMPLIANCE

Yes No * Does project involve human subjects (or material or data from human subjects)?

Yes No * Does project involve stem cells?

* type(s):
embryonic iPSC adult

Yes No * Does project involve vertebrate animals?

Yes No * Does project involve biological agents, infectious agents, or recombinant or synthetic nucleic acid?

Yes No * Does project involve radioactive materials?

Yes No * Does project involve toxic or physically dangerous chemicals or carbon or silica based nanochemistry?

Stem Cell Research Oversight (SCRO) Website

<https://inside.uth.edu/scro/>

- SCRO Application
- Document “SCRO Policy and Procedures”
- Document “Guidelines for SCRO Review”

Levels of SCRO Review and Timelines

- **Expedited Review** (about 1 week turnaround time)
 - *In vitro* work with hESC lines that are approved by NIH or previously approved by UTHealth SCRO
 - *In vitro* work with hiPSC lines
 - Introduction of hESCs (NIH- or UTHealth SCRO-approved) or hiPSCs to animals if:
 - *Cells are transplanted to postnatal animals and there is no likelihood of contributing to the central nervous system or germ line (e.g., the development of a teratoma to evaluate pluripotency).*
- **Full Committee Review** (about 2-week to 2-month turnaround time, but new technology or new ethical issues may take longer)
 - Generation of brain organoids
 - Transplantation of hESCs or hiPSCs to animals if:
 - *There is a likelihood of transplanted cells contributing to the central nervous system or germ line.*
 - Transplantation of hESCs or hiPSCs to humans
 - Any work with hESCs that are not NIH approved or previously approved by UTHealth SCRO
 - Lines listed on NIH Registry are eligible for use in NIH-supported research: https://grants.nih.gov/stem_cells/registry/current.htm
 - Derivation of hESCs
 - Creation of embryos, gametes, or totipotent cells

Stem Cell Research Oversight (SCRO)

Contact Information

- *SCRO Office*
 - SCRO@uth.tmc.edu
 - (713) 500-3587
- *Elizabeth Gendel*
 - Elizabeth.M.Gendel@uth.tmc.edu
 - (713) 500-3587

Regulatory Services for Clinical Trials

FDA INDs and IDEs

ClinicalTrials.gov

Regulatory Services for Clinical Trials

- **IRB submissions (full board) are reviewed to determine:**
 - If a study must be registered at ClinicalTrials.gov
 - If a study of a drug, biological product, or device might need to receive FDA approval before it begins (*that is, if an IND or IDE is needed*)
- **Either the Clinical Trials Resource Center (CTRC) or CPHS will notify your study team if any of the above are required**
- **CTRC can assist with:**
 - ClinicalTrials.gov Registration, Updates, and Results Entry
 - Preparation and Submission of Application to FDA for Approval to Study an Investigational Drug or Device (*that is, an IND or IDE application*), and Preparation of Subsequent IND and IDE Reports
 - Resources for Study Initiation and Management

Clinical Trials Resource Center (CTRC)

website - <https://www.uth.edu/ctrc/>

email - clinicaltrials@uth.tmc.edu

Sujatha Sridhar, MBBS - Associate Vice President, Research Compliance

Elizabeth Gendel, PhD - 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu

Shwetha Pazhoor, MS - 713-500-3578, Shwetha.Pazhoor@uth.tmc.edu

Jessica Martinez Alvarado, MPH - 713-500-3551, Jessica.L.Martinez@uth.tmc.edu

Clinical Trial-Related Newsletters and Forum

Contact CTRC at clinicaltrials@uth.tmc.edu to be
Added to Either Newsletter:

Weekly Clinical Research Coordinator Newsletter

Monthly ClinicalTrials.gov Newsletter

Clinical Coordinator Forum

12-1pm, 4th Wednesday of the Month

<https://www.uth.edu/ctrc/training/clinical-coordinator-forum>

FDA INDs and IDEs

An IND or IDE Application Must be Submitted to FDA for Certain Clinical Studies

- An **Investigational New Drug (IND)** application must be submitted to FDA for certain studies involving drugs or biologic products
- An **Investigational Device Exemption (IDE)** application must be submitted to FDA for certain studies involving medical devices

Elizabeth Gendel and Jessica Martinez of CTRC Assist with Submissions to FDA

Clinical Trials Resource Center (CTRC) - clinicaltrials@uth.tmc.edu
Elizabeth Gendel - 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu
Jessica Martinez - 713-500-3551, Jessica.L.Martinez@uth.tmc.edu

FDA INDs and IDEs

Helpful Tip

- **To avoid delays with study start-up, consider ASAP whether your study involves something FDA views as a “drug” or “device” and whether an IND or IDE might be required**
 - If a product is given to or applied to humans, and the study aims to look at the effect of that product on study participants re: *“diagnosis, cure, mitigation, treatment, or prevention of disease”* or *“affect [on] the structure or any function of the body,”*
 - then FDA may consider that product to meet the definition of “drug,” “biologic,” or “medical device.” If so, then an IND or IDE application might be required.
 - Some examples that may come as a surprise:
 - Products not sold as “drugs” but used as “drugs” [i.e., Supplements, Vitamins, Aromatherapy. Human Tissue Products]
 - Products not sold as “medical devices” but used as “medical devices” [i.e., Virtual Reality Headsets]
 - Software, Algorithms, Artificial Intelligence, or Mobile Apps used as “medical devices” [i.e., Diagnostic Algorithms]

FDA INDs and IDEs

Reporting

- **For studies conducted under an FDA IND or IDE held by the UTHealth PI, the UTHealth PI is responsible for submitting various reports to FDA, per the regulations:**
 - Annual Reports
 - Safety Reports
 - Protocol Amendments
 - Changes to Investigators
 - Changes to the Study Product
 - New Pharmacology-Toxicology or New Clinical Information
 - Withdrawal of the IND or IDE

There are specific requirements for what to submit and how to submit to FDA, with major differences between submissions for INDs (drugs) and IDEs (devices).

Elizabeth Gendel and Jessica Martinez Alvarado of CTRC Can Assist

ClinicalTrials.gov

ClinicalTrials.gov is a Public Database of Clinical Trials

The screenshot shows the ClinicalTrials.gov website. At the top left is the NIH logo and the text "National Library of Medicine National Center for Biotechnology Information". At the top right is a "PRS Login" button. Below the header is the "ClinicalTrials.gov" logo and a navigation menu with items: "Find Studies", "Study Basics", "Submit Studies", "Data and API", "Policy", and "About". On the right side of the navigation menu is "My Saved Studies (0)".

The main content area features a heading: "ClinicalTrials.gov is a place to learn about clinical studies from around the world." Below this is a yellow-bordered box containing a warning icon (a triangle with an exclamation mark) and the text: "The U.S. government does not review or approve the safety and science of all studies listed on this website." To the right of this text is a "+" sign. Below the warning text is a link: "Read our full [disclaimer](#) for details."


Below the disclaimer box is a search section titled "Focus Your Search (all filters optional)" with a link to "Expert Search". The search section contains several input fields:

- Condition/disease**: A text input field.
- Other terms**: A text input field.
- Intervention/treatment**: A text input field.
- Location**: A text input field with the instruction "Search by address, city, state, or country and select from the dropdown list".
- Study Status**: A section with two radio button options:
 - All studies
 - Recruiting and not yet recruiting studies

ClinicalTrials.gov is a Public Database of Clinical Trials

ClinicalTrials.gov
Find Studies ▾ Study Basics ▾ Submit Studies ▾ Data and API ▾ Policy ▾ About ▾ My Saved Studies (0) →

[Home](#) > Search Results

 **The U.S. government does not review or approve the safety and science of all studies listed on this website.** +
Read our full [disclaimer](#) for details.

Search Results **Card View** Table View

Viewing 1-10 out of 16,761 studies Sort studies by ● Relevance ▾

Showing results for: **Other terms: Breast Cancer**

Focus Your Search
(all filters optional)

Condition/disease ⓘ

Other terms ⓘ

Intervention/treatment ⓘ

Location
Search by address, city, state, or country and select from the dropdown list

Clear Filters (1) **Apply Filters**

None Selected ↓ 📖 RSS

NCT06134570 Enrolling by invitation

ALDH1A1 Expression in Invasive Mammary Carcinoma

Conditions
Breast Cancer

Locations
📍 Sohag, Egypt

NCT01522300 Terminated

Etude Tomos- Apport de la Tomosynthèse Dans le Bilan d'Extension locorégional préthérapeutique d'Une Tumeur du Sein : Recherche de multicentricité Tomos Study- Contribution of Tomosynthesis In Locoregional...

Conditions
Mammary Tumor

Once a Trial is Registered, it is Assigned an NCT

NCT # stands for National Clinical Trial #

NCT00000000

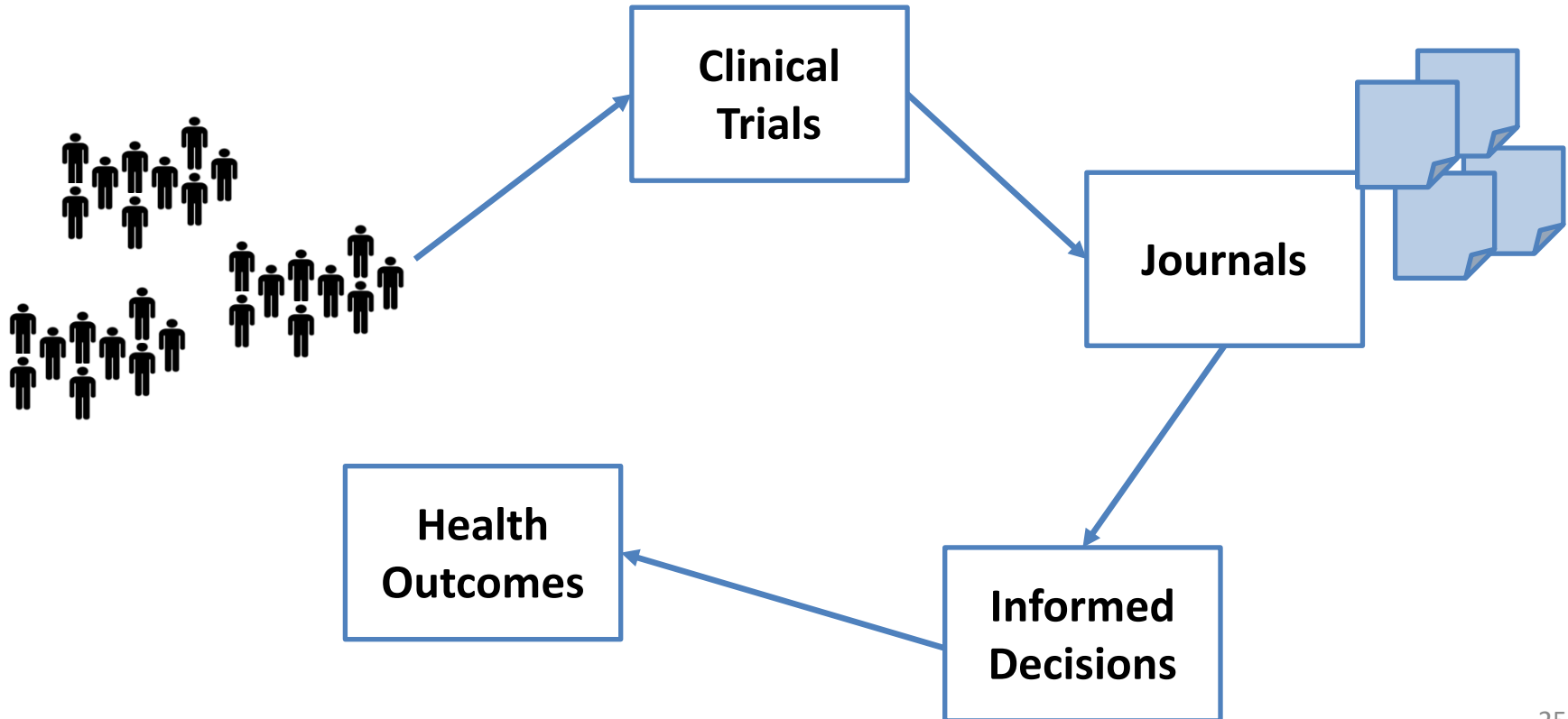
ClinicalTrials.gov Record Life Cycle

- **REGISTER**
 - *before enrollment begins*
- **UPDATE RECORD**
 - *At least once per year until data collection is completed*
- **ENTER RESULTS**
 - *1 year after the date that last piece of primary outcome data was collected*

Why Register and Report Results?

Public Benefits

- Contribute research results to medical knowledge
- Support evidence-based medical decision making
- Fulfill ethical obligations to participants
- Reduce publication and reporting biases



Why Register and Report Results at ClinicalTrials.gov?

- It's the law! *enforceable by fines*
- NIH funding can be terminated or withheld
- It can affect the ability to publish in a medical journals
 - ICMJE = International Committee of Medical Journal Editors
- An NCT # is required by CMS for claims for research-related procedures
- To Avoid Public Shaming for Late Results:
<https://fdaaa.trialstracker.net/>
- Required per UTHealth's HOOP 186
- Can serve as a recruiting tool

FDA Penalties for Late ClinicalTrials.gov Results

- FDA fines of **\$14,262** plus **\$14,262 per day thereafter**
- FDA performs inspections of ClinicalTrials.gov records

FDA Sends Noncompliance Letters to “Responsible Party”

1. FDA **Pre-Notice** of Noncompliance Letter
 - 30 days to correct
2. FDA **Notice** of Noncompliance Letter
 - 30 days to correct
 - Publicly identified in ClinicalTrials.gov
 - Letter publicly posted on FDA website
3. **Monetary Enforcement** by FDA
 - Up to **\$14,262** per day
 - Noted in ClinicalTrials.gov

FDA Website Lists Names of People/Companies Who Have Received Letters or Penalties

ClinicalTrials.gov - Notices of Noncompliance and Civil Money Penalty Actions

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[Email](#)
[Print](#)

Federal law requires responsible parties to submit registration and submission information to the [ClinicalTrials.gov data bank](#) for certain applicable clinical trials. Federal law also requires a submitter of certain applications/submissions to the above-referenced requirements have been met for applicable clinical trials in such applications/submissions. FDA has the authority to issue a Notice of Noncompliance to a responsible party for failure to comply with certain requirements including:

- Failing to submit required clinical trial information
- Submitting false or misleading clinical trial information

FDA also has the authority to issue a Notice of Noncompliance to a responsible party that failed to submit or knowingly submitted a false certification to FDA.

FDA has authority to assess civil money penalties for these violations if a responsible party does not take adequate corrective action within 30 days after receiving a Notice of Noncompliance regarding failure to submit required information, that responsible party may be subject to additional civil money penalties.

FDA will take into consideration any corrective action that is taken by a responsible party after receiving a Notice of Noncompliance when considering civil money penalties. See [Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank](#) and [21 CFR part 17](#) for more information.

Link to All Notices:
<https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions>

Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Light Sciences Oncology	NCT02326454	7/19/2023	11/22/2023	
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accutis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	

Link to All Pre-Notices:
<https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/pre-notices-potential-noncompliance>

On 8/31/21, FDA Issued the First Notice of Noncompliance *to an Individual Investigator*



NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND E-MAIL

August 31, 2021

Andrey Petrikovets, M.D.
1513 South Grand Avenue, Suite 400
Los Angeles, California 90015

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "ICE-T Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Same Day Vaginal Pelvic Reconstructive Surgery: A Randomized Controlled Trial" (NCT03052816)
FDA Reference Number: CDER-2020-109

Dear Dr. Petrikovets:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (a part of the National Institutes of Health), for the above-referenced clinical trial. You are the "responsible party"¹ for the above-referenced clinical trial, which is an "applicable clinical trial"² that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay, a request for an extension of good cause, or a request for a waiver of the requirements for submission of results information.³

[Link to FDA Letter](#)

[Link to STAT article](#)

Effects on Federal Funding

- Federal grant funding can be withheld
- Suspension or termination of NIH funding
- May affect future NIH funding decisions
- Enforcement by NIH at the institutional level


“NIH will withhold clinical trial funding to grantee institutions if the agency is unable to verify adequate registration and results reporting from all trials funded at that institution.”

JAMA: Toward a New Era of Trust and Transparency in Clinical Trials - Kathy Hudson, Michael Lauer, Francis Collins

<http://jamanetwork.com/journals/jama/fullarticle/2553888?guestAccessKey=554e0981-9434-45f2-b122-d0e673cd1182>

Recent NIH Actions to Enhance Compliance

NIH is Sending Letters to Institutions' Sponsored Projects Offices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

[REDACTED]

[REDACTED]

Dear [REDACTED]

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

[REDACTED]

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), [NIH Grants Policy Statement, Section 4.1.3.1](#).

[REDACTED]

Compliance with the NIH policy is a term and condition of this grant award; however, the [REDACTED] has been unable to verify that results information has been submitted to ClinicalTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Science 2023

article:

<https://www.science.org/content/article/nih-toughens-enforcement-delayed-clinical-trials-reporting>

Steady Stream of Public Shaming

FDA and NIH let clinical trial sponsors keep results secret and break the law

By Charles Piller | Jan. 13, 2020, 11:00 AM

Science

- Robert Califf et al., NEJM [report](#) (2015)
- Charles Piller, STAT [report](#) (2015)
- Harlan Krumholz, BMJ [report](#) (2016)
- Ben Goldacre, first TrialsTracker [report](#) (2016)
- Charles Piller/Talia Bronshtein, STAT [report](#) (2018)
- Holly Fernandez Lynch, STAT [editorial](#) (2018)
- Ben Goldacre of University of Oxford, [FDAAA TrialsTracker site](#) launched (2018)
 - [Open letter to FDA](#)
 - [BMJ unreported trial of the week](#)
- TranspariMED and UAEM [report](#) (2019)
 - Nature [report](#) on TranspariMED/UAEM findings (2019)
- John P.A. Ioannidis of Stanford, Annals of Internal Medicine [report](#) (2019)
 - Harlan Krumholz of Yale, Annals of Internal Medicine [editorial](#) (2019)
- Charles Piller, Science [report](#) (2020)
- Charles Piller, NY Times [editorial](#) (2021)
- TranspariMED and UAEM [report #2](#) (2021)
- Reshma Ramachandran, JAMA [report](#) (2021)

The New York Times

OPINION

Biden Made a Promise to Scientists. He Can Still Keep It.

Researchers who receive federal help consistently fail to report their results to the public. The government should hold them accountable.

April 8, 2021

Public Shaming Website for Late Results

<https://fdaaa.trialstracker.net/>



Single trials

Ranked sponsors

FAQ

Blog

Fund this work!

@FDAATracker



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 came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.

Trials reported

16135 out of 20855



Percent reported

77.4%



US Govt could have imposed fines of at least

\$62,988,588,969



Fines claimed by US Govt

\$0



Filter trials by status:

On Overdue On Overdue (cancelled results) Off Ongoing Off Reported On Reported (late)

Search

Showing 1 to 100 of 11,310 entries

↑↓ Status	↑↓ Sponsor	↑↓ Trial ID	↑↓ Title	↑↓ Completion date	↑↓ Days overdue
overdue	Corcept Therapeutics	NCT03437941	Phase 1/2a Dose-Escalation and Expansion Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CORT125281 With Enzalutamide in Patients With Metastatic Castration-Resistant Prostate Cancer	2023-01-09	31
overdue	Columbia University	NCT04528459	Computer-Assisted Surgery for Internal Fixation of Peritrochanteric Femur Fractures: A Randomized Controlled Study	2023-01-09	31

Summary – Potential Consequences of Noncompliance with Registration and Results Reporting Requirements

- Letters of Noncompliance and/or Fines from FDA
- Effects on NIH and other Federal Funding
- NIH Withholds Funding from Entire Institution
- NIH Sends Letter to Institutional Official
- Journals Won't Publish Reports of the Trial
- Trial Listed on Public Shaming Site
- Institution Receives Lower Ranking in National Report of Results Entry Compliance

UTHealth's ClinicalTrials.gov Policy and Procedures

<https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm>

PURPOSE:

- Ensure Compliance with Law and NIH Policy
- Avoid Consequences of Non-Compliance
 - *FDA Letters of Non-Compliance and Fines*
 - *Effects on NIH and other Federal Funding*
 - *NIH Withholds Funding from Entire Institution*
 - *NIH Sends Letter to Institutional Official*
 - *Journals Won't Publish Reports of the Trial*
 - *CMS consequences (an NCT # is required by CMS for claims for research-related procedures)*
 - *Institution Receives Lower Ranking in National Report of Results Entry Compliance*
 - *Public shaming*

UTHealth's ClinicalTrials.gov Policy and Procedures

<https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm>

- **Policy**

- What needs to happen, by who, and by when
- Responsibilities of UTHealth PIs

- **Procedures**

- How responsibilities will be met
- How CTRC can help
- How noncompliance will be handled

The Clinical Trials Resource Center (CTRC) Assists with ClinicalTrials.gov

CTRC - clinicaltrials@uth.tmc.edu

Elizabeth Gendel, PhD - 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu

Shwetha Pazhoor, MS - 713-500-3578, Shwetha.Pazhoor@uth.tmc.edu

Jessica Martinez Alvarado, MPH - 713-500-3551,
Jessica.L.Martinez@uth.tmc.edu

Find Guidance on the CTRC ClinicalTrials.gov website:

<https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm>

ClinicalTrials.gov Process at UTHealth

- **DETERMINATION** - During initial IRB review, Elizabeth Gendel reviews studies that go to the full-board IRB to determine if the study must be registered at ClinicalTrials.gov
 - *Note that expedited studies are not reviewed, but be aware that some expedited studies must be registered*
- **REGISTRATION** - Shwetha Pazhoor notifies study teams if a full-board study must be registered, and provides assistance
- **UPDATES** - Jessica Martinez Alvarado reaches out about updates, and provides assistance
- **RESULTS ENTRY** - Jessica Martinez Alvarado and Elizabeth Gendel reach out about results entry, and provide assistance

Which Studies are Required to Be Registered at ClinicalTrials.gov?

- In general, all “Clinical Trials,” defined as:
 - **A research study in which human subject(s) are assigned to an intervention to evaluate the effect of the intervention on a health-related outcome**
 - **Interventional = Subjects assigned to an intervention as part of a study protocol (*and not as part of routine medical care*)**

Because expedited studies are not reviewed for registration needs, study teams will need to consider whether an expedited study needs to be registered.

Contact Elizabeth Gendel for guidance: 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu

To Help You Keep Track of ClinicalTrials.gov Deadlines, Keep this Guidance PDF on Hand

Download from CTRC website at this link: <https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm>

ClinicalTrials.gov DUE DATES

<https://register.clinicaltrials.gov/>

1. **Registration:** no later than 21 days after enrollment of first participant (per the law and NIH); at or before time of first patient enrollment (per ICMJE journals)
2. **Updates:** at least once per year until the record is closed out; update as soon as changes are made, especially “Recruitment Status” and “Primary Completion Date”
3. **ICF Upload (federally-supported clinical trials):** after trial is closed to recruitment and no later than 60 days after the last study visit by any subject
4. **Results Entry and Protocol Upload:** no later than 1 year after the “Primary Completion Date,” which is defined as *“the date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated”*; contact CTRC at the time of the Primary Completion Date

For assistance with any of the above, please contact CTRC at clinicaltrials@uth.tmc.edu.

Protocol Must Clearly List Primary and Secondary Outcome Measures, *with Timepoints for Each Outcome Measure*

See guidance PDF [at this link](#), as well as guidance within the Complex Protocol Template [at this link](#),
and contact Elizabeth Gendel for further guidance

- Study objectives are distinct from study outcome measures
- Outcome measures (also called endpoints) are specific measurements or observations used to assess the effect of the study intervention
 - *e.g., specific laboratory tests, clinical assessments, psychological assessments, patient-reported outcomes*
- Timepoint = time at which data will be recorded or samples will be obtained
- General formula for an outcome measure:
 - [Thing being measured] as assessed by [type of assessment] at [timepoint(s)]
 - *Examples:*
 - *Quality of life as assessed by the SF-36 survey at baseline and 1 year*
 - *Systolic blood pressure as assessed by blood pressure cuff at baseline, week 1, month 1*
 - *Pain as assessed by a visual analogue scale (VAS) at baseline and day 30*
 - *Cognitive impairment as assessed by the Montreal Cognitive Assessment (MoCA) at baseline and 6 months*
 - *Tumor size as assessed by MRI at baseline and 1 year*
 - *Number of participants with disease progression as assessed by MRI at baseline and 1 year*

THANK YOU!

- **Elizabeth Massey Gendel, PhD**
 - Elizabeth.M.Gendel@uth.tmc.edu
 - (713) 500-3587
- **Clinical Trials Resource Center (CTRC)**
 - clinicaltrials@uth.tmc.edu
 - <https://www.uth.edu/ctrc/>
- **SCRO Office**
 - SCRO@uth.tmc.edu
 - (713) 500-3587
 - <https://inside.uth.edu/scro/>