

ClinicalTrials.gov Record Update Guidance

Record must be updated at least once a year AND 30 days after any changes detailed on page 11 at <https://prsinfo.clinicaltrials.gov/FinalRuleChanges-16Sept2016.pdf>

1. Log in to ClinicalTrials.gov here: <https://register.clinicaltrials.gov/>
 - o Please email clinicaltrials@uth.tmc.edu, if you would like to reset your password.

ClinicalTrials.gov PRS Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://register.clinicaltrials.gov/) Protocol Registration and Results System (PRS). OMB NO: 0925-0596
EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

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

Username:

Password: [Forgot password](#)

2. Open the record for your study.
3. Click "Open" next to the **Protocol Section**

Record Status
In Progress → Entry Completed → **Approved** → Released → PRS Review → Public
[Reset to In-Progress...](#)

Next Step: Correct Error(s)

Record Owner:	Access List: Edit
Last Update: 10/10/2018 10:39 by	Upload: Allowed Edit
Initial Release: 04/30/2018	PRS Review: Review History
Last Release: 05/10/2018 Receipt (PDF)	Public Site: Last Public Release: 05/10/2018 View on ClinicalTrials.gov
FDAAA: Non-ACT (No FDA-regulated drug/device)	

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

Open **Protocol Section**

Identifiers: NCT Unique Protocol ID: HSC-MS-

Brief Title:

Module Status: Study Identification:

Study Status: 5 Errors 1 Warning

4. Click “Edit” next to **Study Status**

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

[Edit](#)

Study Identification

Unique Protocol ID: HSC-MS [REDACTED]
Brief Title: [REDACTED]
Official Title: [REDACTED]
Secondary IDs:

[Edit](#)

Study Status

Record Verification: October 2018

ERROR: A record for an active study (Overall Recruitment Status is not Completed, Terminated or Withdrawn) must be reviewed, updated and verified at least once per year.

Overall Status: Not yet recruiting

Study Start: August 1, 2019 [Anticipated]

WARNING: Start Date August 1, 2019 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: August 1, 2020 [Anticipated]

ERROR: Anticipated Primary Completion Date cannot be in the past.

Study Completion: August 1, 2020 [Anticipated]

ERROR: Study Completion Date must be in the future for a study that is Not yet recruiting.

ERROR: Anticipated Study Completion Date cannot be in the past.

After clicking edit the page will look similar to:

* Record Verification Date: Month: Year:

ERROR: A record for an active study (Overall Recruitment Status is not Completed, Terminated or Withdrawn) must be reviewed, updated and verified at least once per 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 August 1, 2019 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.

ERROR: Anticipated Primary Completion Date cannot be in the past.

* § Study Completion Date: Month: Day: Year: Type:

Final data collection date for study.

ERROR: Study Completion Date must be in the future for a study that is Not yet recruiting.

ERROR: Anticipated Study Completion Date cannot be in the past.

5. Change the **Record Verification Date** to the current month and year.

6. Review **Overall Recruitment Status** and change if necessary.

- Not yet recruiting: Participants are not yet being recruited
- Recruiting: Participants are currently being recruited, whether or not any participants have yet been enrolled
- Enrolling by invitation: Participants are being (or will be) selected from a predetermined population
- Active, not recruiting: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled

- Completed: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant’s last visit has occurred).
 - Suspended: Study halted prematurely but potentially will resume
 - Terminated: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention
 - Withdrawn: Study halted prematurely, prior to enrollment of first participant
7. Review **Study Start Date** and change if the date is incorrect or if an error appears.
- The Study Start Date is defined as “the estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.”
8. Review **Primary Completion Date** and change if the date is incorrect or if an error appears.
- The Primary Completion Date is defined as “the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.”
9. Review **Study Completion Date** and change if the date is incorrect or if an error appears.
- The Study Completion Date is defined as “the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (e.g., last subject’s last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated.”
10. Click “Save” at the bottom of the page and you will be returned to the **Protocol Section**.

If Recruitment status changed follow steps 11 through 13. If not continue to step 14.

11. Scroll down to **Contacts/Locations** and click “Open”

Open

Contacts/Locations

Central Contact Person: [REDACTED]
 Telephone: [REDACTED]
 Email: [REDACTED]

Central Contact Backup:

Study Officials: [REDACTED]
 Study Principal Investigator
 The University of Texas Health Science Center, Houston

▼ Locations: **United States, Texas**

The University of Texas Health Science Center at Houston
 Houston, Texas, United States, 77030
 Contact: [REDACTED]

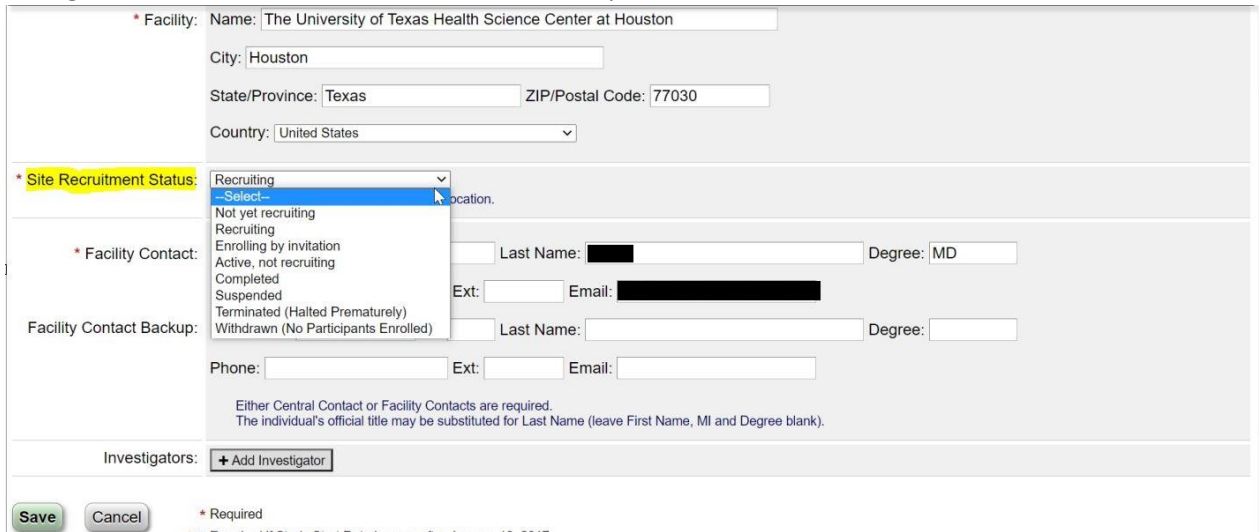
Memorial Hermann Hospital TMC
 Houston, Texas, United States, 77030
 Contact: [REDACTED]

12. Click "Edit" next to Location.



Edit **Location**
The University of Texas Health Science Center at Houston
Houston, Texas, United States, 77030
Contact: [REDACTED] x Delete Location

13. Change "Site Recruitment Status" if needed, then press "Save"



* Facility: Name: The University of Texas Health Science Center at Houston
City: Houston
State/Province: Texas ZIP/Postal Code: 77030
Country: United States

* Site Recruitment Status: Recruiting
--Select--
Not yet recruiting
Recruiting
Enrolling by invitation
Active, not recruiting
Completed
Suspended
Terminated (Halted Prematurely)
Withdrawn (No Participants Enrolled)

* Facility Contact: Last Name: [REDACTED] Degree: MD
Ext: [REDACTED] Email: [REDACTED]

Facility Contact Backup: Last Name: [REDACTED] Degree: [REDACTED]
Phone: [REDACTED] Ext: [REDACTED] Email: [REDACTED]

Investigators: + Add Investigator

Save Cancel * Required
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).

14. Go back to the **Record Summary** page and click the green button to release the record if there are no more errors. If you would like assistance with updating the record, please contact Jessica Martinez at Jessica.L.Martinez@uth.tmc.edu

If your study has been completed AND is required to report results, you will need to enter results within 12 months of the Primary Completion Date, please contact Elizabeth Gendel for guidance at 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu