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ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

INSTRUCTIONS FOR REGISTERING YOUR CLINTRIALS.GOV RECORD

1 Background

University of Houston researchers are responsible for registering their trials and should use the web based data entry system called the Protocol Registration System (PRS).

Access to the PRS system is at https://register.clinicaltrials.gov/, and requires a user name and password.

2 To set up a user account and password:

a. Send an email message requesting an account to: avargas5@central.uh.edu or dgriffi5@central.uh.edu.

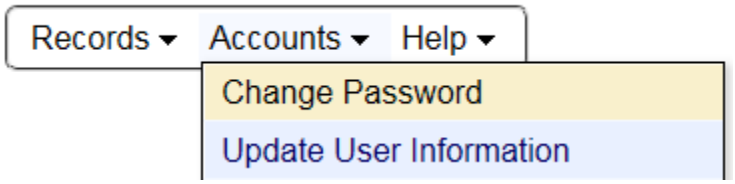
b. Include "CT.gov" in the subject line.

c. Include in the message your full name and telephone number

d. You will receive by return email a login name and a temporary password.

e. Log into the PRS system using your login name and temporary password.

f. Navigate to the 'Accounts' tab and select "Change Password" to replace your temporary password with something you can remember.



3 To register your trial:

a. Go to the Clinicaltrials.gov Registration (URL is https://register.clinicaltrials.gov/).

b. Complete the login fields. In the "Organization" field, enter in the organization name, "UHouston"

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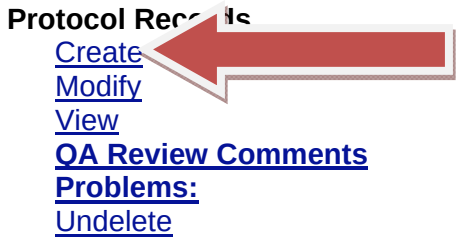
ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

c. Refer to the "User's Guide" for additional information. As the PI, you are a "user," and you are responsible for entering the information about your trial, ensuring that the information is correct, and updating the information in a timely manner.

d. On the Main Menu page, under Protocol Record, hit "Create" and complete the study description template.



e. Note that the ClinicalTrials.gov-required fields are marked with a red asterisk (*) and the FDA-required fields are marked with a green FDAAA.

- Taken together, these data elements represent the requirements for an adequate registration.
- If you do not complete these fields, your trial may not be considered "fully registered."
- Note also that each field of the template is labeled and linked to a definition;

f. Several fields are potentially confusing and should be completed as follows:

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ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

- *Organization's Unique Protocol ID*: Use the IRB protocol number (ID#) EXAMPLE: STUDY00000XXX. This number can be found on any official IRB correspondence or by contacting cphs@uh.edu.

Study Identification

Unique Protocol ID:	STUDY00000XXX
Brief Title:	Testing Testing 123
Official Title:	Testing Testing 123 Longitudinal Sudy
Secondary IDs:	

- *Record Verification Date:* Enter the month and year on which you complete and submit the template. *Note:* This field generates automatic reminders, do not leave it blank.

Study Status

Record Verification:	August 2021
Overall Status:	Not yet recruiting
Study Start:	August 2021
Primary Completion:	February 2021 [Anticipated]
Study Completion:	August 2023 [Anticipated]

- *Responsible Party:* This should always be the Principal Investigator, even though the system defaults to "sponsor."
- *Sponsor*: The database will default to "University of Houston." Although University of Houston is not actually the financial sponsor, choose University of Houston.
- *Collaborators:* Sponsorship can be clarified by entering the actual sponsor's name. For unsponsored research, either leave the field blank or enter "None."

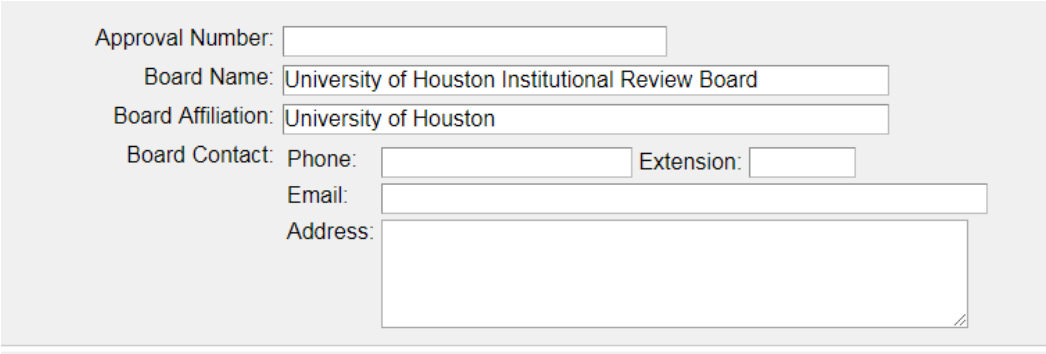
Sponsor/Collaborators

Sponsor:	University of Houston
Responsible Party:	Principal Investigator

ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

	Investigator: John Smith [jsmith] Official Title: Assistant Professor Affiliation: University of Houston
Collaborators:	Society of Physicians US University Industry Pharmaceuticals, Inc.

- *Oversight*: For the Review Board, enter your IRB approval status and use the IRB ID#. For Board Name use "University of Houston Institutional Review Board" For Board Affiliation use "University of Houston."



g. If the PI did not personally complete the template, send the draft template to him/her for review and approval. *Note: This is an important step.* The PI needs to have their own PRS user account and be listed as the Responsible Party for the study. If they are not in the system, email avargas5@central.uh.edu or dgriffi5@central.uh.edu as noted above under #2 to request an account.

h. Submit the completed, PI-approved template by clicking on "Completed" at the top of the Online template.

i. The Principal Investigator must next release the template to ClinicalTrials.gov by clicking on "Release" at the top of the Online template.

j. The study record will be released to the PRS team.

k. The PRS team will do their own quality assurance check. If they have no comments or changes, the study record will be published or updated on the ClinicalTrials.gov website in 2-5 business days.

INSTRUCTIONS FOR COMPLETION OF YOUR CLINTRIALS.GOV RECORD

Section	Field	Field Note
Study Status	Study Start	Month/Day/Year the study starts enrollment
	Primary Completion Date	Final data collection date for primary outcome measure (Month/Day/Year; NOT when the study is *closed* with the IRB)
	Study Completion Date	Final data collection date for the study (Month/Day/Year; NOT when the study is *closed* with the IRB)
Sponsor/ Collaborators	Responsible Party	This should always be the Principal Investigator, even though the system defaults to "sponsor." *Sponsor*: The database will default to "University of Houston." Although University of Houston is not actually the financial sponsor, choose University of Houston.
	Collaborators	Organization(s) providing support: funding, design, implementation, data analysis or reporting. Include all collaborators on the research project. If the study is funded by the NIH, include the name of the agency.
Oversight	U.S. FDA-regulated drug	Yes/No – Does the study involve an FDA-regulated drug or biologic? Note: this is not asking if the drug is investigational.
	U.S. FDA-regulated device	Yes/No – Does the study involve an FDA-regulated device? Note: this is not asking if the drug is investigational.
	Board Information	Name: University of Houston Institutional Review Board Affiliation: University of Houston Phone: (713) 743-9201 Email: cphs@central.uh.edu Address: Institutional Review Board, University of Houston 4800 Calhoun, Houston, TX 77004

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ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

	U.S. FDA IND/IDE Study	Yes/No – Yes if the study is being conducted under an IND or IDE. Answer NO if the study is being conducted under an IND exemption or did not require FDA review.
	Section 801 Clinical Trial	Section 801 Clinical Trial: Yes/No – Is the study an "applicable clinical trial"?
Study Description	Brief Summary	Short description of the protocol intended for the lay public, i.e. "*The purpose of this study is to determine…"*
Conditions	Conditions or Focus of Study	The name(s) of the disease(s) or condition(s) studied in the clinical study, or the focus of the clinical study.
Study Design	Depends on the Study Type	Complete fields based on the type of study (i.e. interventional, observational, expanded access)
Arms and Interventions	Interventions	Include all interventions that the participants will receive. This includes any investigational agents AND when applicable, standard of care treatment.
Outcome Measures	Outcomes	A concise name for the specific measure that will be used to determine the effect of the intervention(s) or, for observational studies, related to core objectives of the study and receiving the most emphasis in assessment. Describes what will be measured and not why it is measured. All primary and secondary outcome measures listed in the protocol must be included. The outcome measures listed in this section will be used for the results section.
	Time Frame	Time point when outcome measure is assessed. Each outcome measure can only have one time point. If multiple outcomes are based on the same underlying measure assessed at different time points (i.e. 8 weeks, 12 weeks and Final Visit), then each unique combination of measurement and time frame is entered as a separate outcome measure (i.e. Change from Baseline to Week 8 in MMSE/ Baseline to Week 12).

ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

	Outcomes using a scale	The following information in the Outcome Measure Description field: • All scale ranges (i.e., minimum and maximum scores) required to interpret any values in the data table. For example, if the *total* score is reported, the *total* range should be provided. If subscale scores are reported, the range for each subscale should be provided. • For each scale range provided, specify which values are considered to be a better or worse outcome (i.e., Do higher values represent a better or worse outcome?). • If subscales are combined to compute a total score, consider indicating how subscales are combined (summed, averaged, etc.).
	Example 1	Title: Systolic Blood Pressure Outcome measure description: Change in Systolic Blood Pressure
	Example 2	Title: Parkinson's Disease Questionnaire – 39 (PDQ-39) Outcome measure description: The PDQ-39 is a measure of quality of life in Parkinson's disease patients. It has 39 questions each with a response from 0-4 for a total of 156 points. The total score is calculated as a percentage so the scores of the 39 items are added and divided by 156 and multiplied by 100. The higher the score the worse quality of life.
A note on Outcomes		All collected data for pre-specified Primary and Secondary Outcome Measures should be reported. Data collected for exploratory outcomes can be included but is not required.
Eligibility	Eligibility	Include protocol specific inclusion/exclusion criteria. Eligibility criteria should be entered in a bulleted list.
Contacts/Locations	Central Contact	Designate a member of the study team (PI, Sub-investigator, Study coordinator) who potential participants can contact for more information. This person should be available via phone or email to field questions about the study. When a Central Contact is listed, a contact for each study location does not need to be listed.

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ClinicalTrials.gov – Instructions for User Account Set-up & Registering Your Trials

References	Citations / Links / Available Study Data and Documents	Include any and all citations/links relevant to the study in this section. If you include this information in any other section (i.e. detailed description), Clinicaltrials.gov will require you to move it before approving the registration.

INSTRUCTIONS FOR UPDATING YOUR CLINTRIALS.GOV RECORD

1 General Information

Studies listed as recruiting on the ClinicalTrials.gov website need to be updated at least every six months, or more often if there are ANY changes to the information presented in the ClinicalTrials.gov study template, including changes in recruitment status, contact persons, etc. Updates can be made at any time, as needed.

Updates are made in the Protocol Registration System (PRS) by the person who does the data entry on the study record. This person is called the "owner" of the study record.

2 To update the study record:

1. The owner needs to update the study record by going to https://register.clinicaltrials.gov/ and logging in using the organization name (UHouston), their individual Username and Password.

2. Locate the study and click on "Open" to view the record in more detail. Navigate to the section(s) you wish to update, open them, and edit the information.

3. Ensure that all other information associated with the registration is current and accurate.

4. Make sure to update the "Verification Date" in the Protocol Section, Study Status to reflect the current month and year that you completed your edit and re-review. The "Verification Date" is the field which generates automatic reminders within the PRS system, and cannot be left blank.

5. When done updating the record, please remember to hit "Completed" at the top of the template.

6. The PI will then need to release the study record to the ClinicalTrials.gov (PRS) team.

7. Publication of the update takes 2-5 business days because the PRS team does their own quality assurance check.