**ClinicalTrials.gov**
**Instructions for Registering Your Trials**

## 1 Background

Einstein/MMC 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: marina.tuzova@einstein.yu.edu.

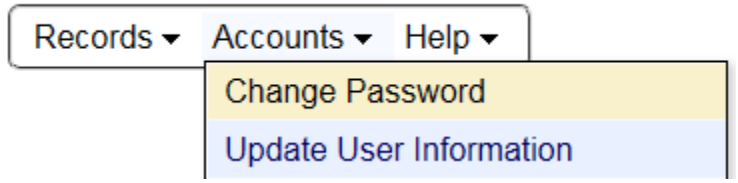
b. Include "CT.gov" in the subject line.

c. Include in the message your full name, telephone number, and MMC or Einstein email address.

d. Within 48 hours 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.

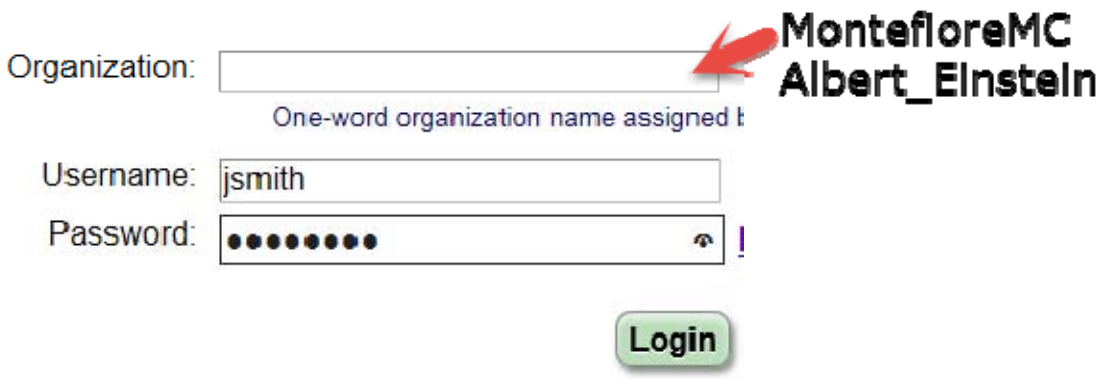
f. Navigate to the 'Accounts' tab and select "Change Password" to replace your temporary password with something you can remember.




## 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, "MontefioreMC" or "Albert_Einstein".




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:

- *Organization's Unique Protocol ID*: Use the IRB number. This number can be found on any official IRB correspondence or by contacting irb@einstein.yu.edu.

Study Identification

| | |
|---|---|
| Unique Protocol ID: | 2016-1234 |
| Brief Title: | Study of the Clinical Impact of Surgical Correction of Tricuspid Insufficiency in Implantable LVAD Patients |
| Official Title: | Randomized Study of the Clinical Impact of Surgical Correction of Tricuspid Insufficiency in Implantable LVAD Patients |

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 2015 |
| Overall Status: | Not yet recruiting |
| Study Start: | August 2015 |
| Primary Completion: | February 2017 [Anticipated] |
| Study Completion: | August 2017 [Anticipated] |

- *Responsible Party:* This should always be the Principal Investigator, even though the system defaults to "sponsor."
- *Sponsor*: The database will default to "Montefiore Medical Center" or "Albert Einstein College of Medicine". Although MMC/Einstein is not actually the financial sponsor, chose the default.
- *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: | Montefiore Medical Center |
| Responsible Party: | Principal Investigator<br>Investigator: John Smith [jsmith]<br>Official Title: Assistant Professor, Dept. of Medicine<br>Affiliation: Montefiore Medical Center |
| Collaborators: | Society of Physicians<br>US University<br>Industry Pharmaceuticals, Inc. |

- *Oversight*: For the Review Board, enter your IRB approval status and use the IRB number as the Approval Number For the Phone, Email and Address, use IRB's general contact information:

Board Status: Submitted, approved

The following information is required if the study meets at least one 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, or is not conducted under an IND or

IDE. [This information is not made public.]

Approval Number: 2016-1234

Board Name: Albert Einstein College of Medicine

Board Affiliation: Albert Einstein College of Medicine

Board Contact: Phone: 718-430-2237 Extension:

Email: irb@einstein.yu.edu

Address: Belfer Building #1002
1300 Morris Park Avenue
Bronx, NY 10461

- *Conditions:* Use the MeSH controlled vocabulary (provided). If you do not, the ClinicalTrials.gov staff is likely to delete your term and choose one of their own.

- *Keywords:* Use the MeSH controlled vocabulary (provided). If you do not, ClinicalTrials.gov staff is likely to delete your term and choose one of their own.

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 marina.tuzova@einstein.yu.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. *Note: This means that you are done with the study record and is the only way the Einstein administrator knows to review and approve your study record.*

i. The completed template will go to the Einstein administrator. *Note: the Einstein administrator does an administrative check on your study record to ensure the Sponsor section is accurate; the Einstein administrator does not review or correct any other content.*

j. Once complete, the Einstein administrator clicks on "Approve" at the top of the online template of the study record.

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

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

m. 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.