

Registro no “ClinicalTrials.gov”

1. Acesse o site: <http://prsinfo.clinicaltrials.gov/>
2. Clique em “Apply for an organization account”

PRS Information

Registration of Clinical Trials

Clinical trials are registered with ClinicalTrials.gov via a web based data entry system called the Protocol Registration System (PRS).

ClinicalTrials.gov allows the reporting of trials that:

- Are in conformance with any applicable human subject or ethics review regulations (or equivalent) and
- Are in conformance with any applicable regulations of the national (or regional) health authority (or equivalent)

ClinicalTrials.gov facilitates registration of trials in accordance with the [International Committee of Medical Journal Editors \(ICMJE\) initiative](#) requiring prior entry of clinical trials in a public registry as a condition for publication.

Multi-site trials and multi-sponsor trials are susceptible to duplicate registration, thus care must be taken in how the trials are registered. For multi-sponsor trials it is the lead sponsor who should take responsibility for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered once and only once.

Account Application Process

Organizations and investigators wishing to register should first apply for a PRS account via the links provided below. Within two business days, ClinicalTrials.gov will create the account and send email with instructions on how to login to the PRS, so that you can register your trials.

There are two types of PRS accounts:

1. **Organization accounts** generally have multiple users and are used to register all the trials being conducted at an organization.
[Apply for an organization account](#)
2. **Individual accounts** are used to register trials conducted by a single investigator.
[Apply for an individual account](#)

If you already have an account but have forgotten the password or other information required to login, use the “Forgot password” link on the PRS login page on the web at register.clinicaltrials.gov

Questions? Contact us at register@clinicaltrials.gov

Additional Information

[Frequently Asked Questions](#) - on obtaining a PRS account and entering protocol data

[PRS and U.S. Public Law 110-85](#) - H.R. 3850, Food and Drug Administration Amendments Act of 2007

[FDAMA 113](#) - U.S. Food and Drug Administration Modernization Act, Section 113, concerning trials of investigational new drugs (IND)

[Registering and Reporting Results with ClinicalTrials.gov](#) - tri-fold PDF brochure

[Data Element Definitions \(DRAFT\)](#) - details on the information that is entered via the PRS

[“Basic Results” Data Element Definitions \(DRAFT\)](#) - details on the information that is entered about results via the PRS

3. Clique em “YES: [Request contact information](#) for your organization's PRS administrator.”

Getting a PRS Organization Account

A PRS organization (administrative) account is established when multiple investigators from the same organization (e.g., company, university, medical center) are conducting trials. The organization designates one or more PRS Administrators to manage protocol registration and to coordinate with investigators.

In order to avoid duplicate registration, trials should be registered only by the lead sponsor.

Please check the current list of [ClinicalTrials.gov](#) to be sure that your organization is not already registered.

Is your organization on the list?

YES: [Request contact information](#) for your organization's PRS administrator.

NO: [Apply for a PRS account](#)

[Return to PRS Information Page](#)

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4. Leia e aceite os termos e condições.
5. Preencha o campo “Organization” com “University of Campinas, Brazil”. Preencha seus dados e clique em “Submit Request”.

Administrator Contact Request

Each entity submitting data to ClinicalTrials.gov must adhere to the following terms and conditions, which are intended to ensure the accuracy, currency and validity of the data.

1. Only data on trials approved by the appropriate regulatory authority may be submitted to ClinicalTrials.gov.
2. Notice of recruiting status changes must be done immediately, and all submitted data must be reviewed, verified, and updated every six months.
3. The submitting organization is responsible for the completeness and accuracy of the data submitted to ClinicalTrials.gov.
4. Trial data must be submitted in English.
5. Multiple groups within a single entity (e.g., company, university, government agency) must share a single PRS organization account.

Accept Do Not Accept

If your organization is already registered with ClinicalTrials.gov, provide the following information to request contact with your organization's PRS administrator.

Organization:

Requestor Information

Name:

Department or Group:

Phone:

Email:

Questions about this form and the Protocol Registration System (PRS) may be sent to register@ClinicalTrials.gov.

6. O *PRS (Protocol Registration System) Team* enviará um e-mail indicando que entre em contato com o administrador (Prof. Heitor Moreno Júnior; hmoreno@uol.com.br) solicitando login e senha.
7. Um login será criado e enviado ao seu e-mail pelo *PRS Team*.
8. Acesse: <https://register.clinicaltrials.gov/> para login (*username* e *password* enviados) e registre seu estudo.