

## Terms of use of the Humanitas Clinical Institute trials portal

### Registration to the Humanitas Clinical Institute trials portal

Humanitas Clinical Institute requires the electronic application for clinical trials which have to be submitted to the approval of the Independent Ethics Committee. The portal, a documents repository, is protected and the access is reserved to Users with assigned authentication credentials.

The registration of the Sponsors, or the CROs delegated by them (hereinafter referred to as "Applicants"), is required for the submission.

Direct access to the Humanitas Clinical Research Information System will allow Applicants to apply for the approval of the clinical trial and will allow to update them about its evaluation.

Sponsor and CRO (when delegated) will also be able to consult at any time all the documentation, information and communications, according to their respective roles.

### Portal usage conditions

The clinical trial portal is property of Humanitas Clinical Institute, which reserves, at its own discretion, the right to change its terms and conditions of use and to further implement the portal itself.

The Applicant is responsible for retaining copies of documents that modifies, replaces and deletes in the portal.

By accessing the portal, Applicant accepts the following:

1. The portal or parts of it may be inaccessible temporarily due to malfunctions and / or connection defects or any events outside the control of Humanitas Clinical Institute;
2. Humanitas Clinical Institute has no control over the nature of the tools used by the Applicant to connect to the Database or how to consult the Database through them;
3. Humanitas Clinical Institute is not responsible for the conduct of the Users during the consultation of the Database.

In the consultation of the portal, the Applicant undertakes for itself and for all its internal Users to:

1. Do not copy the portal, either in whole or in part. Any form of extraction or reuse of even small parts of the Database is prohibited;
2. Do not use the portal to pursue illegal purposes or to disclose or disseminate in any way material or content pre- ordered to the commission of illegal activity;
3. Do not damage or make less efficient part or all the portal.

**Assign Credentials to the Applicant**

For registration purposes, Applicants must provide, under their responsibility, the correct contact details indicated in the registration form and required documents. Please note in particular that the email address must be active and must correspond to an actual mailbox. All communications and notifications from the Humanitas Clinical Research System will be directed to this mailbox.

Authentication credentials consist of a code identifying the user (user-id / login) associated with a password. Access credentials will be sent to the e-mail address indicated and will be disabled after a period of 180 days of subsequent downtime.

The Applicant undertakes to keep it confidential and not to relinquish, transfer or transmit third-part identification codes and key words assigned to him by Humanitas Clinical Institute.

The Applicant has the right to choose Unique Credentials for Individual Users (suggested option) or a single user identification code with a keyword that will assign to all Internal Users that need access to the Humanitas Clinical Research Portal.

In both cases, the Applicant will be responsible for any damages incurred by Humanitas Clinical Institute and / or third parties and resulting from non-compliance with the terms of use. If the Applicant chooses to assign only one user ID, and password, he will also be responsible if his internal user has violated the terms of use after he has ceased collaborating with the Applicant or forbidding the Applicant's internal rules. Any breach of the terms of use will result in the revocation of the Applicant's credentials that is responsible of the violation.

If the Applicant chooses to assign unique credentials to individual Users, he must provide Humanitas Clinical Institute the list of internal Users. In addition, he must promptly inform Humanitas Clinical Institute of any loss by one or more Internal Users of the qualification required to access the portal (eg due to the termination of the collaboration relationship with the Applicant), so that Humanitas Clinical Institute may disable his credentials.

Applicant: \_\_\_\_\_  
                  [signature]

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date and place: \_\_\_\_\_

*This document is contractual between Humanitas Clinical Institute and the Applicant. By signing it, the petitioner ensures that the requisite signature powers are provided with the Applicant's organization.*