TO THE SPONSOR OF A CLINICAL TRIAL

Thank you for conducting your trial at our centre. We would like to inform you of the following.

TPI²/EPIC is the electronic medical record of all the patients in the Cliniques universitaires Saint-Luc. This software is provided by Epic firm.

In order to ensure an adequate confidentiality of our medical files, we request that your CRA be identified in our system by means of an identification badge that will have to be renewed yearly. This badge will give them access[1] to our electronic database and only to the patients entered in the trial. You will find hereafter the process to obtain the badge. A training to TPI² will be available to the CRA within the software.

In case of request, this badge will also give the CRA an Internet access to the eCRF of the trial he/she is in charge.

We remind you that a monitoring visit can only take place with the agreement of the investigation team, at the monitor's request.

In the event of incorrect or excessive use, the Institution/Investigator shall have the right to terminate or to suspend immediately the access. The Institution /Investigator/Local Clinical Research Coordinator shall contact the sponsor project manager or representative in order to resolve the issue and to permit again the patient data reviewing/monitoring in appropriate conditions.

How will the CRA get access to the medical records of a study participant?

1. The Study coordinator or the PI provides the CRA, during the initiation visit or by email, the Confidentiality Agreement Form (AAHRPP-FORM-021) and the Principal Investigator Authorization Form (AAHRPP-FORM-020) completed and signed by the PI.
2. The CRA returns the two documents completed and signed as well as a copy of his/her identity card and the date of the first monitoring visit to the investigator or to the CRCM, by email, before the first day of monitoring.
3. Those information are sent to the Access Management Unit who creates the CRA profile, allowing access to TPI² (and to the Internet if requested), valid from the date of the first monitoring and for a renewable period of 1 year.
4. The CRA goes to the Access Management Unit on the first day of monitoring with of his/her identity card and receives an identification badge and a login and password for the given study (Cliniques universitaires Saint-Luc, Main Building Employees Entrance, level -3, (Tél: **02/764.15.55**, gestiondesacces@saintluc.uclouvain.be).

Badge, login and password provided are unique, personal and non-assignable.

The CRA must have their badge available at all times when on the premises of the Saint-Luc hospital to perform their duty.

[1] In relation to the recommendations of the "ICH Topic E6 Guideline for Good Clinical Practice", point 4.1.4. : "The investigator should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies)"

The fees to issue all the badges needed for one clinical research are included in the start-up fees of commercial sponsors and invoiced directly after the agreement is being signed.

For any badge loss an invoice of 25€ will be edited.

5. The Study coordinator or the PI Links the CRA in Claire (CUSL study database) to the study(s) for which he/she is responsible
6. From a CUSL computer, the CRA accesses and reads the User Guide on the home screen in TPI², prints and completes the training certificate. This certificate will be kept in the study investigator file.
7. The CRA follows the instructions in the guide to obtain the list of patients involved in his/her study and access their chart.

How to get a renewal of access after one year ?

Annually the CRA will have to renew his/her identification in order to maintain the access to the electronic patient medical record. Without renewal, the badge will be deactivated and the access cancelled.

Get the Principal Investigator Authorization Form (AAHRPP-FORM-020) completed and signed by the PI and complete the Identification Renewal Form (AAHRPP-FORM-022)

Go to the Access Management Unit with your badge and the completed forms to get a validity extension.

The yearly renewal will be carried out at no charge.

What must we do in case of badge loss?

Should you loose your badge, please fill out the Declaration of Loss Form (AAHRPP-FORM-023). This form must be countersigned by the investigator or the study coordinator who will invoice 25€ to the company.

Address yourself to the Access Management Unit. A new badge and login will be given.

What is the process to obtain a badge for auditors / inspectors?

The procedure to obtain a badge for auditors and inspectors is the same as for the badge designated to the CRA. Nevertheless, a badge with a limited validation period will be provided to them for free.