DATA PRIVACY PROTECTION IN CLINICAL RESEARCH: Questionnaire 1

The sponsor/CRO must fill and sign this document. The CTC central desks (academic/commercial) will provide it at the first contact with the sponsor/CRO.

According to the Belgian law of 30/07/2018 (art.198), any data collected in the context of a clinical study must be recorded in such a way that third parties outside the clinical trial site team cannot identify the subject.

The CTC central desk will analyze answers to the questions below against the General Data Protection Regulation (GDPR 2016/679). If necessary, an opinion from the DPO[[1]](#footnote-1) or DAC[[2]](#footnote-2) will be requested. A complementary questionnaire may be sent to the sponsor/CRO. The DPO's opinion must be attached to the initial submission file if it is sent to the CUSL Hospital-Faculty Ethics Committee. Analysis by the DAC will take place in parallel with the submission, and the DAC's opinion will be taken into account at the time of contract negotiation.

|  |  |
| --- | --- |
| 1) Will the data be transferred outside of Cliniques universitaires Saint-Luc (CUSL)? | [ ]  YES[ ]  NO |
| * If YES, specify the transfer modalities : Cliquez ou appuyez ici pour entrer du texte.
 |
| 2) Will the data be transferred outside of EU? | [ ]  YES[ ]  NO |
| 3) Will data be collected identifying the study subject (name, administrative number, NISS, phone, email, facial image, address, account number, video conference, sounds, etc.)? | [ ]  YES[ ]  NO |
| * If YES, will this data be shared outside of CUSL?
 | [ ]  YES[ ]  NO |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| 4) Does any application or software need to be installed on a CUSL computer? | [ ]  YES[ ]  NO |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| 5) Answer only if you are a CUSL academic sponsor, otherwise check "NA" a) Will you use a database (CRF) with REDCap or another system meeting the following conditions:- password protection- backup done- located on a CUSL serverb) If it is not REDCap, which database is it? Cliquez ou appuyez ici pour entrer du texte. | [ ]  YES[ ]  NO[ ]  NA |
| 6) Is the use of an e-TMF / e-ISF planned for this study? | [ ]  YES[ ]  NO |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| 7) Is artificial intelligence planned as part of the study (feed/use)? | [ ]  YES[ ]  NO |
| 8) Does the sponsor provide electronic equipment to the patient for data recording, either on-site or at home (pc, tablet, phone, connected watch, etc.)? | [ ]  YES[ ]  NO |
| 9) Will the patient use his/her own equipment (pc, tablet, phone, connected watch, etc.) for the study? | [ ]  YES[ ]  NO |
| 10) Does the study involve the use by the patient of a mobile App, web-app, portal, website, online form, email, etc. to collect source data directly from the patient | [ ]  YES[ ]  NO |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| * Is specific patient consent requested in the information and consent document?

Please give us a copy of ICF | [ ]  YES[ ]  NO |
| 11) Will the patient have to use an online platform for reimbursement of study-related expenses (travel, etc.)? | [ ]  YES[ ]  NO |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| * Is specific patient consent requested in the information and consent document?

Please give us a copy of ICF | [ ]  YES[ ]  NO |
| If the answers to questions 8, 9, 10 and 11 are "NO", check "NA" in the questions below |
| 12) Is any information shared with the patient via his/her own e-mail address? | [ ]  YES[ ]  NO[ ]  NA |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |
| 13) Will source data collected directly from the patient using specific electronic equipment or using a mobile app, web-app, portal, website, online form, email, etc. be added to the patient's medical record if the investigator deems it useful for medical follow-up (manual transcription or document storage)? | [ ]  YES[ ]  NO[ ]  NA |
| 14) Will data collected from the patient using specific electronic equipment be stored in an ISO27001 or HIPAA environment? | [ ]  YES[ ]  NO[ ]  NA |
| 15) Will the patient's IP or FSM-MAC addresses be accessible by the sponsor/CRO? | [ ]  YES[ ]  NO[ ]  NA |
| * If YES, specify : Cliquez ou appuyez ici pour entrer du texte.
 |

As [representative of][[3]](#footnote-3) the study sponsor, I confirm that collection and processing during clinical trials is done in full compliance with the European Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the national laws adopted under the GDPR.

STUDY NUMBER/ACRONYM :

INVESTIGATOR’S NAME, SURNAME:

SPONSOR/CRO's NAME :

DATE AND SPONSOR/CRO'S SIGNATURE :

1. DPO : Data Protection Officer [↑](#footnote-ref-1)
2. DAC : Data Access Committee [↑](#footnote-ref-2)
3. Delete as appropriate or remove [ ]. [↑](#footnote-ref-3)