Compliance with Spain applicable rules for the collection, storage and future use of human biological samples (Article 7.1h)

Full title of the clinical trial	**EU trial number**
Click or tap here to enter text.	**Click or tap here to enter text.**
Responsible entity for the samples (legally): **Click or tap here to enter text.**	

How to use this document

This form may be used by Sponsors of clinical trials in the Part II application dossier to provide information about “compliance with the applicable rules for the collection, storage and future use of biological samples from clinical trial subjects" (Regulation (EU) No 536/2014, Article 7.1 (h)). This is not a mandatory form and different national arrangements may be in place, which should be confirmed prior to submission.

If the information is already provided elsewhere in the Application Dossier, a reference should be provided. To facilitate use of the template, each section can be compressed by clicking on the title.

This Part II template has been developed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No 536/2014 Clinical Trials on Medicinal Products for Human Use.

I - Description of the biological samples involved in the clinical trial
Section 1 - Does this clinical trial involve new sampling of the subjects (newly collected samples)? **☐ Yes, please fill in the requested information in section 1** **☐ No, not applicable. Please continue with section 2** **Note: The sponsor needs to fill in *at least one* of the sections 1 or 2**
1.1 What type(s) of samples will be collected from the subject? *State the original material that is collected from the patient e.g. blood, tissue (state type of tissue), urine, saliva etc. Do not include information on the preparation of the sample.* **Click or tap here to enter text.**
1.2 Total number of samples, fragments (e.g. aliquots, tissue blocks, sections) and the total volume (if applicable) per individual subject: **Click or tap here to enter text.**
1.3 The maximum number of samples and maximum volume (if applicable) on one single occasion: **Click or tap here to enter text.**

1.4 Will the samples be collected as part of routine health care?
Click or tap here to enter text.

Section 2 - Does this clinical trial involve the collection of existing archive samples (e.g. archived diagnostic material or other biobank material)?

☐ Yes, please fill in the requested information in section 2
☐ No, not applicable. Please continue with section 3

Note: The sponsor needs to fill in at least one of the sections 1 or 2

2.1 What type(s) of archived material/samples will be used?
Click or tap here to enter text.

2.2 Provide the total number of samples, fragments (e.g. aliquots, tissue blocks, sections) and total volume (if applicable) that the Sponsor needs access to from each individual subject.
Example: 20 sections per biopsy from each individual subject is needed
Click or tap here to enter text.

2.3 Will new consent be obtained for the use of the archive samples in the clinical trial (if in line with national legislation)? If not, explain.
(if applicable, add the text of the original consent)
Click or tap here to enter text.

II – Use, storage, and transfer of biological samples

Section 3 – Use of samples for a purpose within the objective of this clinical trial (i.e. for use described in the protocol)

Note: This section must be filled in for both newly collected and existing archive samples

3.1 Where will the samples be analysed?
i.e. within the clinical laboratory, within/outside the Sponsor's organization, within/outside the Member State where collected or within/outside EU/EEA.
Click or tap here to enter text.

3.2 If the samples will be sent to another organisation for analyses (as part of the trial), how will they be managed after the analyses have been carried out?
i.e. destroyed, returned to responsible entity for the samples (legally), stored at the site where analysed, anonymised etc.

Note: An agreement (Material Transfer Agreement or equivalent) that regulates how the sample are to be handled shall be established with the recipient
Click or tap here to enter text.

3.3 Where will the samples be stored?
i.e. within/outside the Sponsor's organisation, within/outside the Member State where collected or within/outside EU/EEA
Click or tap here to enter text.

3.4 How long will the samples be stored?
Click or tap here to enter text.

3.5 What type of connection is available between samples and individual subjects?
- ☐ Direct connection *(samples marked with e.g. initials, date of birth)*
- ☐ Pseudonymised connection *(samples marked with code)*
- ☐ No connection, samples are anonymised *(i.e. samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor)*

3.6 Who will have access to the samples?
Click or tap here to enter text.

3.7 Who will have access to the sample code list (if applicable)?
Click or tap here to enter text.

Section 4 - Will newly collected samples or existing archive samples be stored for future use?
For other use than described in the protocol. Note that some purposes (secondary use of samples) may require additional approval, in Most Member States by an ethics committee

☐ Yes, please fill in the requested information in this section
☐ No, samples will be destroyed, please continue with section 5

4.1 What is the purpose of the future use?
Click or tap here to enter text.

4.2 How long will the samples be stored?
Click or tap here to enter text.

4.3 Where will the samples be stored?
Click or tap here to enter text.

4.4 What type of connection is available between samples and individual subject?
- ☐ Direct connection *(samples marked with e.g. initials, date of birth)*
- ☐ Pseudonymised connection *(samples marked with code)*
- ☐ No connection, samples are anonymised *(i.e. samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor)*

4.5 Who will have access to the samples?
Click or tap here to enter text.

4.6 Who will have access to the sample code list (if applicable)?

Click or tap here to enter text.

4.7 Will the donor be recontacted to give new consent to the use of the samples in future research? If not, explain

Click or tap here to enter text.

4.8 If secondary future use of the samples will be in question, will an ethics committee or biobank committee be reviewing whether the purpose of the new study is within the scope of the original provided consent (if applicable according to national legislation)?

Click or tap here to enter text.

4.9 Who will be able to make use of the samples?

Click or tap here to enter text.

4.10 How will unsolicited findings be handled?

Click or tap here to enter text.

III – Additional information

Section 5 - Additional information that is required by the current Member States national arrangements and regulations. The sponsor should confirm this prior to submission

Note: This section will only be filled in if applicable

5.1 Provide any information (not described above) that is of relevance to the Member State applicable rules on collection, storage, transport and future use of the samples, e.g. on specific national arrangements and regulations regarding the use of human biological samples.

"Information on biological samples management is included in the Informed Consent. All biological samples will be processed and notified as necessary for the purposes of this study and in accordance with Law 14/2007, of July 3rd, on Biomedical Research, and Royal Decree 1716/2011, of November 18th, which establishes the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and for the treatment of biological samples of human origin, and regulates the operation and organisation of the National Registry of Biobanks for biomedical research.

La información correspondiente a la gestión de muestras Biológicas se recoge en el documento de Consentimiento Informado. Todas las muestras biológicas que se obtengan se procesarán y notificarán según sea necesario para los fines de este estudio y con arreglo a la Ley 14/2007, de 3 de julio, de Investigación biomédica, y al Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica."