National Research Ethics Committee for Clinical Trials (NREC-CT)

Compliance with Member State applicable rules for the collection, storage and future use of human biological samples

This template should be used by Sponsors of clinical trials as part of the Part II application dossier when Ireland is a Member State concerned 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)).

Sections which are not appropriate should either be deleted or marked as Not Appropriate / NA.

This template was originally developed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use and adapted by the National Office for Research Ethics Committees.

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| 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. | |

1. Description of the biological samples involved in the clinical trial

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| Section 1  Does this clinical trial involve new sampling of the participants (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 participant?  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 participant: |
| 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. |

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| 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 to access from each individual participant.  Example: 20 sections per biopsy from each individual participant 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. |

B. Use, storage, and transfer of biological samples

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| 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 is the connection between samples and individual participant? |
| 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. |

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| 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 is the connection is between samples and individual participant? |
| 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 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 use these samples? |
| Click or tap here to enter text. |
| 4.10 How will unsolicited findings be handled? |
| Click or tap here to enter text. |