Guidance Notes for Clinical Studies Data Protection Notice Template

UCC has developed a **template** Data Protection Notice (DPN) which can be used as a base for creating a detailed study-specific DPN for UCC Clinical Studies. **Please note that the DPN should be separate for each study,** and specific information about the data processing that you are carrying out will need to be added to the DPN template as required.

A DPN can be a separate document to be signed by the researcher, or it can be incorporated into the Participant Information Leaflet/Informed Consent Form (PIL/ICF). This document is a guideline for the different sections of the DPN.

Please note that information on privacy and data protection should only be provided to the research participant once – if some of this information is already included in the PIL/ICF then it does not need to be repeated here. Data Protection Notices should be created in conjunction with the PIL/ICF and the Data Protection Impact Assessment (DPIA).

Introduction

This paragraph introduces the DPN, the wording should not be changed.

Who we are

This outlines who the Sponsor for the study is. If UCC is the study Sponsor then the Research Centre conducting the research should be entered here. If UCC is not the study Sponsor, this DPN should not be used. If there is a website for the research centre the URL should be added here.

How we will use your personal data

This section is important to outline how you will be collecting data for the research study, e.g. from the participant, from their medical records, from another organisation. Please note that if not already detailed in the PIL/ICF, you need to clearly outline what personal data will be collected and what the data will be used for.

The bullet points in this section should outline the type of data collected, and **should be amended to include information specific to your research study.** The bullet points that are not relevant to your research can be removed, and if there are any additional personal data you will be collecting as part of the research, it should be added here. If the final highlighted bullet point (*information from the medical records held by the hospital / general practice*) is relevant, then more details on what information will be collected can be added here.

Please note that if you are not collecting any blood samples, then blood samples should not be mentioned in the DPN.

Who will access my personal data?

This section should identify all bodies/institutions who will be able to access the data collected as part of the research study. The template DPN outlines additional wording that should only be used if the study is a Regulated Study approval from the Health Products Regulatory Authority (HPRA). If there are any other bodies/organisations who will be able to access the participants' personal data, these should be added here. This section also outlines who the results of the data will be shared with and at what stage data will be anonymised.

The purpose and legal basis for collecting your data

The wording in this section should not be changed, unless there is an alternative legal basis you are using for the research study. The legal basis used in this DPN is Article 9(2)(g): 'processing is necessary for reasons of substantial public interest, on the basis on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection, and provide for suitable and specific measures to safeguard the fundamental rights and interests of the data subject.'

The purpose of the research study should be outlined clearly in the PIL.

How long we will keep your data

The DPN needs to describe how long the data will be kept for, and why the data will be kept for this length of time.

If the research is a HPRA-regulated Study, then data will need to be kept for 25 years, in line with the upcoming Clinical Trial Regulation.

For non HPRA-regulated studies, UCC's Code of Research Conduct states that *'The University expects data to be securely held for a minimum period of ten years after the completion of a research project'.*

It is also important that the researcher check the requirements of the funder, who may require data be retained for longer periods. Additionally, some publications require data be retained for a number of years following the publication of the results, so this might also need to be considered.

In some circumstances, it may not be possible to determine how long the data will be retained for. If this is the case then you should detail how this will eventually be determined, and when the data will be anonymised.

Cross-border data transfers

This section should only be included if you are transferring data outside the EEA. Transferring data outside the EEA will require additional safeguards which should also be outlined here. The primary safeguard used is the EU Commission's Standard Contractual Clauses, however there could be other safeguards depending on the country the data will be sent to. More information about this can be found in GDPR Article 46 (https://gdpr.algolia.com/gdpr-article-46).

Your rights

The wording in this section should stay the same unless it has already been detailed elsewhere in the PIL/ICF. It outlines the rights of the data subject with regards to processing of their personal data.

Questions or Complaints

Contact information for the research team applicable to your research study should be added to this section. Other wording in the section should not be changed.

As long as it is clear in the PIL/ICF that the information in the Data Protection Notice has been read and understood, and that the participant has indicated they are aware of their data protection rights (e.g. via a tick box in the ICF '*I have read and understood the UCC Data Protection Notice*'), then the DPN does not need to be signed by the research participant.