

Dublin Academic Medical Centre

Standard Operating Procedure
Dublin Academic Medical Centre
UCD Clinical Research Centre

SOP Number	1.3
Version Number	**1**
SOP Title	**Patient Information Leaflets for Investigator led Studies**

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Purpose

This SOP provides an overview of the requirement for appropriate patient information leaflet for all studies conducted at the CRC

Specific procedure

1. All potential research subjects will be given sufficient information to decide whether or not they want to take part in a research study.

2. A suitably worded, user friendly, patient information leaflet in the first language of the research participant will be issued appropriate to the specific study protocol and of which the Mater Misericordiae or St Vincent's University Hospital Research Ethics Committee has approved in writing. This will preferably not contain any technical terms that the research participant may have difficulty understanding. The first page of the patient information leaflet will be printed on Mater Misericordiae or St Vincent's University Hospital headed paper.

3. The principal investigator and his/her study group will draw up a patient information leaflet for the research study to include the following:

    - Study title
    - Purpose of the study

- Duration of the study
- How participants are chosen
- Voluntary participation
- What the research study entails
- Disadvantages in taking part in the research study
- Risks of taking part in the research study
- Benefits of taking part in the research study
- Permission for access to medical records
- Data confidentiality
- Data storage
- Access to personal results of the research study
- Access to overall results of the research study
- Details of the study investigators
- Contact information

4. All research project patient information leaflets used in the Clinical Research Centre will have the project title and version date clearly printed on them.

5. The research personnel will ensure that the research subject has ample opportunity to read and consider the research information leaflet.

6. The patient information sheet about the research project will be given to the research subject to keep and questions encouraged prior to written consent being obtained.

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Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.