RESEARCH ETHICS

After reading this Fact Sheet you should:

- Understand the guidelines underpinning good research ethics.
- Have links to related resources.

The goal of clinical research includes development of knowledge that can improve human health, but clinical research participants are placed at risk of harm for the good of others and there is the potential for exploitation of these volunteers. Medical device innovators should become familiar with the ethical guidelines necessary for the protection of patient volunteers and to preserve integrity of the science.

What are guidelines and principles for ethical research?

Applying for ethical approval can be daunting for researchers and a thorough understanding of the principles of respect for persons, beneficence and justice (the **Belmont Report**) are an essential starting point before embarking on the process for ethical approval. Innovators should read "**Research ethics application: a guide for the novice researcher**" and also the ethical guidelines published by the US's **NIH**, which cover research ethics aspects such as:

- Social and clinical value
- Scientific validity
- Fair subject selection
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

What is the Irish landscape regards research ethics committees?

Clinical investigations: The **National Office for Research Ethics Committees** (the National Office) was recently established and is implementing a national system of research ethics review for regulated remits, including clinical investigations of medical devices. The National Office will establish National Research Ethics Committees (NRECs) in prescribed areas of health research, with a mandate to return ethics decisions that are respected nationally ('single national ethics opinion'), in compliance with EU MDR 2017/745. Already a **National Research Ethics Committee for Medical Devices** (NREC-MD) is in place. The NREC-MD will work alongside local research ethics committees (and supported by the National Office team) in a mixed-model system to support research ethics in medical devices. NREC-MD members, meetings & cut-off dates, and reporting forms & templates forms are available at the **NREC-MD website**. The National Office "can offer advice prior to and during an application process, providing guidance and resources on ethics considerations and practical tips on procedural matters". The National Office website has many useful resources and FAQs for research participants, local RECs and researchers (including the **Application Documents** and an **Application Toolkit**).

Non-clinical investigations: The NREC-MD has a defined health research remit in line with the EU MDR 2017/745 regulations. This does not affect the local REC jurisdiction in relation to health research that falls beyond the scope of the NREC-MD remit. i.e., The NRECs will not review studies that do not fall under these regulations. The clinical evaluations that *do* fall within the remit of the NREC-MD are listed in the Clinical Evaluations Fact Sheet, under section "Types of Clinical Investigations".

According to the Ireland **HSE** there are at least 32 local Research Ethics Committees (RECs) in the publicly funded health service. Some can approve research taking place in the organisation to which they belong, while others have a regional remit and can approve hospital and Community Health Organisation (CHO) based research. To determine the process for obtaining ethical approval, first identify the appropriate REC/s to consider to understand the REC's purpose and the types of studies the REC reviews. Use the website links at **RECs for CHO-Based Research** and/or **RECs for Hospital-Based Research**. Thereafter you will be able to establish - for the appropriate REC you have selected - the exact process, documents required, and indicative timelines for ethical approval.

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