NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Ethical considerations for applicants

24 July 2025

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Background

This document was created as a resource for Sponsors and research teams in the preparation of applications to the Research Ethics Committees (NRECs). It outlines some of the key areas that Committee members consider when reviewing an application and should be reviewed with this in mind prior to submission to the National Office, or the Clinical Trials Information System, as applicable.

This document comprises considerations specified in the legislation pertaining to applications within the scope of NRECs review: (EU Medical Devices Regulation EU No 2017/745, EU In-Vitro Diagnostics Regulation EU No. 2017/746, S.I. 671/2023 and S.I. 257/2022, EU Clinical Trials Regulation EU No 536/2014, S.I. 41/2022 and S.I. 99/2022). These elements of the study should be clearly and comprehensively outlined in the study documentation.

Please note that this list is not exhaustive and in its review the Committees consider the circumstances of each study independently.

Study design and procedures

- Are the aims of the study clearly described?
- Are all aspects of the study methodology clearly described in the protocol?
- Is the study design and proposed statistical analysis suitable for the study in question?
- Are there any plans to involve patients, service users or the public, in the design, management, and undertaking of the study?
- Does the study comply with the requirements of the specific article of the EU Regulation as it relates to vulnerable populations?
- Are the study termination criteria outlined and justified?
- Do the study termination criteria include common considerations such as futility, safety and efficacy?
- Are the study procedures, study visits, monitoring of participants, risk minimisation measures and participant follow up clearly described?

Dissemination of study results

- Will participants be advised of study results or given feedback? If not, why not? If so, how will participants find out about study results? Is this information clearly stated in participant information leaflet and protocol?
- How will the study results be shared with the wider scientific and general population? If there is no intention to share this information, has justification been provided?

Anticipated benefits/risks for participants

- Have the risks and benefits of the study been identified and fully evaluated?

- If risks have been identified, have all mitigating actions been explored?
- Do the potential benefits justify any risks or does the study have a high degree of risk to participants?
- How will the safety and efficacy of the study be monitored throughout the duration of the study?
- Are all risks and benefits, along with their chance of happening, accurately described in the participant facing documentation?
- What arrangements are in place to inform participants of newly discovered risks / benefits of the study?
- Are the benefits and risks of the study distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture?
- Where a study involves people who may be vulnerable, such as those unable to make independent decisions, what measures have been put in place to minimise any harm?

Site and staff suitability

- Does the study site have appropriate facilities, equipment, certification (if applicable) and staff for the study procedures?
- Do the investigators have the experience and qualifications, including GCP training, required to carry out the study? Are the investigators experience and qualifications noted in their CV, e.g. most recent relevant studies led by the investigator?
- Do any members of the study team have any conflicts of interest (financial or otherwise)? If yes, how will the conflict be managed to ensure any risk of bias is minimised?

Recruitment and consent

- Is the study aiming to involve the appropriate type and number of participants for the study design?
- Is the study population representative of the patient population? Have the exclusion criteria been appropriately justified with reasonable accommodations made to be inclusive, and facilitate participation?
- Are the ways in which participants will be approached and informed about the study clearly described?
- Do recruitment materials, such as information leaflets or advertising, give the potential participants a clear idea of the purpose and procedures of the study?
- Who will be approaching the participants? Does the person undertaking the interview / recruitment and consent process have the appropriate qualifications?
- Is the person who will be approaching participants directly involved in their clinical care? If yes, what measures will be put in place to minimise any perception of undue influence?

- Is there any undue influence, including that of a financial nature, exerted on the participant, or, where applicable, on his or her legally designated representatives, to participate in the study?
- Are all participants likely to have capacity to decide whether or not to participate? If not, how is this addressed in the protocol and consent form?
- Is the process by which participants consent to participate clearly described in the study protocol and consent form?
- Where a participant lacks decision-making capacity, is there a protocol and participant information leaflet/consent form, for deferred consent/consent to continue in the study, in the event capacity is regained by the participant.
- Where a participant lacks decision-making capacity, are there clear protocols for a legally designated representative, who understands the will and preference of the participant, to consent on their behalf?
- Has the HSE National Policy for Consent in Health and Social Care Research policy been considered.
- Is the proposed approach to decision-making capacity and consent aligned with the HSE National Policy for Consent in Health and Social Care Research?
- Where obtaining consent from the study participant is not possible, is an application to seek a consent declaration from the Health Research Consent Declaration Committee required for the study?

Study withdrawal

- Will participants be able to have all their samples and/or data withdrawn from the study if they wish to do so? Have all withdrawal options been made clear in information documentation and consent forms i.e. fully withdraw from the study, withdraw from study treatment but agree to follow up etc.?
- Is it clearly outlined in the participant information leaflet what will happen to the participants samples and/or data upon withdrawal from the study?
- Is there any restriction on participant's ability to request retrieval and return /destruction of their data and/or samples? If so, is this restriction made clear to potential participants in the consent form.

Insurance and financial information

- Is there adequate insurance and indemnity in place for the duration of the study? Are the policies aligned with National Treasury Management Agency (NTMA) and Irish Pharmaceutical Healthcare Association (IPHA) guidelines?
- Is adequate financing of the study ensured?
- Do the financial arrangements introduce possible bias to the study teams?

- What arrangements are in place for reimbursement for direct costs related to research participation and compensation for lost income, time and inconvenience, incurred?

Data protection

- Does the study protocol include a detailed analysis of the ethics issues raised by your study methodology, including an overview of all planned data collection and processing operations; identification and analysis of the ethics issues that these raise; and an explanation of how you will mitigate these issues in practice.
- Has the National Office guidance documents on data protection been considered?
- Has it been adequately outlined how personal information will be managed and safeguarded according to national and European and national legislation throughout the lifecycle of the study?

Biological samples

- Is there a comprehensive description of the aims and scope of biological sample collection?
- Is it clear what type and amount of biological sample will be taken, as well as the (bodily) location that the tissue will be taken from, the manner by which the tissue will be taken and the safety and invasiveness of this?
- Is it clearly described where the samples will be transferred, processed and stored, and for how long and to what purpose?
- Is the process for reporting of incidental findings clearly outlined and justified?
- Has the National Office guidance document on use of biological samples and associated data been reviewed?

Genetic data and findings

- Does the study involve the collection and analysis of genetic material and data? If so, have the procedures involved in the study taken Article 4 of the IVDR into consideration, specifically the requirement to ensure that there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable according to the state of science and technology.
- Will participants be informed if the research has the potential to generate significant information about their personal health or that of a family member or children? Will participants be advised if the research has the potential to generate information of social significance, for example non-paternity or information that may influence access to insurance?
- Have you considered Section 3.4 of the HSE National Policy for Consent in Health and Social Care Research in relation to incidental findings.

Future research

- Will the data and samples provided by participants, be used only for the current study? If not, what else will they be used for i.e. related research? future undefined research? Is it documented in the consent form that separate ethics approval from a recognised research ethics committee will be sought, once the future research question is defined?
- If the applicant proposes to retain data and/or samples from this study for the purpose of future research:
    a. Is this specific and justified?
    b. Is this limited to future research related to the topic/ drug/ device under investigation?
    c. Will you seek participant consent to be contacted in the future about other research studies?
    d. Is the proposed future research clearly outlined in participant facing documents?
    e. Have you reviewed our guidance document on the future use of data?

Participant information leaflet / informed consent form (PIL/ICF)

- Is the information presented in appropriate, clear and understandable language for the study participants it is aimed at?
- Does the PIL comprehensively inform study participants about the purpose of the study, its procedures, potential risks, benefits, and alternatives?
- Does the PIL/ICF comprehensively outline proposed personal data processing activities, in clear and understandable language?
- Are potential participants given adequate time to review the documentation before consenting to take part, taking into consideration the nature and circumstances of the study (e.g. minimum 24 hours to decide).
- Does the consent form have an unbundled approach? Are there consent statements relating to the following (non-exhaustive list):
    a. Confirming they have read and understood the ICF
    b. That a copy of the signed ICF will be provided to them
    c. That their participation is voluntary and they are free to withdraw at any time (is there detail if the withdrawal is limited.)
    d. That their data/medical records might be viewed by sponsor, auditors, regulatory authorities etc
    e. Understanding that their data may be sent outside of the EU (if relevant)
    f. That their GP can/will be informed?
- Are there any optional components to the study. If yes, are these detailed in the ICF and is the consent for optional components separate from consent to the main study with separate signature sections?

- If data is to be anonymised, is there a consent statement for the processing of participant data from identifiable to anonymised as per GDPR requirements?
- Are the PIL and ICF a combined document rather than two separate documents?
- Is the data presented in a format that participants provide a consent to individual items (i.e. checkbox/ initials for each consent statement).
- Where a legally designated representative is providing consent on behalf of the participants, is the PIL and ICF tailored appropriately for them taking into consideration the points within this section, such that an informed decision can be made on behalf of the participant?