

STANDARD APPLICATION FORM –

FOR THE ETHICAL REVIEW OF HEALTH-RELATED
RESEARCH STUDIES WHICH ARE NOT CLINICAL TRIALS OF
MEDICINAL PRODUCTS FOR HUMAN USE AS DEFINED IN
STATUTORY INSTRUMENT 190/2004

GUIDANCE MANUAL

PREPARED BY:

STANDARD APPLICATION FORM CONSULTATION GROUP

SEPTEMBER 2011

"Engagement with [Research] Ethics Committees

I appreciated that my Office was approached during the year to participate in the finalisation of a draft Common Application Form for persons or entities applying for ethical approval to [Research] Ethics Committees in various hospitals and HSE areas. The process which was convened by Molecular Medicine Ireland was intended to assist in streamlining the process for researchers applying for ethical approval to Research Ethics Committees. It provided a key opportunity for my Office to assist [Research] Ethics Committees to highlight to applicants for ethical approval what the key data protection requirements are for any work with personal data for research purposes. A pilot of the new application form will now be put in place across selected hospitals and I look forward to continuing to work on this important initiative."

Billy Hawkes
Data Protection Commissioner

March 2010

[From the Twenty-First Annual Report of the Data Protection Commissioner 2009](#)

"Molecular Medicine Ireland is a charitable company established by TCD, UCD, RCSI, UCC and UCG to foster institutional collaboration between their five respective medical schools and academic hospitals in clinical and translational research and post graduate education. This has led to a number of collaborative initiatives including the Wellcome Trust and Health Research Board (HRB) funded Dublin Centre for Clinical Research (DCCR), the HEA funded Clinician Scientist Fellowship Programme (CSFP) and the HRB/HSE funded Irish Clinical Research Infrastructure Network (ICRIN). Key to the success of these initiatives is the development of a more streamlined approach to clinical research governance and ethical review..For academic and investigator led research studies that do not involve medicinal products covered by SI 190, the conduct of multi-site clinical research requires that a separate application is made to the ethics committee of each hospital before a study can commence. With more collaborative and networked clinical research activities taking place in Ireland, applications for approval of the same study to multiple hospital Research Ethics Committees (RECs) are increasing and will continue to grow in number. At present each REC has its own application form, adding considerable to the complexity of conducting multi-site clinical studies."

Dr. Ruth Barrington
Chief Executive
Molecular Medicine Ireland

May 2009

"The St. James's Hospital & Adelaide & Meath Hospital Dublin, incorporating the National Children's Hospital Research Ethics Committee is one of the busiest in the country. The Committee reviews many clinical trials and academic and investigator led research studies that do not involve medicinal products covered by SI 190. The SJH/AMNCH Ethics Committee and Secretariat has been very happy to play a role in creating a collaborative research network across the county. It is hoped that the work to date on streamlining the processes and procedures will continue and so facilitate the review and conduct of research in Ireland."

Dr. Ray McDermott
Consultant Medical Oncologist
Chairperson Research Ethics Committee
Adelaide and Meath Hospital, Dublin,
Incorporating the National Children's Hospital

July 2010

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FOREWORD

Biomedical research, whether by means of a physical intervention on patients or healthy volunteers, use of stored biological material, or data obtained by questionnaires, seeks to diminish existing uncertainties and improve our understanding of health and disease. Ultimately, the results obtained in such research, contribute to appropriate and improved healthcare directed at meeting the needs of patients.

Research Ethics Committees (RECs) play a central role in the research process. The task of RECs has become increasingly demanding and complex over the last decade. As well as upholding the rights of research participants, RECs are tasked with assessing the risks and benefits of research, ensuring consent is valid, protecting confidentiality and privacy, and more recently with the monitoring and auditing of ongoing and completed research. Increasingly, biomedical research is being conducted at multiple research sites both nationally and internationally and because of the volume and varied nature of the research reviewed, members of local RECs have a demanding task maintaining a coherent approach.

It has been recognised that the efficiency of ethical review and the diversity of practice amongst committees has posed a challenge for the research community. The ethical review process had become regarded by some as an obstacle to research rather than a facilitator of it. In response, RECs have adopted a pro-active approach in dispelling this view. By September 2008, RECs recognised for the review of clinical trials of medicines were all utilising a single application form devised by the Irish Council for Bioethics, at the request of the Department of Health & Children. Also in 2008, a group of REC administrators launched a initiative to draft a common application form for research proposals which fall outside the remit of the regulations for clinical trials for medicinal products. A comprehensive series of consultations among the Research Ethics Committees and with the broader research community and State agencies was undertaken and a common form was piloted from January 2010 by four RECs. A formal evaluation of the pilot phase accompanies the final draft of the common application form and guidance manual.

This initiative originated from the RECs themselves and without the energy, enthusiasm and dedication of, in particular, REC administrators and members, this project would not have

V5.5 September 2011

succeeded. The significant contribution of the Dublin Centre for Clinical Research, Molecular Medicine Ireland, the Office of the Data Protection Commissioner, the State Claims Agency, the Irish Medicines Board and A&L Goodbody Solicitors should also be acknowledged.

Research ethics committee members dedicate significant time and effort, on a voluntary basis, to undertake their duties, often without adequate financial support, and in so doing, provide an invaluable public service. Undoubtedly, the introduction of a common application form, will significantly contribute to a more streamlined approach that should facilitate efficient ethical review and should improve the calibre of application completed by researchers and submitted to RECs. It will also be key in facilitating communication and interaction between researchers and ethics committees, allowing both to work together as partners in the process of ethical review.

Dr. Siobhan O'Sullivan
Scientific Director
Irish Council for Bioethics
July 2010

INTRODUCTION

This Guidance Manual accompanies the Standard application Form developed for health-related research studies not covered by SI 190. Its purpose is to guide applicants when completing the form. It is a reference document that provides detailed context for the questions asked and directs applicants to other related sources of information. The Guidance Manual will be reviewed and updated on a regular basis. The need for a Guidance Manual was identified during the development of the Standard Application Form.

The Guidance Manual has benefited from wide ranging and comprehensive input. As well as input from Research Ethic Committees, it has benefited from consultation from a wide range of bodies including State Claims Agency, Irish Medicines Board, Office of Data Protection Commissioner, The National Centre for Medical Genetics and Irish Council for Bioethics. A full list can be found in Appendix 7.

In 2009 a Consultation Group was formed by representatives of hospital Research Ethics Committees (RECs) from across Ireland (see Appendix 6 - Consultation Group) to work towards developing a Standard Application Form. This form is to be used for the ethical review of health-related research studies that are not clinical trials of medicinal products for human use as defined by SI 190. While trials of medicinal products are subject to a common application form issued by the Department of Health and Children, this has not been the case for other types of clinical research. This includes, for example, investigator led research, radiotherapy trials and trials of medical devices. This places a burden on those researchers wishing to undertake multi-site studies who must complete a separate REC application for each hospital site. The main rationale of the Standard Application form project was that applicants would be able to complete a form once and submit it to multiple committees. One of the anticipated benefits of the Standard Application form is that the research ethics application process will become more streamlined and the costs of clinical research, which are often funded by charitable bodies, will be reduced.

The Consultation Group's mandate comes from its members who have voluntarily agreed to collaborate on the development of this Standard Application Form. Each REC is independent and will need to formally decide to adopt the Standard Application Form and the accompanying Guidance Manual.

LIST OF SECTION HEADINGS IN THE STANDARD APPLICATION FORM

SECTION A	GENERAL INFORMATION	MANDATORY
SECTION B	STUDY DESCRIPTORS	MANDATORY
SECTION C	STUDY PARTICIPANTS	MANDATORY
SECTION D	RESEARCH PROCEDURES	MANDATORY
SECTION E	DATA PROTECTION	MANDATORY
SECTION F	HUMAN BIOLOGICAL MATERIAL	OPTIONAL
SECTION G	RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION	OPTIONAL
SECTION H	MEDICAL DEVICES	OPTIONAL
SECTION I	MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS	OPTIONAL
SECTION J	INDEMNITY	MANDATORY
SECTION K	COST AND RESOURCE IMPLICATIONS AND FUNDING	MANDATORY
SECTION I	ETHICAL ISSUES	MANDATORY

IN DEPTH INSTRUCTIONS ON HOW TO COMPLETE EACH QUESTION IN THE STANDARD APPLICATION FORM

This Application Form is divided into Sections.

Sections A, B, C, D, E, J, K, L are **MANDATORY**

Sections F, G, H, and I are **optional**. Sections F, G, H, and I may be deleted where these sections do not apply to the application being submitted for review.

IMPORTANT NOTE: It is imperative that the Standard Application Form is not completed if there is any possibility that the study for review is a clinical trial of medicinal product as defined by Statutory Instrument 190/2004.

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: The application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Each question should be responded to carefully. Refer to the in-depth instructions prior to deleting any question.

SECTION A GENERAL INFORMATION

A1 Title of the Research Study:

[TYPE ANSWER=TA]

A2 Principal Investigator(s): (The Principal Investigator takes overall responsibility for the study. Please provide a 2 page curriculum vitae of the Principal Investigator for review.)

Title: DR / MS / MR / PROF

Name: [TYPE ANSWER=TA]

Qualifications: [TA]

Position: [TA]

Dept: [TA]

Organisation: [TA]

Tel: [TA]

E-mail: [TA]

Action: Please copy and paste the headings in Question A2, should you wish to add a Joint Principal Investigator.

A3 (a) Is this a multi-site study?

Yes / No

A3 (b) Please name each site where this study is proposed to take place and state the lead investigator for each site: (the 'lead investigator' at a site takes primary responsibility for the study at that site.)

SITE:	LEAD INVESTIGATOR:
[TYPE ANSWER=TA]	[TYPE ANSWER=TA]

Action: Please add rows to the above table should you wish to add a site.

A3 (c) For any of the sites listed above, have you got an outcome from the Research Ethics Committee (where applicable)? (Please ensure that you have provided copies of any approvals which you have referred to in your response.)

[TYPE ANSWER]

A4: Co-Investigators: (Please provide the details of the Main 'Co-Investigators')

Name of Site: [TYPE ANSWER=TA]

Title: DR / MS / MR / PROF

Name: [TA]

Qualifications: [TA]

Position: [TA]

Organisation: [TA]

Role in Research: [TA]

Action: Please copy and paste the headings in Question A4 should you wish to add a Co-Investigator

A5. Lead contact person who is to receive correspondence in relation to this application / who is to be contacted if a query arises in relation to this application.

(For administrative and correspondence purposes, committees require a person who is familiar with this study who is available to address queries as they arise. This person can be the Principal Investigator, or any person who has been delegated this task by the Principal Investigator.)

Title: DR / MS / MR / PROF

Name: [TA]

Address: [TA]

Tel (work): [TA]

Tel (mobile): [TA]

E-mail: [TA]

A6 Please provide a lay description of the study. (The lay summary should be in simple language between 100 and 500 words in length only. There is a word limit in place.)

[TYPE ANSWER]

A7 (a) Is this study being undertaken as part of an academic qualification? (Students are encouraged not to complete this application form without the assistance of an academic supervisor)

Yes / No

Action: If you chose 'no' please delete Question A7 (b).

A7 (b) If yes, please complete the following:

Student name: [TA]

Course: [TA]

Institution: [TA]

Academic supervisor: [TA]

SECTION B STUDY DESCRIPTORS

APPLICANTS MAY COPY AND PASTE FROM STUDY PROTOCOLS AS A STARTING POINT TO RESPONDING TO THE QUESTIONS IN SECTION B. PLEASE HOWEVER AVOID STATEMENTS SUCH AS 'SEE ATTACHED PROTOCOL FOR DETAILS'

B1. Provide information on the study background. (Committees are interested in knowing where the idea for this study has come from, if a literature review has been done and what the rationale for doing this study is. Your answer should be between 100 – 500 words in length to include a maximum of five references. There is a word limit in place. If a study protocol is available, please ensure that the study protocol has been provided for the review of the committee. Please note that study protocols are not distributed to all committee members. However, all committee members will receive a copy of this application form.)

[TYPE ANSWER]

B2. List the study aims and objectives. (Any study proposed which cannot answer the research question posed is unethical)

[TYPE ANSWER]

B3. List the study endpoints (if applicable). (A study 'endpoint' is the outcome that this study is designed to evaluate.)

[TYPE ANSWER]

B4. Provide information on the study design. (The study design chosen should be appropriate to achieving the aims and objectives stated in response to B2)

[TYPE ANSWER]

B5. Provide information on the study methodology. (Please ensure that you provide copies of any instruments / questionnaires etc. referred to in your response.)

[TYPE ANSWER]

B6. What is the anticipated start date of this study?

[TYPE ANSWER]

B7. What is the anticipated duration of this study?

[TYPE ANSWER]

B8 (a) How many research participants are to be recruited in total? (State total number of participants.)

[TYPE ANSWER]

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice. (It is important to get the advice of a statistician in relation to all

research studies. The statistician will advise if a statistical approach is relevant to this particular research study.)

[TYPE ANSWER]

B8 (c) Please give a brief justification of sample size and details of the sample size calculation (including minimum clinically important difference). (It is important to obtain the advice of a statistician in relation to all research studies.)

[TYPE ANSWER]

B8 (d) Where sample size calculation is impossible (e.g. it is a pilot study and no previous studies can be used to provide the required estimates) then please explain why the sample size to be used has been chosen. (It is important to obtain the advice of a statistician in relation to all research studies.)

[TYPE ANSWER]

SECTION C STUDY PARTICIPANTS

SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1. 1 How many research participants are to be recruited? At each site (if applicable)? And in each arm of the study (if applicable)?

(You have already provided the overall totals in your response to Question B8 (a) and B8 (b). The overall totals were relevant in respect of research design and statistical analysis.

The focus of this question (C1) is different and is on the totals at each site. Committees will have a particular interest in knowing the numbers of participants at the site or sites for which they provide an ethical review.)

NAME OF SITE:	Names of arms (if applicable)		
	Insert name of arm (if applicable): [TYPE NAME OF ARM]	Insert name of arm (if applicable): [TYPE NAME OF ARM]	Insert name of arm (if applicable): [TYPE NAME OF ARM]
[TYPE ANSWER]	[TYPE NUMBER]	[TYPE NUMBER]	[TYPE NUMBER]

Action: Please add rows to the above table should you wish to add a site.

Action: Please add columns to the above table should you wish to add an 'arm'

C1.2 How will the participants in the study be selected?

(Please outline how you will identify the participants for the study e.g. referral list to hospital clinic, random selection of patients from GP Register etc.)

[TYPE ANSWER]

C1.3 How will the participants in the study be recruited?

(Please indicate how and who will identify the participants for the study e.g. letter of invitation, verbal approach when attending the clinic, poster advertisement, web advertisement etc. Please ensure that you provide copies of all letters and advertisements referred to in your response for review)

[TYPE ANSWER]

C1.4 What are the main inclusion criteria for research participants? (Please justify)

(Please be careful when responding to this question especially if there is more than one grouping of research participants. Please state the inclusion criteria for each group of research participants.)

[TYPE ANSWER]

C1.5 What are the main exclusion criteria for research participants? (Please justify)

(Please be careful when responding to this question especially if there is more than one grouping of research participants. Please state the exclusion criteria for each group of research participants.)

[TYPE ANSWER]

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project? (Researchers should consider the effect of over-burdening participants in terms of the number of research projects they are invited to participate in.)

Yes / No / Not to my knowledge

SECTION C2 PARTICIPANTS – INFORMED CONSENT

“In medical research regarding competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researchers, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study.... After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must seek the potential subject’s freely-given informed consent, preferably in writing.....”
[World Medical Association Declaration of Helsinki, 2008.](#)

“Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members....., no competent individual may be enrolled in a research study unless he or she freely agrees.”
[World Medical Association Declaration of Helsinki, 2008.](#)

C2.1 (a) Will informed consent be obtained?

Yes / No

Action: If you chose ‘no’ please delete C2.1 (c) (d) (e) (f) (g) and (h)

Action: In addition, if you chose ‘no’ please delete the following questions in Section C4: C4.4, C4.5 C4.6 and C4.7 (These questions relate to consent of parents/legal guardians of children and assent of children)

Action: If you chose ‘yes’ please delete C2.1 (b)

C2.1 (b) If no, please justify.

[TYPE ANSWER]

C2.1 (c) If yes, how will informed consent be obtained and by whom?

(Only appropriately qualified and competent persons should take informed consent. Please ensure you provide copies of any Information Leaflets, Consent Forms and Assent Forms referred to in response to this question.)

[TYPE ANSWER]

C2.1 (d) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.

(“A patient’s refusal to participate in research must not influence your care of that patient in any way.”
[Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2009.](#)

“The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.”

[World Medical Association Declaration of Helsinki, 2008.](#)

It is noted that in some studies, e.g. those involving anonymous questionnaires it will be impossible for the research participant to withdraw from the study. However, where withdrawal is a possibility, please confirm that all identifiable data and identifiable human biological tissue samples will be destroyed either when the participant withdraws or when the research participant specifically requests that this occur. All relevant Information Leaflets should also include this information.)

[TYPE ANSWER]

C2.1 (e) If No, please justify.

[TYPE ANSWER]

C2.1 (f) Will there be a time interval between giving information and seeking consent?

(Research participants should be given a reasonable period of time in order to make a decision about whether or not they wish to participate in a research study. Ideally, there should be adequate time for the participant to consult with family, friends and general practitioners before making a decision.

It is recognised however that some studies are low-risk and participants may be asked to make a decision with regard to participation there and then. In other cases, it may be impossible due to the nature of the study for participants to be given an extended period of time to make a decision.)

Yes / No

Action: If you chose ‘no’ please delete C2.1 (g)

Action: If you chose ‘yes’ please delete C2.1 (h)

C2.1 (g) If yes, please elaborate. (Please comment on how much time participants will be given to make a decision)

[TYPE ANSWER]

C2.1 (h) If no, please justify. (Where participants are required to make an instantaneous decision, please justify.)

[TYPE ANSWER]

SECTION C3 ADULT PARTICIPANTS - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent?

An adult is defined as a person aged 18 years or over. ⁱ

Capacity is defined as the ability to understand the nature and consequences of a decision in the context of available choices at the time the decision is to be made. ⁱⁱ

A person lacks the capacity to make a decision if he or she is unable -

(a) to understand the information relevant to the decision,

OR

(b) to believe the information

OR

(c) to retain that information long enough to make the decision,

OR

(d) to use or weigh that information as part of the process of making the decision,

OR

(e) to communicate his or her decision (whether by talking, using sign language or any other means ⁱⁱⁱ

Yes / No / Non Applicable

Action: If you chose 'yes' please delete C3.1 (b) (c) and (d)

Please ensure you chose 'Non Applicable' if you responded 'no' to Question C2.1 (a)

Action: If you chose 'non applicable' please delete C3.1 (b) (c) and (d)

C3.1 (b) If no, please elaborate. (Please state clearly how capacity to participate in this research study will be determined. Please also state clearly how the issue of consent and assent will be managed for those research participants who lack capacity)

[TYPE ANSWER]

C3.1 (c) If no, is this research of such a nature that it can only be carried out on adults without capacity? (If this research study can validly take place using adult participants with capacity, adult participants without capacity should not be included.)

Yes / No

C3.1 (d) What arrangements are in place for research participants who regain their capacity during the study?

[TYPE ANSWER]

SECTION C4 PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. children?

(A "child" is a person under the age of 18 years as per Section 2 of the Child Care Act 1991)

Yes / No

Action: If you chose 'no' please delete all remaining questions in C4.

C4. 1 (b) If yes, please specify:

Persons < 16 (Persons under the age of 16^{iv} cannot give consent to take part in most research studies, and (if consent is being sought) it should be sought from one parent or one legal guardian. It is

recommended however that persons under the age of 16 be assented to participate in a manner appropriate to their age and level of understanding. **It is strongly recommended that expert advice be sought where the research study involves persons under 16.)**

Yes / No

Persons aged 16 – 18 (Persons between the ages of 16 and 18 form a special category of persons under the age of 18 who can legally give consent for medical, surgical and dental treatment.^v It can be argued that this entitlement does not extend to participation in medical research.^{vi} This has not been tested in the Irish courts however. Therefore the conservative approach would be (if consent is being sought) to approach one parent or one legal guardian to give consent on their behalf and for the persons between 16-18 to read an Information Leaflet appropriate for young persons and to sign an Assent Form. This matter however will need to be dealt with on a case by case basis, as some research studies involve the collection of data only.^{vii}^{viii} **It is strongly recommended that expert advice be sought where the research study involves persons between 16 – 18)**

Yes / No

Children in Care (There may be legal difficulties in recruiting a child who is the subject of a care order under Section 18 of the Child Care Act 1991 to a research study. This issue also arises in respect of a child who is in foster care as per the 1995 Children in Foster Care Regulations.^{ix} **It is strongly recommended that expert advice be sought where the research study involves children in care.)**

Yes / No

C4.2 Is this research of such a nature that it can only be carried out on children?

(Research which can validly take place using adult participants should proceed without the inclusion of child participants)

Yes / No

C4.3 Please comment on what will occur if the researcher discovers that a child is at risk during the course of this study? (It is recommended that all researchers familiarise themselves with the [Children First National Guidelines for the Protection and Welfare of Children.](#))

[TYPE ANSWER]

Action: The following questions apply only if consent is being sought as per your response to Question 2.1 (a).

If you responded 'no' to Question C2.1 (a), please delete C4.4, C4.5, C4.6 and C4.7.

C4.4 Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the study? Please elaborate.

(Age-Appropriate Information Leaflets and Assent Forms are important in this respect e.g. an Information Leaflet should be designed for 12-16 year olds, for 8 to 12 year olds and for children under 8. While children over 8 may read the Information Leaflet themselves, children under 8 should have the Information Leaflet read to them.)

[TYPE ANSWER]

C4.5 Will the explicit wish of the child who is capable of forming an opinion and assessing information to refuse to participate or to be withdrawn from the study be considered by the lead investigators, co-investigators and principal investigator? Please elaborate.

(Where the child refuses to participate or wishes to be withdrawn from a study, it is strongly recommended that the wishes of the child be upheld. Children may not always be in a position to form an opinion however, either due to their age or depending on how sick they are.)

[TYPE ANSWER]

C4.6 Please comment on the involvement (if any) of Parents / Legal Guardians of the child in the consent process. (Please note that it is only necessary (where consent is being sought from parents / legal guardians) for one parent or one legal guardian to sign a Consent Form in order for the child to participate in a research study. Please also refer to the Endnotes at the rear of the Guidance Manual – Appendix Nine.)

[TYPE ANSWER]

C4.7 Please explain your approach to reviewing assent where research subjects reach the age of 18 during the course of the study.

[TYPE ANSWER]

SECTION C5 PARTICIPANTS - CHECKLIST

“Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence. “

[World Medical Association Declaration of Helsinki, 2008.](#)

Please confirm if any of the following groups will participate in this study. This is a quick checklist for research ethics committee members and it is recognised that not ALL groups in this listing will automatically be vulnerable or lacking in capacity.

C5.1 Patients (Patients should be made aware that should they decide not to participate in a research study that this will have not have any impact on their care. Patients may be vulnerable and may find it difficult to say ‘no’ especially in cases where the researchers are also involved in their care. This difficulty may increase in cases where patients are chronically ill, severely ill or terminally ill and are in a dependent relationship with the Principal Investigator, Lead Investigator or Co-Investigators)

Yes / No

C5.2 Unconscious patients (Unconscious patients cannot give consent. Where possible however, assent should be obtained from the next of kin. This assent where it applies to research interventions / procedures, and not to the ‘processing of personal data,’ has no legal value but performs the function of informing the next of kin that the patient is participating in a research study.

In relation to the ‘processing of personal data’ only, valid consent can be given by the certain named classes of next of kin.^x – Please refer to Section E also on this point.

Patients should be informed of their involvement in a research study upon regaining capacity and consent should be obtained from patients themselves at this time.^{xi})

Yes / No

C5.3 Current psychiatric in-patients (A number of committees provide an ethical review for research studies taking place in psychiatric in-patient facilities. **It is strongly recommended that expert advice be sought where the research study involves current psychiatric in-patients.**)

Yes / No

C5.4 Patients in an emergency medical setting (Patients should be made aware that should they decide not to participate in any research study that this will have not have any impact on their care. Patients in an emergency setting may be in vulnerable and may find it difficult to say ‘no’ especially in

cases where the researchers will also be involved in their care. Secondly, trauma, shock or injury may also affect capacity on a case by case basis. Thirdly, many patients in an emergency setting may be unconscious, intubated etc.)

Yes / No

C5.5 Relatives / Carers of patients (Relatives or Carers of Patients recruited due to their relationship with the patient must be consented separately for their own involvement in any research study.)

Yes / No

C5.6 Healthy Volunteers (It is not uncommon for researchers to seek healthy volunteers in particular as act as 'controls' in respect of a given research study.)

Yes / No

C5.7 Students (A number of committees provide an ethical review for studies taking place in schools and educational facilities. In these cases, students can be primary, post-primary or third level students. A number of further committees provide an ethical review for studies in healthcare settings. Students in this context can therefore include undergraduate medical and nursing students etc. Students in training towards a professional qualification may be vulnerable and unable to say 'no' in terms of participation in a research study by virtue of their position in the organisation or their relationship with the Principal Investigator, Lead Investigator or Co-Investigator.)

Yes / No

C5.8 Employees / staff members (Employees and staff members may be vulnerable and unable to say 'no' in terms of participation in a research study by virtue of their position in the organisation or their relationship with the Principal Investigator, Lead Investigator or Co-Investigator. This is particularly the case where employees or staff members are in a dependent relationship with the Principal Investigator, Lead Investigator or Co-Investigators.)

Yes / No

C5.9 Prisoners (A number of committees provide an ethical review for studies taking place in prison facilities.)

Yes / No

C5.10 Residents of nursing homes (A number of committees provide an ethical review for research studies taking place in community settings including private and public nursing homes)

Yes / No

C5.11 Pregnant women (Committees are interested to know if pregnant women are being recruited to a study. This applies to studies involving exposure to radiation in particular. Secondly, a number of research ethics committees provide an ethical review specifically on behalf of maternity hospitals.)

Yes / No

C5.12 Women of child bearing potential (Committees are interested to know if women who may be or may become pregnant are being recruited to a study. This applies to studies involving exposure to radiation in particular.)

Yes / No

C5.13 Breastfeeding mothers (Committees are interested to know if breastfeeding mothers are being recruited to a study. This applies to studies involving exposure to radiation in particular.)

Yes / No

C5.14 Persons with an acquired brain injury (Some research participants may lack capacity by virtue of an acquired brain injury. However, capacity should be assessed on a case by case basis.)

Yes / No

C5.15 Intellectually impaired persons (Some research participants may lack capacity by virtue of an intellectual disability. However, capacity should be assessed on a case by case basis. There is no available definition for 'intellectual impairment' and hence this term should be taken to refer to both learning disability and intellectual disability. A number of committees provide an ethical review for research occurring in the community, including specifically the 'intellectual disability' services.)

Yes / No

C5.16 Persons aged > 65 (Persons over the age of 65 are not necessarily either vulnerable or lacking in capacity)

Yes / No

C5.17 If yes to any of the above, what special arrangements have been made to deal with issues of consent and assent (if any)? (It is recognised that not ALL groups in the above listing will automatically require special arrangements in relation to consent and assent. Secondly, you may have already provided the necessary information in your response to Question C3.1 (b). There can be a crossover between groups which may be vulnerable, groups which may require special arrangements in relation to consent and assent and persons who lack capacity.)

[TYPE ANSWER]

SECTION D RESEARCH PROCEDURES

D1. What research procedures or interventions (over and above those clinically indicated and/or over and above those which are part of routine care) will research participants undergo whilst participating in this study?

(This means research procedures or interventions which the participants are undergoing as part of the research study, and not those procedures and interventions which participants are undergoing as part of routine care (or equivalent) i.e. which they would undergo irrespective of involvement in this research study or not. 'Research Procedures' is a very broad term which encompasses medical examinations, laboratory tests, x-rays, other imaging, physiotherapy sessions, counselling sessions, psychological assessments, questionnaires, interviews and focus groups i.e. any type of intervention or measure which research participants will engage in.

It is further noted that not all research participants will be patients. For a healthy volunteer or staff member taking part in a research study, no procedures or interventions will be 'clinically indicated' or 'part of routine care.' Nevertheless, please also list interventions or procedures which healthy volunteers or staff members will undergo due to their involvement in this research study only.

Secondly, committees are also interested in knowing if there are any extra tests or analyses being done on samples taken which are over and above those tests done as part of routine clinical care. Please also refer to tests / analyses in response to this question where this applies.)

[TYPE ANSWER]

D2. If there are any potential harms resulting from any of the above listed procedures, provide details below:

(All research on human beings carries the possibility of harm. Whether the risk of harm is acceptable or not depends on the importance of the question being addressed and the likelihood of a meaningful result from the study.

Harms can be physical, psychological, psychosocial or other and can include pain, discomfort, inconvenience or change to lifestyle. Even seemingly innocuous questionnaires can upset patients and / or change the way they view or manage their illness.

It is also wise to classify the harms listed. Harms can be classified as serious, non-serious, transient etc. It is also useful to committees if you state the risk (probability) of the harms occurring, where this is possible: the risk of harms occurring can in some studies be stated with accuracy. It is recognised however that for many studies the risk (probability) of harm occurring will not be quantifiable.

Where relevant, please also state in your answer what measures will be put in place, if any, to ensure the risk of these harms occurring is minimised.

Important Note: Please ensure any relevant harms listed in response to this questions are clearly outlined in any Information Leaflets related to this study

Important Note: All serious adverse events occurring during the course of this research study must be reported as per each committee's local guidelines in this matter.

Note: The term 'serious adverse event' is more typically associated with clinical trials of medicinal products. A generic definition for a 'serious adverse event' outside of S.I. 190/2004 is not available. Hence, please report all Serious Adverse Events in line with each committee's local definitions and guidelines in this matter.)

[TYPE ANSWER]

D3. What is the potential benefit that may occur as a result of this study? (There may be a direct benefit for research participants. There may be a benefit for the researcher in terms of academic qualification or career advancement. There may be a benefit for the healthcare system in general or for an organisation / site or service. There may be a benefit to a pharmaceutical company, device manufacturer, charity etc.)

[TYPE ANSWER]

D4 (a) Will the study involve the withholding of treatment? ('treatment' may include prescribed drugs, surgery, radiotherapy, physiotherapy, occupational therapy etc.)

Yes / No / Non-Applicable

Action: If you chose 'no' or 'non-applicable' please delete D (b) and D (c)

D4 (b) Will there be any harms that could result from withholding treatment?

Yes / No

Action: If you chose 'no' please delete D (c)

D4 (c) If yes, please elaborate.

[TYPE ANSWER]

D5. How will the health of participants be monitored during and after the study?

(Some research studies may involve special arrangements in this regard. However, it is recognised that in many research studies, especially those involving staff members, monitoring of the health of participants is neither appropriate nor necessary.

Please provide details however if the health of participants is being monitored. Participants should also be informed of this monitoring in all relevant Information Leaflets.

Committees will also have a particular interest in knowing if the study/trial itself is being monitored / overseen by an Independent Data Safety Monitoring Board. Again, a DSMB is neither appropriate nor necessary for many research studies)

[TYPE ANSWER]

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? (This question should be interpreted in a broad sense e.g. in a study which provides a broadband connection free of charge to research participants, 'free broadband' is the intervention and question relates to whether this will continue to be provided after the study has finished.)

"At the conclusion of a the study, patients entered into the study are entitled....to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits."

[World Medical Association Declaration of Helsinki, 2008.](#)

Yes / No

Action: If you chose 'no' please delete D6 (b)

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention? (Committees are interested in knowing if the interventions provided during the course of this study which are being made available to research participants after the study has ended, will be free of charge to research participants. The term 'cost of provision' also refers to the cost to sites / organisations in providing the ongoing interventions in question.)

[TYPE ANSWER]

D7. Please comment on how individual results will be managed. (It is extremely important for researchers to decide in advance if research participants will receive individual results in relation to this study, or alternatively, if study results will be sent to the research participant's general practitioner or consultant (subject to consent). Secondly, a definite plan needs to be decided in terms of what referral or care pathways will be in place in case of a negative finding / result / outcome for any individual research participant. Finally, a definite plan needs to be decided in terms of 'incidental findings.' 'Incidental findings' are findings which are discovered during the course of a research study which are 'incidental' i.e. a researcher may not be conducting research into cholesterol, but during the course of his / her research study may 'incidentally' discover that a participant has high cholesterol. It should be decided in advance whether 'incidental findings' will be relayed to the research participant. It is recognised however that not all research studies generate results which have individual meaning and not all research studies include the possibility of either 'negative findings' or 'incidental findings'.')

[TYPE ANSWER]

D8. Please comment on how aggregated study results will be made available.

Researchers should decide in advance in so far as possible what their intention is in terms of release of overall study results. This may include publication in peer-reviewed journals, poster and verbal presentations, or submission of a final thesis to a university.

Researchers should be aware that if the research study fulfils the World Health Organisation definition of a 'clinical trial' that they must register the trial in a publicly accessible database.

"Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject."

[World Medical Association Declaration of Helsinki, 2008.](#)

"For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted

to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

[World Health Organization](#))

Researchers may also wish to consider if it will be appropriate or meaningful to inform individual participants or collectives of research participants (e.g. Patient Organisations) of the overall outcome of the research study. The guidance in the Declaration of Helsinki is as follows:

"At the conclusion of the study, patients entered into the study are entitled to be informed of the outcome of the study..."

[World Medical Association Declaration of Helsinki, 2008.](#)

[TYPE ANSWER]

D9. Will the research participant's general practitioner be informed the research participant is taking part in the study (if appropriate)? (If yes, please ensure permission is sought from the research participant for the researcher to make contact with the research participant's general practitioner. If the general practitioner is being informed, please provide a copy of the letter to the GP for review by the committee.

Patient Safety should the key factor is deciding whether it will be necessary to inform the participant's General Practitioner.)

Yes / No / Non-Applicable

D10. Will the research participant's hospital consultant be informed the research participant is taking part in the study (if appropriate)? (If yes, please ensure permission is sought from the research participant for the researcher to make contact with the research participant's consultant. If the hospital consultant is being informed, please provide a copy of the letter to the hospital consultant for review by the committee.

Patient Safety should the key factor is deciding whether it will be necessary to inform the participant's hospital consultant.)

Yes / No / Non-Applicable

SECTION E DATA PROTECTION

SECTION E1 DATA PROCESSING - CONSENT

RESEARCHERS ARE REMINDED THAT THE DATA PROTECTION LEGISLATION APPLIES IN RESPECT OF THE PROCESSING OF 'PERSONAL DATA' OF LIVING PERSONS.

DURING STUDY DESIGN STAGE RESEARCHERS ARE ADVISED TO ASK THEMSELVES THESE QUESTIONS:

1. Does this study involve the processing of personal data of living persons?
2. Is it possible for this study to be undertaken using irrevocably anonymised data?
3. Is it possible for this study to be undertaken using pseudonymised data?

"Irrevocable anonymisation of personal data puts it outside data protection requirements as the data can no longer be linked to an individual and therefore cannot be considered to be personal data."

"Equally, it is recognised that the need to link episodes of care and prevent duplication of data in research, in some instances, requires that information may need to be capable of being matched or linked. This can

be achieved through appropriate pseudonymisation (e.g., use of initials, coding) methods without the need to retain all identifying characteristics with the data."

"Similar to the advice above in relation to anonymisation, where pseudonymisation methods are used, it is recommended that extra efforts, beyond use of initials etc, be incorporated where a condition is particularly rare. Where sufficient measures are put in place to ensure that personal data is not accessible or likely to be identifiable by parties external to the data controller, the requirement to capture consent to use the data for research purposes, in such circumstances, will no longer apply"

[Data Protection Guidelines on Research in the Health Sector.](#)

STUDIES WHERE WRITTEN CONSENT OF RESEARCH PARTICIPANTS** IS OBTAINED FOR THE PROCESSING OF PERSONAL DATA ARE THE GOLD STANDARD. THE DATA PROTECTION LEGISLATION HOWEVER ALSO PERMITS CONSENT** TO BE GIVEN BY PERSONS OTHER THAN THE DATA SUBJECT WHERE HE/SHE LACKS CAPACITY TO GIVE CONSENT FOR PROCESSING OF PERSONAL DATA.

Section 2A(1) of the Acts provides that, where a person by reason of his or her physical or mental incapacity or age, is or is likely to be unable to appreciate the nature and effect of giving consent, such consent may be given by a [parent or guardian or a grandparent, uncle, aunt, brother or sister](#) of the person provided that the giving of such consent is not prohibited by law.^{xii}

Please refer to your response to Question C2.1 (a) before responding to Question E1.1 (a)

E1.1(a) Will consent be sought for the processing of data? (Consent is an absolute requirement for the processing of 'personal data' only. 'Personal data' is defined in the Data Protection Acts as follows: "data relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller." It covers any information that relates to an identifiable, living individual. However, it needs to be borne in mind that data may become personal from information that could likely come into the possession of a data controller. Often a case by case assessment must be made taking account of some of the above considerations as to whether data could be deemed to be personal.)

Yes / No

Action: If you chose 'yes' please delete E1.1 (b)

E1.1(b) If no, please elaborate. (If consent is not being sought irrevocably anonymised data and/or appropriately pseudonymised data may be processed ONLY. The 'appropriateness' of the pseudonymisation proposed should be assessed on a case by case basis.)

[TYPE ANSWER]

SECTION E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected? (Please ensure to inform research participants in all relevant Information Leaflets who will have access to the data collected.)

[TYPE ANSWER]

E2.2 What media of data will be collected? (Data can be hard copy or electronic; data can be visual e.g. video recordings, clinical photographs, images; data can be audio data e.g. tape recordings.)

[TYPE ANSWER]

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data? (Please note that different media

may be classed differently. Questionnaires for example may be completely anonymous rendering it impossible to ascertain which research participant completed an individual questionnaire. In a research study involving an anonymous questionnaire it would be impossible for a research participant to withdraw from the study once data collection has occurred. Images may be identifiable in particular where images are clearly marked with a patient's name or medical record number. Photographs of the face and video-recordings, for example, are identifiable. The term 'irrevocably anonymised' applies when the data which was originally identifiable has been rendered 'anonymous' by the researcher e.g. to delete the patient name, medical record number from an 'x-ray' would irrevocably anonymise the X-Ray. It should be noted that it can be more difficult to successfully de-identify photographs of the face and video-recordings. The term 'pseudonymised' is a form of anonymisation wherein duplication is avoided by the use of 'initials / year of birth' for example. Finally, data is often coded i.e. it is possible to identify the participant from the data via a code which is retained by the researcher.)

[TYPE ANSWER]

E2.3 (b) If 'coded' please confirm who will retain the 'key' to re-identify the data?

(It is recommended that the key to re-identify 'coded' data remain at the site of origin of the data. It is further recommended that the person who holds the 'key' to re-identify be the lead investigator at the site.)

[TYPE ANSWER]

E2.4. Where will data which is collected be stored? (Please note that different media may be stored in different fashions.)

[TYPE ANSWER]

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data. (These measures would include locked filing cabinets, password protected computers, encryption of desktop computers and portable devices and encryption of individual files. It is strongly advised that 'personal' data is not stored on portable devices or home-based desktops. However, where this is absolutely necessary, encryption software should be installed. Researchers should be aware of their responsibilities under the data protection legislation to keep electronic and hard copy 'personal data' safe and secure.)

[TYPE ANSWER]

E2.6 (a) Will data collected be at any stage leaving the site of origin?

Yes / No

Action: If you chose 'no' please delete E2.6 (b)

E2.6 (b) If yes, please elaborate. (Please state what data, what medium of data, what class of data etc. will be sent and state where and to whom this data will be sent? Please ensure to inform research participants in all relevant Information Leaflets of the details which you supply in response to this question. It is particularly important to inform research participants if data is leaving the country, and especially if the data is leaving the European Economic Area. EEA Transfers of personal data to non-EEA countries must take place in compliance with the Data Protection Acts, e.g. where the individual has consented to that transfer. It is recommended that only non-identifiable data leave the EEA where at all possible.)

[TYPE ANSWER]

E2.7 Where will data analysis take place and who will perform data analysis (if known)? (While is advisable to obtain the advice of a statistician while designing any research study, it may not be known at the point of submitting an ethics application where the data analysis will take place at the end of the study or throughout the study and/or it may not be known who will be performing the data

analysis. However, if there is a possibility that data will be leaving the site of origin for the purposes of data analysis, it is important to inform the research participant.)

[TYPE ANSWER]

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

[TYPE ANSWER]

E2.8 (b) Please elaborate. (Different media of data may be treated differently in respect of retention / destruction. Similarly, different classes of data may be retained e.g. identifiable data may be destroyed, while irrevocably anonymised data may be retained for the purposes of future publication.)

[TYPE ANSWER]

E2.8 (c) If destroyed, how, when and by whom will it be destroyed? (Please note different media may be destroyed in different fashions)

[TYPE ANSWER]

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

(Please inform research participants in all relevant Information Leaflets of the details which you supply in response to this question. Researchers should be aware of their responsibilities under the data protection legislation not to retain 'personal data' for longer than is necessary to fulfil the purpose for which the data was originally collected. There are no such time restrictions in place with regard to the retention of anonymous or irrevocably anonymised data. Please note that although a number of committees may specify timelines that research data must be retained for e.g. 5 years / 7 years, the only legal requirement is that data should not be held for longer than necessary to fulfil the purpose for which it was originally collected. Where the data forms part of the patient's healthcare record however, the timelines listed in the [NHO Code of Practice on Records Management](#) apply.)

[TYPE ANSWER]

E2.9 Please comment on the confidentiality of collected data. (Identifiable data should only be disclosed to third parties if consent is in place for this disclosure to take place. If there is a possibility of a situation arising where it may become necessary to breach confidentiality, research participants should be informed of this in all relevant Information Leaflets.)

[TYPE ANSWER]

E2.10 (a) Will any of the data collected consist of audio recordings / video recordings?

Yes / No

Action: If you chose 'no' please delete E2.10 (b)

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

[TYPE ANSWER]

E2.11 (a) Will any of the data collected consist of photographs / video recordings?

Yes / No

Action: If you chose 'no' please delete E2.11 (b)

E2.11 (b) If yes, please elaborate. (Please focus on consent in your response, in particular, if it is proposed to publish or present photographs / video recordings.)

[TYPE ANSWER]

SECTION E3 ACCESS TO HEALTH CARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?

Yes / No

Action: If you chose 'no' please delete all the remaining questions in Section E3

E3.1 (b) If yes, please elaborate. (Please state what healthcare records will be accessed (e.g. hard copy charts, computer systems etc), for what purpose healthcare records will be accessed and what data it is proposed to collect from these records)

[TYPE ANSWER]

E3.1 (c) Who will access these healthcare records? (Research participants should be informed in any information leaflets or consent forms who will have access to their healthcare records.)

[TYPE ANSWER]

Studies in which written consent is in place to access healthcare records are the gold standard. The ideal situation is one where written consent is sought to access healthcare records.

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? (Research participants should be informed in any Information leaflets or consent forms that it will be necessary to access their healthcare records as part of their participation in this study.)

Yes / No

Action: If you chose 'yes' please delete Questions E3.2 (a) and E3.2 (b)

In cases where consent is not being sought to access healthcare records, the following issues should be considered by the researcher. It is common, for example, for healthcare records to be accessed without consent at an early stage in any research study for the purposes of identifying patients who fulfil the inclusion / exclusion criteria prior to recruitment.

E3.2 (a) Who or what legal entity is the DATA CONTROLLER in respect of the healthcare records?

(Data Controllers are those who, either alone or with others, control the contents and use of personal data. Examples of Data Controllers:

- Data Controllers can be either legal entities such as companies, government departments or voluntary organisations, or they can be individuals such as GPs, pharmacists or sole traders.
- The data controller can be an individual hospital consultant in the case of private patients.

- The data controller is however the hospital board in respect of independent teaching hospitals.
- The data controller is the HSE in respect of HSE hospitals.
- The data controller can be the individual GP in respect of patients attending a General Practice but can in certain cases be the practice itself.

The Data Subject is an individual who is the subject of personal data.)

[TYPE ANSWER]

E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?

(Will the data controller nominate the researcher as an agent? Will the researcher enter into a confidentiality agreement with the data controller? Does a memorandum of understanding or other agreement exist between the legal entity which is the data controller and the legal entity to which the researcher is affiliated? Is the researcher involved in the direct care of the patient(s) whose healthcare records he / she proposes to access? Is the researcher bound by confidentiality via the terms of his / her contract of employment or his / her code of professional conduct? Is it possible for the data controller to access the healthcare records on the researcher's behalf and to issue irrevocably anonymised or pseudonymised data only to the researcher? Is it possible for the data controller to act as 'gatekeeper' and select / recruit patients on behalf of the researcher?

IMPORTANT NOTE: Access to Healthcare Records should occur in line with local institutional / organisational policies in this area.

IMPORTANT NOTE: A list of patients should not be provided to a third party or health professional not involved in the care of these patients for the purposes of making contact unless patients have specifically consented to this.)

[TYPE ANSWER]

SECTION F HUMAN BIOLOGICAL MATERIAL

It is recommended that all researchers familiarise themselves with the Irish Council for Bioethics Guidelines: [Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005](#).

F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

"A human biological specimen is any material derived from a human subject-such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids-whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures."

[United States Department of Veteran Affairs VA Tissue Banking Program](#)

F1.1 (a) Does this study involve human biological material?

Yes / No

Action: If you chose 'no' please delete all remaining questions in Section F and all sub-sections of Section F

F2 BODILY TISSUE / BODILY FLUID SAMPLES PROSPECTIVELY COLLECTED

F2.1 Does this study involve the prospective collection of human biological material?

Yes / No

If you chose 'no' please delete the remaining questions in Section F2

F2.2 Please state the type of human biological material which is being prospectively collected.

[TYPE ANSWER]

F2.3 Who or what institution will be the custodian of the prospectively collected human biological material?

(Please note that for applications to set up a biobank, the custodian should be an institution as opposed to an individual e.g. a hospital / a university etc.

For all other research applications, "the investigator responsible for collecting and maintaining the material (the custodian) should control access to this material for the duration of his/her studies."

[Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.](#))

[TYPE ANSWER]

F2.4 (a) Will the human biological material be collected as part of routine clinical care?

(The participant may be undergoing surgery requiring the taking of a biopsy, or may be giving blood samples as part of routine clinical care)

Yes / No

F2.4 (b) Will the human biological material be collected specifically for the purposes of this research study?

(The participant may for example be undergoing a procedure which does not normally involve taking of a tissue sample and therefore a sample is being taken for the purposes of this study)

Yes / No

F2.4 (c) With reference to your responses to Question F2.4 (a), F2.4 (b), please provide more detail, in particular, in relation to whether participants will be consented to the taking of a sample or to the use of a sample (or part of a sample) which will be taken anyway for clinical reasons.

(Please ensure that the consent for either the taking of a sample for research or for the use of a sample which it is planned to take for clinical reasons is clearly separated from CONSENT FOR SURGERY / CONSENT FOR TREATMENT. A Study Information Leaflet and Consent Form specific to this research study is required. The consent form used for surgery or treatment is insufficient in this regard.)

[TYPE ANSWER]

F2.5 (a) With respect of human biological material which it is proposed to prospectively collect for the purposes of this research study, after the laboratory analysis which this research study involves, will any human biological material remain?

Yes / No

Action: If you chose 'no' please delete F2.5 (b) (c) (d) (e) (f) and (g)

F2.5 (b) If yes, will this remaining biological material be retained? (This question refers to the human biological material which is taken for the purposes of this research study. It is understood that if material has been collected as part of routine clinical care, hospital laboratory practices and procedures will apply in relation to retention)

Yes / No

Action: If you chose 'no' please delete F2.5 (c) (d) (e) (f) and (g)

F2.5 (c) If yes, for how long and where will samples be retained?

[TYPE ANSWER]

F2.5 (d) If yes, for what purpose will samples be retained?

[TYPE ANSWER]

F2.5 (e) If yes, please comment on consent for retention of biological material.

[TYPE ANSWER]

F2.5 (f) If yes, will this human biological material and/or any data derived from it be used for any other purpose (including future research projects)?

Yes / No

Action: If you chose 'no' please delete F2.5 (g)

F2.5 (g) If yes, please comment on consent for future use of human biological material.

[TYPE ANSWER]

F2.6 (a) Will the human biological material be collected specifically for the purposes of depositing this human biological material in a biobank? (A 'biobank' is a collection or repository of human biological material. "While any biological sample archive can be termed a 'biobank' the term is normally applied to a centralised archive of material from which materials are made available for approved research." [Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.](#))

Yes / No

Action: If you chose 'no' please delete F2.6 (b) and (c)

F2.6 (b) If yes, please provide specific information in relation to this proposed biobank. (Researchers should consider setting up a steering committee for the biobank. There should be procedures and guidelines in place as to when exactly permission will be granted for access to the biobank for future research studies to occur.)

[TYPE ANSWER]

F2.6 (c) If yes, will research participants be informed in all Information Leaflets and Consent Forms that this is a biobank? (Researchers should emphasise the permanency of a biobank and indefinite nature of retention of human biological material (if this is the case). They should further emphasise that the material may be used in future research projects as yet undevised. Participants need to be clearly informed if this is a commercial biobank, or if there is any possibly of profit being made. Participants should be informed if research ethics committee approval will be required in order to use biobank material in the future. Finally, the extent to which the participants are giving permission for their material to be used in the future must be clearly stated.)

[TYPE ANSWER]

F3 BODILY TISSUE / BODILY FLUID SAMPLES RETROSPECTIVELY COLLECTED

F3.1 Does this study involve accessing retrospectively collected human biological material?

Yes / No

Action: If you chose 'no' please delete the remaining questions in Section F3

F3.2 Please state the type of human biological material which is being accessed.

[TYPE ANSWER]

F3.3 Who will access the material?

[TYPE ANSWER]

F3.4. Who (or which institution) is the current custodian of the material?

[TYPE ANSWER]

F3.5 Please state for what purpose the human biological material was originally collected and please comment on the nature of consent for the collection of this material.

[TYPE ANSWER]

F3.6 (a) Do you intend to contact patients to seek their consent to use stored human biological material?

Yes / No

Action: If you chose 'yes' please delete Question F3.6 (b)

Before responding the next question, please refer to Recommendations 10 and 11 [Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005](#).

Recommendation 10:

"Archival material that is *already* anonymous or unlinked at the time of this report does not require informed consent for the obvious reason that it is impossible to identify the individual from whom the material was obtained. By definition anonymous or unlinked archival material has no connection with an individual; therefore no harm can be done to an individual. Archival material can be anonymous with respect to an individual's identity but may not be anonymous with respect to classes of individuals. Thus research can accumulate on groups, e.g. caucasians, females, that may damage or put at risk individual members of that group at risk of discrimination or stigmatisation. For this reason, a Research Ethics Committee should review all research protocols seeking to use anonymous archival biological material in order to safeguard the rights of groups and communities. Where archival biological material was obtained from persons for research or clinical purposes, for which consent may or may not have been given, where material is not individually identifiable (anonymous/unlinked material), and where there are no potential harms to the person from whom the material was obtained, human biological material should be exempt from consent requirements subject to Research Ethics Committee approval."

[Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005](#).

Recommendation 11:

"Research on identifiable/coded human biological material and personal data should be done in conformity with appropriate information and consent procedures. Where consent documents exist, Research Ethics Committees should determine whether these provide an adequate basis to infer consent for use of the biological material in the proposed research. Unfortunately, existing consent may be considered inadequate and in some cases, consent may never have been obtained. Where identified or coded material can be traced back to an individual there is an onus on an investigator to seek consent from that individual(or next of kin) to use their biological material for research purposes. In this way, the autonomy of and respect for persons is safeguarded. In some situations it may be extremely difficult or impossible for investigators to recontact individuals and obtain consent for use of their archival biological material in research. Material may have been stored for long periods of time, individuals may have died, or become untraceable. In some cases it might be prohibitively costly to recontact large numbers of individuals to seek consent, especially for academic-led studies. Therefore, where it is not *practicable* to obtain consent from individuals for use of their archival material for research, Research Ethics Committees may waive

the requirement for consent. In determining whether consent can be waived, Research Ethics Committees should take into account the extent to which the proposed research poses a risk to the privacy of the individual, whether the research is an extension of, or closely related to a previously approved study and whether the proposed research is scientifically sound and fulfils important needs. Where archival biological material was obtained from persons for research or clinical purposes, for which consent may not have been given or was not adequate for the current proposed research, where existing material is individually identifiable (identified/coded), researchers should seek to obtain free and informed consent from individuals, or from an authorised third party, for the use of their archival biological material.

Where it is not practicable to obtain consent, a Research Ethics Committee may waive the consent requirement, in which case it should take into account:

- (a) whether the overall benefit to research is real and substantial
- (b) the extent to which the proposed research may pose a risk to the privacy or well being of the individual
- (c) the nature of any existing consent relating to collection and storage and use of material
- (d) whether the research proposal is an extension of, or closely related to a previously approved research project.
- (e) the justification presented for seeking waiver of consent, including the extent to which it is impossible, difficult or intrusive to obtain consent."

[Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.](#)

F3.6 (b) If no, please justify why you consider existing consent to cover this project, or that a waiver of consent from the Research Ethics Committee is warranted.

[TYPE ANSWER]

F4 BODILY TISSUE / BODILY FLUID SAMPLES – SAMPLE MOVEMENT

F4.1 (a) Will human biological material at any stage leave the institution of origin?

Yes / No

Action: If you chose 'no' please delete all the remaining sections in Section F4

F4.1 (b) If yes, for what purpose?

[TYPE ANSWER]

F4.1 (c) If yes, please state where samples will be sent?

[TYPE ANSWER]

F4.1 (d) If yes, please state if the samples leaving the institution of origin will be anonymous, irreversibly anonymised, coded, identifiable etc?

[TYPE ANSWER]

F4.1 (e) If 'coded' please confirm who will retain the 'key' to re-identify the samples? (It is recommended that the key to re-identify 'coded' samples remain at the site of origin of the samples. It is further recommended that the person who holds the 'key' to re-identify be the lead investigator at the site or the custodian of the samples.)

[TYPE ANSWER]

F4.1 (f) Does a Memorandum of Understanding (or agreement / contract) exist between the institution of origin and the institution to which the samples will be sent? Please elaborate. (Researchers should note the value of putting such agreements in place in order to avoid against

misunderstandings as to how samples can be used in the future. There may however be no intention to put an agreement between institutions in place, or an agreement between institutions may not be in place at the time of submission of the ethics application for review.)

[TYPE ANSWER]

F5 GENETIC TESTING

" 2) A person shall not engage in the processing of genetic data in relation to—

- (a) the employment of a person save in accordance with the provisions of section 12A of the [Data Protection Act 1988](#) (as inserted by [the Data Protection \(Amendment\) Act 2003](#)),
- (b) a policy of insurance or life assurance,
- (c) a policy of health insurance or health-related insurance,
- (d) an occupational pension, a retirement annuity contract or any other pension arrangement,
- (e) the mortgaging of property.

(3) A person shall not process genetic data unless all reasonable steps have been taken to provide the data subject with all appropriate information concerning—

- (a) the purpose and possible outcomes of the proposed processing, and
- (b) any potential implications for the health of the data subject which may become known as a result of the processing.

(4) A person who contravenes *subsection (2) or (3)* shall be guilty of an offence; an offence under this subsection shall be deemed to be an offence to which [section 31 of the Data Protection Act 1988](#) applies."

[Section 4 of the Disability Act 2005.](#)

F5.1 (a) Does this research study involve 'genetic testing'? ("genetic testing" means the examination of samples taken from a living person for the purpose of analyzing the person's deoxyribonucleic or ribonucleic acid by means of chromosomal analysis or by any other means for the purpose of (a) confirming the identity or nature of an existing symptomatic disease; (b) **ascertaining whether the person has a genetic predisposition or susceptibility to a disease**, or (c) identifying the carrier of a disease. "Genetic Data" means data relating to a living person derived from genetic testing of the person. These definitions are taken from [Section 4 of the Disability Act 2005.](#))

Yes / No

Action: If you chose 'no' please delete F5.1 (b)

F5.1 (b) If yes, please specify the nature of the genetic testing (It is important that this information should be prominently placed in any Information Leaflets or Consent Forms. It is extremely important that research participants be told whether they have a particular disease or that they are a 'control' in this research study. Participants may not understand the term 'control' and may need this to be explained to them. It is very important that the implications of any testing be stated clearly in any Information Leaflets, in particular, if there are implications for next of kin, offspring or future offspring)

[TYPE ANSWER]

F6 COMMERCIAL VALUE

F6.1 (a) Will the human biological material in this research study or the data derived from the analysis of the human biological material be commercially valuable or is there

the possibility that it will become commercially valuable? ("Researchers should discuss with research participants the potential commercial uses of their biological material, and also make clear that they will not be entitled to share in any profits that might ensue from their biological material. Donors must be allowed to withhold their consent for commercial use of products developed from their biological material, as an exercise of control over the terms and conditions of their participation in the research. Disclosure of potential commercial applications is further indicated because of the practical consequences for research if people come to distrust doctors and researchers because they feel they were deceived or treated unjustly."

[Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.](#))

Yes / No

Action: If you chose 'no' please delete F6.1 (b)

F6.1 (b) If yes, please elaborate. (It is important that this information should be prominently placed in any Information Leaflets or Consent Forms)

[TYPE ANSWER]

SECTION G RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION

G1 RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION - GENERAL

G1.1 (a) Does this study/trial involve exposure to radioactive materials OR Does this study/trial involve other diagnostic or therapeutic ionising radiation?

(Radioactive materials can be administered, either by injection, inhalation or oral administration.

One diagnostic example of the use of radioactive materials would be the use of radioactive iodine in the imaging of the thyroid gland.

A therapeutic example would be the use of radioactive materials to kill cancerous tissue, reduce the size of a tumour, or reduce pain e.g. **teletherapy** (an intense beam of radiation), **brachytherapy** (surgical implant or injection of radioactive materials), and **therapeutic nuclear medicine** (high doses of radioactive material ingested or injected). An example of therapeutic nuclear medicine would be the use of radioactive iodine to destroy or shrink a diseased thyroid.

Examples of diagnostic ionising radiation are x-rays and CT scans, but not MRI scans or ultrasounds. An example of therapeutic ionising radiation is radiotherapy or radiation treatment)

Yes / No

Action: If you chose 'no' please delete all remaining questions in section G and all sub-sections of section G

G1.1 (b) If yes, please specify:

Exposure to Radioactive Materials: Yes / No

Therapeutic Ionising Radiation: Yes / No

Diagnostic Ionising Radiation: Yes / No

"10.1. Medical exposure for biomedical and medical research shall not be permitted save in accordance with such criteria as may be directed by the Medical or Dental Councils and approved by the local medical ethics committee.

10.2. Without prejudice to the generality of paragraph 10.1, the practitioner shall ensure that for each biomedical and medical research project each participating individual shall participate voluntarily, the practitioner shall seek where practicable to obtain previous diagnostic information or medical records relevant to the individual, that the individual is informed about the risks of this exposure and that he or she gives his or her informed consent in writing and that a dose constraint is established for that individual.

10.3. In the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutical benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner"

[Communities \(Medical Ionising Radiation Protection\) Regulations, 2002 \(S.I. No. 478 of 2002\)](#)

G1.2 (a) Does this study / trial involve additional radiation exposure to radioactive materials or diagnostic or therapeutic ionising radiation other than normally received as part of standard care?

Yes / No

Action: If you chose 'no' please delete Question G1.2 (b)

G1.2 (b) If yes, please elaborate (For diagnostic ionising radiation, please state what is the total research protocol dose from the exposure and what component of this is the additional dose over and above standard practice, and state the risks associated with this dose.)

[TYPE ANSWER]

G1.3. Is this an application to conduct research involving radioactive materials or diagnostic or therapeutic radiation at a RADIATION ONCOLOGY UNIT? (There are currently a small number of radiation oncology units in the Republic of Ireland e.g. St. Luke's Radiation Oncology Network (Rathgar, St. James's & Beaumont), the UPMC Beacon Hospital, the Hermitage Medical Clinic, Limerick Regional Hospital (Limerick Regional Hospital is a satellite unit of the Mater Private Hospital), the Mater Private Hospital, St. Vincent's Private Hospital, University College Hospital Galway, University College Hospital Cork and the UPMC Whitfield Cancer Centre.)

Yes / No

Action: If you chose 'No' please delete all remaining sub-sections of Section G i.e. G2, G3 and G4

IMPORTANT NOTE PRIOR TO COMPLETING SECTIONS G2, G3 & G4:

IT IS ADVISABLE TO DISCUSS THE PROPOSED RESEARCH STUDY AT AN EARLY STAGE WITH A MEDICAL PHYSICIST AND A RADIATION ONCOLOGIST WHO SHOULD CARRY OUT THE ASSESSMENTS REQUIRED AS PART OF SECTIONS G3 & G4.

SECTION G2 RADIOTHERAPY TRIALS

(THE PRINCIPAL INVESTIGATOR FOR RADIOTHERAPY TRIALS INVOLVING PATIENTS MUST be A RADIATION ONCOLOGIST. Please revisit your response to Question A2 if applicable.)

(It is recognised however that rare exceptions will occur to the above rule, for example in a dermatology trial where radiotherapy is administered by a radiation therapist and overseen by a dermatologist, it may be inappropriate to name a radiation oncologist as the principal investigator. Nevertheless, as both a medical

physicist and a radiation oncologist are required to carry out the assessments required as part of Sections G3 and G4, at the very least, a radiation oncologist would be listed as a co-investigator in such a trial.)

G2.1 Does the study/trial involve patients?

Yes / No

Please ensure to choose 'no' if you chose 'no' to Question C5.1 (Patients)

Action: If you chose 'no' please delete all remaining questions in Section G2

G2.2 If yes, will the patient receive radiotherapy?

Yes / No

Action: If you chose 'no' please delete all remaining questions in Section G2

G2.3 Is the radiotherapy part of standard treatment or is it experimental?

Standard Treatment / Experimental

Action: If you chose 'Standard' please delete G2.5.

G2.4 In relation to the radiotherapy please provide the following information:

G2.4 (a) Volume of interest (tumour related volume and organs at risk)

[TYPE ANSWER]

G2.4 (b) (i) Technique to be used, e.g. 3-DCRT (3-dimensional conformal radiation therapy, IMRT (intensity modulated radiation therapy)

[TYPE ANSWER]

G2.4 (b) (ii) Technique to be used, e.g. IGRT (image guided radiation therapy), etc.

[TYPE ANSWER]

G2.4 (c) Radiation schedule:

(i) total dose

[TYPE ANSWER]

(ii) dose per fraction

[TYPE ANSWER]

(iii) number of fractions per day

[TYPE ANSWER]

G2.4 (d) Dose volume constraints (DVCs) for organs at risk

[TYPE ANSWER]

G2.4 (e) Expected spectrum of acute and long-term radio-induced side effects

[TYPE ANSWER]

G2.4 (f) Details of patient positioning/immobilisation

[TYPE ANSWER]

G2.4 (g) Details of radiotherapy plan evaluation parameters (i.e. planning target volume [PTV] coverage)

[TYPE ANSWER]

G2.4 (h) What toxicity scoring criteria are to be used?

[TYPE ANSWER]

G2.5 For experimental radiotherapy, please provide the following information:

(a) Standard alternatives

[TYPE ANSWER]

**(b) Potential risks associated with the experimental
(c)**

[TYPE ANSWER]

G2.6 (a) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. physics quality assurance (beam and dose)

[TYPE ANSWER]

G2.6 (b) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. clinical quality assurance

[TYPE ANSWER]

G2.7 Clinical Monitoring during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study / trial

[TYPE ANSWER]

SECTION G3 RADIONUCLIDES

"A Radionuclide is an isotope of artificial or natural origin that exhibits radioactivity. Radionuclides serve as agents in nuclear medicine and genetic engineering, play a role in computer imaging for diagnosis and experiment, and account for a percentage of background radiation to which humans are exposed. In

cancer therapy, radionuclides that localize to certain organs (e.g. radioactive iodine or gallium) deliver cytotoxic radiation doses to tumours. Similarly, radionuclides can be yoked to monoclonal antibodies engineered to attach specific populations of cancerous cells. In positron emission tomography, glucose molecules tagged with radionuclides are injected into the bloodstream. The gamma radiation emitted by the decay of radionuclides reveals areas of active glucose uptake and thus offers a gauge of cell metabolism and function."

[Biology Online Dictionary](#)

Please complete the tables below for each radionuclide to be administered

G3.1 (a) Will any of the study/trial participants be patients?

Yes / No

Please ensure to choose 'no' if you chose 'no' to Question C5.1 (Patients)

Action: If you chose 'no' please delete the table which follows:

Details of patients to be studied				
Number (whole study)	Age range	Sex	Clinical condition	Total effective or target tissue dose per individual
[TA]	[TA]	[TA]	[TYPE ANSWER=TA]	[TA]

Action: Please add rows to the table above to add a radionuclide.

G3.1 (b) Will any of the study/trial participants be healthy volunteers?

Yes / No

Please ensure to choose 'no' if you chose 'no' to Question C5.6 (Healthy Volunteers)

Action: If you chose 'no' please delete the table which follows:

Details of healthy volunteers to be studied			
Number (whole study)	Age range	Sex	Total effective dose per individual
[TA]	[TA]	[TA]	[TYPE ANSWER=TA]

Action: Please add rows to the table above to add a radionuclide.

G3.2 Dose and Risk Assessment

Please note, special attention must be paid to pregnant/potentially pregnant women or those who are breast feeding or other potentially vulnerable groups

G3.2 (a) What is the total research protocol dose from the exposure in G2 (if any) and what component of this is the additional dose over and above standard practice? What are the risks associated with this dose?

[TYPE ANSWER]

G3.2 (b) DECLARATION BY MEDICAL PHYSICIST

I am satisfied that the information in sub-section G3.1 and the assessment in sub-section G3.2 provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks

Signature:

Date:

Please Print Name:

SECTION G4 CLINICAL ASSESSMENT

Please note, special attention must be paid to pregnant/potentially pregnant women or those who are breast feeding or other potentially vulnerable groups

G4.1 Will the exposure exceed the exposure that might be received as part of normal care?

Yes / No

G4.2 Assessment of additional exposure

G4.2 (a) Please explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.

[TYPE ANSWER]

Action: Please delete Question G4.2 (b) if you answered 'no' in respect of Question C5.11 (Pregnant women) or C5.13 (Breastfeeding Mothers)

G4.2 (b) If pregnant or breastfeeding mothers are to be studied give reasons and details of special radiation protection measures to be taken.

[TYPE ANSWER]

G4.3 DECLARATION BY RADIATION ONCOLOGIST

I am satisfied that the exposure to ionising radiation planned in this research study (as defined in sub-section G2 and/or G3) is reasonable and that the risks are adequately described in the participant information sheet for the study.

Signature:

Date:

Please Print Name:

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? (The term 'medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. It includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames or other assistive technology products; pregnancy tests, blood glucose monitors and pacemakers - many thousands of items used each and every day by healthcare providers and patients. Medical devices do not include ambulance vehicles, general workshop equipment such as power or machine tools, or general purpose laboratory equipment. Pre-filled devices, for example, drug inhalers, syringes and certain other drug / device combinations are classed as medicines, not medical devices.

[Irish Medicines Board.](#))

Yes / No

If you are uncertain as to the definition of a medical device, please contact the Irish Medicines Board.

Action: If you chose 'No' please delete all remaining questions in Section H.

H1 (b) If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?

[TYPE ANSWER]

H1 (c) If yes, please provide a general description of the medical device.

[TYPE ANSWER]

<p>H2 (a) Does the device have a CE mark? (CE stands for 'Conformité Européene' and is mandatory conformity mark on many products placed on the single market in the European Economic Area. If the device has a CE Mark, please ensure to enclose the relevant certificate for review.) <input type="checkbox"/> Yes / <input type="checkbox"/> No</p> <p>Action: If you chose 'no' please delete question H2 (b) (c) (d);</p> <p>Action: If you chose 'yes' please delete question H2 (e)</p>	
<p>H2 (b) If the device has a CE Mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?</p> <p>Within / Outside</p> <p>Action: If you chose 'within' please delete question H2 (c);</p>	<p>H2 (e) If the device does not have a CE Mark, is this study being undertaken for the purposes of obtaining a CE mark?</p> <p><input type="checkbox"/> Yes / <input type="checkbox"/> No</p>
<p>H2 (c) If outside, please elaborate:</p> <p>[TYPE ANSWER]</p>	
<p>H2 (d) CE MARK NUMBER: (This is a unique 4 digit code which refers to the 'Notifying Body' which awarded the CE Mark and can be found in the bottom right hand corner of the CE Mark)</p> <p>[TYPE NUMBER]</p>	

H3. If an application to conduct a clinical investigation of a medical device, will the medical devices section of the Irish Medicines Board be reviewing this clinical investigation of a medical device? (Please note that review by the IMB will be required if you

completed H2 (c) or stated 'yes' in response to H2 (e) above. Please refer to the Medical Devices Section of the Irish Medicines Board website.)

Yes / No / Non Applicable

SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

SECTION I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

Clinical trials of medicinal products that require authorisation in accordance with [SI No 190 of 2004](#) will not be accepted on this application form. You are referred to the [Department of Health and Children Application Form](#) should you wish to make an application for the ethical review of a clinical trial of a medicinal product.

I 1.1 (a) Does this study involve a medicinal product? (Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Further information on the definition of a medicinal product is provided in the [Irish Medicines Board Guide to the Definition of a Human Medicine.](#))

Yes / No

Action: If you chose 'No' please delete Questions I 1.1 (b), I 1.2 (a) and I 1.2 (b)

IMPORTANT NOTE: If you chose 'No' to Question I 1.1. (a) this study is not a 'clinical trial of a medicinal product' and you are completing the correct application form.

I 1.1 (b) If yes, please state:

I. the trade name of the medicinal product:

[TYPE ANSWER]

II. the name of the active substance: (To source the active substance: [Human Medicines Product List.](#))

[TA]

III. the formulation: (To source the formulation: [Human Medicines Product List.](#))

[TA]

IV. the authorisation / product number: (To source the authorisation / product number: [Human Medicines Product List.](#) Please note if there is no product authorisation number, then the study is an interventional trial)

[TA]

Action: Please copy and paste the headings above to add a medicinal product.

Before responding the next question, please log on to [European Commission website](#) scroll to Chapter V: Additional Information 'Questions and Answers Document' and refer to the [algorithm](#) appended to this document.

If you have difficulty in locating this [algorithm](#), a copy is also placed at the rear of this Guidance Manual for ease of reference.

If after referring to this [algorithm](#), you remain unsure if this study is a clinical trial of a medicinal product or a non-interventional trial of a medicinal product, please send a brief summary of the study to the Irish Medicines Board requesting their advice (Clinical.Trials@imb.ie). If the definition of non-interventional is not met, the study should be considered interventional and requires authorisation in accordance with SI No 190 of 2004.

I 1.2 (a) Is this an application to conduct a non-interventional trial of a medicinal product?

("non-interventional trial": a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation, where the assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice, where the prescription of the medicine is clearly separated from the decision to include the patient in the study and where no additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.)

Yes / No

I 1.2 (b) Is this trial a post-authorisation safety study?

(A pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product. Post authorisation safety studies fall under the definition of non-interventional trials and should be conducted in accordance with the requirements outlined in Volume 9A of the Rules Governing Medicinal Products in the European Union, Guidelines on Pharmacovigilance for Medicinal Products for Human Use available from the [European Commission website](#). Scroll to Volume 9A)

Should you answer 'yes' to question I 1.2 (b), the trial can be notified to the Irish Medicines Board.

Yes / No

IMPORTANT NOTE: If you responded 'No' to Question 1.2 (a) and 'No' to Question 1.2 (b) there is a strong possibility that this study is a clinical trial of a medicinal product. Please liaise with the Irish Medicines Board if you are unsure. You are referred to the [Department of Health and Children Application Form](#) should you wish to make an application for the ethical review of a clinical trial of a medicinal product.

SECTION I.2 COSMETICS

I 2.1 (a) Does this study involve a cosmetic? ("any substance or preparation **intended to be placed in contact** with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity **with a view exclusively or mainly** to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition"

[Council Directive 76/768/EEC and amendments.](#))

Yes / No

Action: If you chose 'no' please delete Question I 2.1 (b)

I 2.1 (b) If yes, please state:

I. the trade name of the cosmetic:

[TYPE ANSWER]

II. the ingredients/composition: (the Cosmetics Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic products may contain only under the restrictions and conditions laid down (Annex III), and lists of colourings (Annex IV), preservatives (Annex VI) and UV filters (Annex VII) permitted in cosmetic products. The Directive also outlines the requirements for labelling)

[TA]

Action: Please copy and paste the headings above to add a cosmetic.

SECTION I.3 FOOD AND FOOD SUPPLEMENTS

I 3.1 (a) Does this study involve food or food supplements? "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

(b) "nutrients" means the following substances:

- (i) vitamins,
- (ii) minerals.

Yes / No

Action: If you chose 'no' please delete Question I 3.2 (b)

I 3.2 (b) If yes, please elaborate:

[TYPE ANSWER]

IMPORTANT NOTE: a food supplement that is used in a trial to treat or prevent disease in human beings may be considered a medicinal product and as such may require authorisation in accordance with [SI No 190 of 2004](#). Further information on the definition of a medicinal product is provided in the [Irish Medicines Board Guide to the Definition of a Human Medicine](#).

SECTION J INDEMNITY

J1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? (The CIS covers

- All Health Service Executive facilities, public hospitals and other agencies providing clinical services;
- Non-consultant hospital doctors, nurses and other clinical staff employed by health agencies whether permanent, locum or temporary;
- Consultant hospital doctors are covered with effect from February 1st. 2004 in respect of alleged clinical negligence incidents on or after that date.
- Clinical support staff in pathology and radiology services;
- The clinical activities of public health doctors, nurses and other community-based clinical staff;
- Dentists providing public practice;

- Certain other ancillary healthcare providers. Participating enterprises are specified in Schedule 1, Part 1 of the National Treasury Management Agency (Delegation of Functions) Order 2003 [S.I. No. 63 of 2003]

[State Claims Agency.](#)

Yes / No

Action: If you chose 'yes' please delete 'J1 (b)'

J1 (b) If the answer is 'no' for any site, what other arrangements are in place in terms of indemnity / insurance?

[TYPE ANSWER]

J2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? (The CIS covers

- All Health Service Executive facilities, public hospitals and other agencies providing clinical services;
- Non-consultant hospital doctors, nurses and other clinical staff employed by health agencies whether permanent, locum or temporary;
- Consultant hospital doctors are covered with effect from February 1st. 2004 in respect of alleged clinical negligence incidents on or after that date.
- Clinical support staff in pathology and radiology services;
- The clinical activities of public health doctors, nurses and other community-based clinical staff;
- Dentists providing public practice;
- Certain other ancillary healthcare providers. Participating enterprises are specified in Schedule 1, Part 1 of the National Treasury Management Agency (Delegation of Functions) Order 2003 [S.I. No. 63 of 2003]

[State Claims Agency.](#)

Yes / No

Action: If you chose 'yes' please delete 'J2 (b)'

J2 (b) If no, do members of the investigative team not covered by the Clinical Indemnity Scheme (CIS) have either current individual medical malpractice insurance (applies to medical practitioners) or current professional liability insurance either individually or as provided by their hosting/employing institution (generally applies to allied healthcare professionals, university employees, scientists engineers etc.)?

(Please provide a copy of any certificates referred to in your response for review.)

[TYPE ANSWER]

IMPORTANT NOTE: ALL STUDIES SUBMITTED TO A RESEARCH ETHICS COMMITTEE ARE CLASSED AS SPONSORED STUDIES. THE SPONSOR IS THE INDIVIDUAL, COMPANY, INSTITUTION OR ORGANISATION WHICH TAKES RESPONSIBILITY FOR THE INITIATION, MANAGEMENT OR FINANCING OF THIS RESEARCH STUDY.

[ICH GCP Guidelines 1996](#)

J3 (a) Who or what legal entity is the sponsor of this research study? (The sponsor may be the Principal Investigator himself / herself. Alternatively, the sponsor may be an external organisation e.g. a pharmaceutical company, a medical device company, a university, a charity etc. Please name the sponsor i.e. the individual, company, institution or organisation which takes responsibility for the initiation, management or financing of this research study.)

[TYPE ANSWER]

J3 (b) What additional indemnity arrangements has the sponsor put in place for this research study in case of harm being caused to a research participant (if any)? (Additional indemnity arrangements would include the taking out of insurance by the sponsor, the sponsor entering into a contract of indemnity with the site, the sponsor ensuring that product liability is in place where required. Please ensure that you have provided a copy of any certificates or contracts referred to in your response to this question.

"The CIS will cover claims from patients whose treatment was part of a clinical trial or other approved research project subject to certain criteria;

- The trial has received approval from the relevant Ethics Committee.
- The trial is designed by an enterprise or any of its employees, covered by the scheme.
- Where a trial is sponsored by external organisations such as pharmaceutical companies, the CIS cover extends to treatment only and does not cover product liability or claims arising from trial design or protocol."

[State Claims Agency.](#)

[TYPE ANSWER]

SECTION K COST AND RESOURCE IMPLICATIONS AND FUNDING

K1 (a) Are there any cost / resource implications related to this study? (This refers to cost and resource implications for the researcher and for the institution(s) at which the research study is proposed to take place.)

Yes / No

Action: If you chose 'no' please delete 'K1 (b)'

K1 (b) If yes, please elaborate.

[TYPE ANSWER]

K2 (a) Is funding in place to conduct this study? (Non-disclosure of funding will result in revocation of ethical approval)

Yes / No

Action: If you chose 'yes' please delete question K2 (b)

K2 (b) If no, has funding been sought to conduct this study? (An important part of any research study is ensuring that funding is in place to conduct it)

Yes / No

Action: If you chose 'no' please delete K2 (c), (d), (e) (f) and (g)

K2 (c) Please state the source of funding (industry, grant or other) and the amount of funding.

[TYPE ANSWER]

K2 (d) Is the study being funded by an external agency?

Yes / No

If you chose 'no' please delete question K2 (e)

K2 (e) Is the external agency a 'for profit' organisation?

Yes / No

K2 (f) Do any conflicts of interest exist in relation to funding? Please elaborate.

"53.6 If you are paid, directly or indirectly, by pharmaceutical, medical device or other commercial companies or organisations to conduct medical research, you must make sure that such payment does not influence your study design or interpretation of research data."

"53.7 If you receive payment, directly or indirectly, from pharmaceutical, medical device or other commercial companies or organisations in connection with medical research, you must address any potential conflict of interest arising from such payment and make an appropriate disclosure in any publication of research results."

[Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2009.](#))

See also the [International Committee of Medical Journal Editors](#) for more information on conflicts of interest. Researchers will be required to disclose all conflicts of interest prior to publication.)

[TYPE ANSWER]

K2 (g) Please provide additional details in relation to management of funds?

(Schedule of Payments, how payments will be made, how payments will be phased, name of bank account into which funds will be lodged.)

[TYPE ANSWER]

K3 Please provide details of any payments (monetary or otherwise) to investigators:

(Non-disclosure of payments (monetary or otherwise) to investigators will result in revocation of ethical approval)

[TYPE ANSWER]

K4 Please provide details of any payments (monetary or otherwise) to participants:

(Committees are interested to know if any payments (monetary or otherwise) will be made to participants. This is particularly the case where these could be considered an inducement to take part in the study. It may be acceptable to reimburse participants all reasonable travel expenses incurred due to participation.)

[TYPE ANSWER]

SECTION L ETHICAL ISSUES

L1 Please identify any particular additional ethical issues which this project raises and discuss how you have addressed them.

(It may be prudent to think carefully before replying 'none' in response to this question.)

[TYPE ANSWER]

APPENDIX ONE: EUROPEAN COMMISSION ALGORITHM REQUIRED TO ANSWER QUESTION I 1.2 (a)

Q I 1.2 (a)

IS IT A CLINICAL TRIAL OF A MEDICINAL PRODUCT?

This algorithm and its endnotes will help you answer that question. Please start in column A and follow the instructions. Additional information is provided in the notes at the end of the table. If you have doubts about the answer to any of the questions contact the clinical trials unit of your competent authority.

A	B	C	D	E
A CLINICAL TRIAL OF A MEDICINAL PRODUCT?				A NON-INTERVENTIONAL CLINICAL TRIAL?
Is it a medicinal product (MP)?ⁱ	Is it not a medicinal product?	What effects of the medicine are you looking for?	Why are you looking for those effects?	How are you looking for those effects?
<p>If you answer no to <u>all</u> the questions in column A, the activity is not a clinical trial on a MP.</p> <p>If you answer yes to <u>any</u> of the questions below go to column B.</p>	<p>If you answer yes to the question below in column B the activity is not a clinical trial on a MP.</p> <p>If you answer no to this question below go to column C.</p>	<p>If you answer no to <u>all</u> the questions in column C the activity is not a clinical trial under the scope of Directive 2001/20/EC.</p> <p>If you answer yes to <u>any</u> of the questions below go to column D.</p>	<p>If you answer no to <u>all</u> the questions in column D the activity is not a clinical trial under the scope of Directive 2001/20/EC.</p> <p>If you answer yes to <u>any</u> of the questions below go to column E.</p>	<p>If you answer yes to <u>all</u> these questions the activity is a non-interventional trial which is outside the scope of Directive 2001/20/EC. If your answers in columns A,B,C & D brought you to column E and you answer no to <u>any</u> of these questions the activity is a clinical trial within the scope of the Directive.</p>
<p>A.1 Is it a substanceⁱⁱ or combination of substances presented as having properties for treating or preventing disease in human beings ?</p> <p>A.2 Does the substance function as a medicine? i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose?</p> <p>A.3 Is it an active substance in a pharmaceutical form?</p>	<p>B.1 Are you <u>only</u> administering any of the following substances?</p> <ul style="list-style-type: none"> • Human whole bloodⁱⁱⁱ; • Human blood cells; • Human plasma; • Tissues except a somatic cell therapy medicinal product^{iv}; • A food product^v (including dietary supplements) not presented as a medicine; • A cosmetic product^{vi} • A medical device 	<p>C.1 To discover or verify/compare its clinical effects?</p> <p>C.2 To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics?</p> <p>C.3 To identify or verify/compare its adverse reactions?</p> <p>C.4 To study or verify/compare its absorption, distribution, metabolism or excretion?</p>	<p>D.1 To ascertain or verify/compare the efficacy^{vii} of the medicine?</p> <p>D.2 To ascertain or verify/compare the safety of the medicine?</p>	<p>E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the Member State concerned?</p> <p>E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation?</p> <p>E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol^{viii}?</p> <p>E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study?</p> <p>E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice?</p> <p>E.6 Will epidemiological methods be used for the analysis of the data arising from the study?</p>

ⁱ Article 1.2 of Directive 2001/83/EC is replaced by Article 1.1 of Directive 2004/27/EC which provides the definition of "medicinal product" which applies for the purposes of Directive 2001/20/EC.

ⁱⁱ Substance is any matter irrespective of origin e.g. human, animal, vegetable or chemical that is being administered to a human being.

ⁱⁱⁱ This does not include derivatives of human whole blood, human blood cells and human plasma that involve a manufacturing process.

^{iv} Somatic cell therapy medicinal products use somatic living cells of human (or animal) origin, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventative effect (in humans) through metabolic, pharmacological and immunological means.

^v Any ingested product which is not a medicine is regarded as a food. A food is unlikely to be classified as a medicine unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose.

^{vi} The Cosmetic Directive 76/768/EC, as amended harmonises the requirements for cosmetics in the European Community. A "cosmetic product" means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with the view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.

^{vii} Efficacy is the concept of demonstrating scientifically whether and to what extent a medicine is capable of diagnosing, preventing or treating a disease and derives from EU pharmaceutical legislation.

^{viii} Assignment of patients to a treatment group by randomisation planned by a clinical trial protocol cannot be considered as current practice.

APPENDIX TWO:

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI 2008

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.
2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
 - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
 - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

22.10.2008

[World Medical Association Declaration of Helsinki, 2008.](#)

APPENDIX THREE TEMPLATE LOCAL CHECKLIST

LOCAL COMMITTEE CHECKLIST:

COMMITTEE CONTACT DETAILS:

Name of Committee:

Contact Person:

Position:

Address:

Tel:

E-Mail:

Website (if any):

COMMITTEE REMIT:

Reviews applications to conduct research in:

SECTIONS OF STANDARD APPLICATION FORM TO BE COMPLETED:

Complete all Sections with the Exception of Sections:

LOCAL REQUIREMENTS (IF ANY):

LOCAL RESTRICTIONS (IF ANY):

FEES:

DOCUMENTS REQUIRED (IF APPLICABLE):

Documents Required:	Number of Copies Required:	Yes / No / N/A	Document Version / Date
Local Checklist			
Standard Application Form			
Local Declaration and Signatory Page			

APPENDIX FOUR TEMPLATE LOCAL DECLARATION AND SIGNATORY PAGE

LOCAL COMMITTEE DECLARATION AND SIGNATORY PAGE:

Name of Committee:

Title of Study:

DECLARATION OF PRINCIPAL INVESTIGATOR:

- The information on this form is accurate to the best of my knowledge and I take full responsibility for it.
-
-
-
-
-
-
-
-
-
-

Name of Principal Investigator: _____

Signature of Principal Investigator: _____

Date Proposal Form Submitted: ____/____/____

APPENDIX FIVE KEY DEFINITIONS

STANDARD APPLICATION Form: Application Form for the Ethical Review of Health-Related Research Studies which are not clinical trials of medicinal products for human use as defined in Statutory Instrument 190/2004. Standard Application Form is available on the Molecular Medicine Ireland website and from research ethics committees.

Clinical trial of a Medicinal Product:

any investigation in human subjects, other than a non-interventional trial, intended

- (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal products, or
- (b) to identify any adverse reactions to one or more such investigational medicinal products, or
- (c) to study absorption, distribution, metabolism and excretion of one or more such investigational medicinal products, or
- (d) to discover, verify, identify or study any combination of the matters referred to at subparagraphs (a), (b), and (c),

with the object of ascertaining the safety or efficacy of such products, or both.

(European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (S.I. No. 190 of 2004)

Department of Health and Children Form: Application Form for ethical review of clinical trials of medicinal products for human use as defined in S.I. 190/2004. This application form is available on the Department of Health and Children website and from research ethics committees.

APPENDIX SIX WORKING GROUP MEMBERS

PILOT WORKING GROUP

In alphabetical order:

Collins, Claire	Irish College of General Practitioners
Gaynor, Siobhan	Irish Clinical Research Infrastructure Network
Lamb, Caroline	HSE South East
McCourt, John	Dublin Centre for Clinical Research
McDonnell, Joan	St. Vincent's Healthcare Group
O'Neill, Sarah	Mater Misericordiae University Hospital
Ryan, Ursula	Adelaide & Meath Hospital, Dublin, incorporating the National Children's Hospital / St. James's Hospital
Saunders, Jean	Mid Western Regional Hospital Complex
Towns, Jeremy (Facilitator)	Dublin Centre for Clinical Research

CONSULTATION GROUP

In alphabetical order:

Bradley, Colin	Irish College of General Practitioners
Byrne, Ned	St. Vincent's Hospital (Fairview)
Collins, Claire	Irish College of General Practitioners
Fitzgerald, Barbara	Naas General Hospital
Gargan, Angela	National Maternity Hospital
Jensen Kavanagh, Mette	Sligo General Hospital
Kirkham, Colin	Rotunda Hospital
Lamb, Caroline	HSE South East
Leonard, Marie	Our Lady's Children's Hospital
Lynch, Dan	Adelaide & Meath Hospital, Dublin, incorporating the National Children's Hospital / St. James's Hospital
Marsden, Paul	HSE Midland Area
Mayne, Philip	Children's University Hospital
McCourt, John	Dublin Centre for Clinical Research
McDonnell, Joan	St. Vincent's Healthcare Group
McLoughlin, Declan	St. Patrick's University Hospital
O'Neill, Sarah	Mater Misericordiae University Hospital
McQuillan, Regina	St. Francis Hospice (Raheny)
Owens, Valerie	St. Luke's Hospital (Rathgar)
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Stanton, Alice	Beaumont Hospital
Toomey, Dave	Dublin Centre for Clinical Research
Towns, Jeremy (Facilitator)	Dublin Centre for Clinical Research
Vale, Gillian	Beaumont Hospital

For the patient provision of IT expertise and support throughout the consultation and pilot phase of this project: -

McCourt, John
Toomey, Dave

Dublin Centre for Clinical Research
Dublin Centre for Clinical Research

For the provision of advice to ensure compliance with the Declaration of Helsinki 2008 and ICH GCP 1996: -

Gaynor, Siobhan

Irish Clinical Research Infrastructure Network

For generous assistance and support throughout the consultation and pilot phase of this project: -

Molecular Medicine Ireland / Dublin Centre for Clinical Research

For generous assistance and invaluable advice throughout the consultation and pilot phase of this project: -

In alphabetical order:

Breen, Ciaran
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Green, Andrew
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Herron, Michaela
Hickie, Nicola
MacHale, Siobhan
MacAleenan, Niall
O'Neill, Brian
O'Sullivan, Ciara M.
O'Sullivan, Siobhan
Ryan, Kieran

State Claims Agency
Irish Medicines Board
A&L Goodbody Solicitors
Office of Data Protection Commissioner
National Centre for Medical Genetics
UPMC Whitfield Cancer Centre
A&L Goodbody Solicitors
Irish Medicines Board
The College of Psychiatry of Ireland
Irish Medicines Board
St. Luke's Hospital (Rathgar)
Office of Data Protection Commissioner
Irish Council for Bioethics
Royal College of Surgeons in Ireland

For support of this project at the pre-consultation stage, to include presenting or facilitating at seminars held in May and June 2009.

In alphabetical order:

Barrington, Ruth
Fletcher, Godfrey

Molecular Medicine Ireland
Irish Platform for Patients' Organisations, Science and Industry

Kehily, Derval
Louet, Sabine
O'Connor, Robert
O'Connor, Catherine
Rowland, Marion

Beaumont Hospital (Cancer Clinical Trials Unit)
Irish Pharmaceutical Healthcare Association
The All Ireland Co-Operative Oncology Research Group
Alpha One Foundation
Children's Research Centre, Our Lady's Children's Hospital

APPENDIX EIGHT BIBLIOGRAPHY

Advanced Healthcare Decisions Bill 2010
Age of Majority Act 1985
Child Care Act 1991
Children in Foster Care Regulations 1995
Council Directive 76/768/EEC and amendments
Criminal Law (Sexual Offences) Act 2006
Department of Health and Children, Children First National Guidelines for the Protection and Welfare of Children 2004
Data Protection Act 1988
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European Commission Volume 9A of the Rules governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance of Medicinal Products for Human Use 2008
European Communities (Medical Ionising Radiation Protection) Regulations, 2002 (S.I. No. 478 of 2002)
European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (S.I. No. 190 of 2004)
Fitzpatrick v K (2008) IEHC 104
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WEBSITES

Biology Online Dictionary
Data Protection Commissioner
Department of Health and Children
European Commission
International Committee of Medical Journal Editors
Irish Council for Bioethics
Irish Medicines Board
Irish Medical Council
Irish Statute Book
Molecular Medicine Ireland
State Claims Agency
United States Department of Veteran Affairs
World Medical Association
World Health Organization

APPENDIX NINE ENDNOTES

(COURTESY OF A&L GOODBODY SOLICITORS)(2009)

ⁱ "Adult" does not have a legislative definition in Ireland, however, pursuant to the Age of Majority Act, a person who has not attained full age (i.e. 18 years of age) and who is not or has never been married prior to attaining full age, is a minor. By way of implication an adult is a person who has attained 18 or a person who has married prior to that age

ⁱⁱ *The Mental Capacity Bill 2008*.

However, this definition is open to change as it proceeds through the legislative process and therefore it would not be advisable to rely on this definition until such time the Bill becomes Law.

Interestingly, the recently published *Advanced Healthcare Decisions Bill 2010* has a different definition of capacity to that contained within the *Mental Capacity Bill* in that it is defined in terms of lacking capacity:

"For the purposes of this Act a person shall lack the capacity to make an advance healthcare decision or any decision in respect of treatment if at the material time, he or she is unable,
(a) to understand the information relevant to the decision
(b) to retain that information
(c) to use or weigh that information as part of the process of making the decision (whether by talking, using sign language or any other means) or, if the decision requires the act of a third party to be implemented to communicate by any means with that third party".

This should also not be relied upon until the Bill becomes Law.

ⁱⁱⁱ For present purposes the interpretation of capacity should be that as held by Laffoy J in *Fitzpatrick v K* which is that in determining whether a patient does not have capacity (cognitive ability) the test is *"whether the patient's cognitive ability has been impaired to the extent that he or she does not sufficiently understand that nature, purpose and effect of the proffered treatment and the consequences of accepting or rejecting it in the context of the choices available at the time the decision is made"*.

The following is helpful in applying the test, also from *Fitzpatrick v K*, "The patient's cognitive ability will have been impaired to the extent that he or she is incapable of making the decision to refuse the proffered treatment if the patient: -

A. has not comprehended and retained the treatment information and, in particular, has not assimilated the information as to the consequences likely to ensue from not accepting the treatment,
B. has not believed the treatment information and, in particular, if it is the case that not accepting the treatment is likely to result in the patient's death, has not believed that outcome is likely and;
C. has not weighed the treatment information, in particular the alternative choices and the likely outcomes, in the balance in arriving at the decision."

^{iv} The preponderance of legal opinion is that under sixteen's in Ireland have no personal power to consent to medical treatment. The seed of this reasoning is the special position of the family based on marriage, recognised in Article 41 of the Irish Constitution, which vests authority for decisions in relation to the family within the family and therefore in effect vests decision making authority with the parents. In the case of a child whose parents are married to each other both parents are legal guardians of the child. In the non-marital family, the natural mother is legal guardian and a natural father may be appointed guardian by agreement or by order of the District Court.

^v Section 23 of the Non Fatal Offences against the Person Act 1997 states that a minor who has attained the age of 16 can consent to any "surgical, medical or dental treatment" and such consent shall be as effective as if it were given by a person of 18 years of age or over. In this section "surgical, medical or dental treatment" includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure which is ancillary to any treatment as it applies to that treatment. Sixteen and Seventeen year olds have the power to consent to medical treatment in relation to "surgical, medical or dental treatment" only. So, for the purposes of psychiatric treatment a person is only considered an adult from the age of 18

^{vi} Section 43.2 Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2009, page 41

^{vii} The minimum age at which a person can give consent to having their personal data processed is not specified in the [Data Protection Acts](#).

^{viii} The legal age to consent to sexual intercourse is 17 under the Criminal Law (Sexual Offences) Act 2006. The legal age to buy alcohol is 18 under Section 31 Intoxicating Liquor Act 1988. The legal age to buy cigarettes is 18 under the Section 45 Public Health (Tobacco) Act 2002.

^{ix} Participation in research is unlikely to constitute "necessary treatment or assessment" and therefore these children ought to be excluded from participation in clinical trials and research as the HSE (or Foster Parents or Relatives acting under a Court Order), do not have the authority to grant consent to their participation in such research. Where it is felt that participation in a clinical trial or other research is in the best interests of an individual child or children, then an application can be made to the District Court under Section 47 of the Child Care Act 1991.

^x Legally valid consent can be given on behalf of an adult without capacity whether due to physical or mental incapacity or age, by a parent, guardian, grandparent, uncle, aunt, brother or sister of the data subject. There is a noted omission in the data protection legislation of consent from a spouse or a son or daughter. Such persons would normally be the subject's next of kin and should be consulted. Even though they are not authorised under the data protection legislation to consent, their views should be considered.

^{xi} Persons who regain capacity should be given a full explanation and they have the right to revoke permission and withdraw from the trial or research. The effect of this is that information/data gathered about them or samples obtained from them, cannot be used in the research and must be deleted or destroyed.

^{xii} See 'X'