STANDARD APPLICATION FORM

For the Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004 The Primary Care Research Committee does not provide Ethical Approval

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study:_____

Principal Investigator:_____

Applicant's Signature:_____

For Official Use Only – Date Stamp of Receipt by REC:

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This Application Form is divided into Sections.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

A1 Title of the Research Study:

Answer

A2 Principal Investigator(s):
Title: Dr. / Ms. / Mr. / Prof. **Name:**
Qualifications:
Position:
Dept:
Organisation:
Address:
Tel: **E-mail:**

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:

Site:	Lead Investigator:

A3 (c) For any of the sites listed above, have you got an outcome from the research ethics committee (where applicable)?

Answer

A4. Co-Investigators:

Name of site

Answer

Title: Dr. / Ms. / Mr. / Prof. **Name:**
Qualifications:
Position:
Organisation:
Address:
Role in Research:

A5. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Title: Dr. / Ms. / Mr. / Prof. **Name:**
Address:
Tel (work): **Tel (mob.):**
E-mail:

A6. Please provide a lay description of the study.

Answer

A7 (a) Is this study being undertaken as part of an academic qualification? Yes / No

A7 (b) If yes, please complete the following:
Student Name: **Course:**
Institution: **Academic Supervisor:**

A7 (c) If HSE employed, have you approval of your HSE Line Manager. Please forward copy of this approval with your application.
Name and Title of Line Manager: _____
Contact email address of Line Manager:_____

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. Provide information on the study background.

Answer

B2. List the study aims and objectives.

Answer

B3. List the study endpoints (if applicable).

Answer

B4. Provide information on the study design.

Answer

B5. Provide information on the study methodology.

Answer

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

Answer

B7. What is the anticipated duration of this study?

Answer

B8 (a) How many research participants are to be recruited in total?

Answer

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.

Answer

B8 (c) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Answer

B8 (d) Where sample size calculation is impossible (e.g. It is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Answer

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

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SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

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

Name of site:	**Names of Treatment Group (if applicable)**		
	Insert name of group:	**Insert name of group:**	**Insert name of group:**
(Insert rows as required)			

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

Answer

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

Answer

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

Answer

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

Answer

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project?
Yes / No / Not to my knowledge

SECTION C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes / No

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

Answer

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

Answer

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

Yes/No

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

Answer

C2.1 (f) Will there be a time interval between giving information and seeking consent? Yes / No

C2.1 (g) If yes, please elaborate.

Answer

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

Answer

SECTION C3 ADULT PARTICIPANTS - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes / No / Non-Applicable

C3.1 (b) If no, please elaborate.

Answer

C3.1 (c) If no, is this research of such a nature that it can only be carried out on adults without capacity? Yes / No

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

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?
Yes / No

C4.1 (b) If yes, please specify:
Persons < 16 Yes / No
Persons aged 16 – 18 Yes / No
Children in care Yes / No

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

Answer

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

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.

Answer

C4.6 Please comment on the involvement (if any) of parents / legal guardians of the child in the consent process.

Answer

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

Answer

SECTION C5 PARTICIPANTS - CHECKLIST

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 Yes / No
C5.2 Unconscious patients Yes / No
C5.3 Current psychiatric in-patients Yes / No
C5.4 Patients in an emergency medical setting Yes / No
C5.5 Relatives / Carers of patients Yes / No
C5.6 Healthy Volunteers Yes / No
C5.7 Students Yes / No
C5.8 Employees / staff members Yes / No
C5.9 Prisoners Yes / No
C5.10 Residents of nursing homes Yes / No
C5.11 Pregnant women Yes / No
C5.12 Women of child bearing potential Yes / No
C5.13 Breastfeeding mothers Yes / No
C5.14 Persons with an acquired brain injury Yes / No
C5.15 Intellectually impaired persons Yes / No
C5.16 Persons aged > 65 years 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)?

Answer

SECTION D DATA PROTECTION

SECTION D IS MANDATORY

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SECTION E1 DATA PROCESSING - CONSENT

D1.1 (a) Will consent be sought for the processing of data? Yes / No

D1.1 (b) If no, please elaborate.

Answer

SECTION D2 DATA PROCESSING - GENERAL

D2.1 Who will have access to the data which is collected?

Answer

D2.2 What media of data will be collected?

Answer

D2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

Answer

D2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

Answer

D2.4 Where will data which is collected be stored?

Answer

D2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

Answer

D2.6 (a) Will data collected be at any stage leaving the site of origin? Yes / No

D2.6 (b) If yes, please elaborate.

Answer

D2.7 Where will data analysis take place and who will perform data analysis (if known)?

Answer

D2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Answer

D2.8 (b) Please elaborate.

Answer

D2.8 (c) If destroyed, how, when and by whom will it be destroyed?

Answer

D2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Answer

D2.9 Please comment on the confidentiality of collected data.

Answer

D2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? Yes / No

D2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Answer

D2.11 (a) Will any of the study data collected consist of photographs/ video recordings? Yes / No

D2.11 (b) If yes, please elaborate.

Answer

SECTION D3 ACCESS TO HEALTHCARE RECORDS

D3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? Yes / No

D3.1 (b) If yes, please elaborate.

Answer

D3.1 (c) Who will access these healthcare records?

Answer

D3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? Yes / No

D3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?

Answer

D3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?

Answer

SECTION E INDEMNITY

SECTION E IS MANDATORY

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E1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? Yes / No

E1 (b) If the answer is 'no' for any site, what other arrangements are in place in terms of indemnity / insurance?

Answer

E2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? Yes / No

E2 (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.)?

Answer

E3 (a) Who or what legal entity is the sponsor of this research study?

Answer

E3 (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)?

Answer

SECTION F COST AND RESOURCE IMPLICATIONS AND FUNDING

SECTION F IS MANDATORY

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F1 (a) Are there any cost / resource implications related to this study? Yes / No

F1 (b) If yes, please elaborate.

Answer

F2 (a) Is funding in place to conduct this study? Yes / No
F2 (b) If no, has funding been sought to conduct this study? Yes / No

F2 (c) Please state the source of funding (industry, grant or other) and the amount of funding.

Answer

F2 (d) Is the study being funded by an external agency? Yes / No
F2 (e) Is the external agency a 'for profit' organisation? Yes / No
F2 (f) Do any conflicts of interest exist in relation to funding? Please elaborate.

Answer

F2 (g) Please provide additional details in relation to management of funds.

Answer

F3. Please provide details of any payments (monetary or otherwise) to investigators.

Answer

F4. Please provide details of any payments (monetary or otherwise) to participants.

Answer

SECTION G ETHICAL ISSUES

SECTION G IS MANDATORY

G1. Please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.

Answer

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.