ST PATRICK'S UNIVERSITY HOSPITAL, DUBLIN

RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

SOP Title: St. Patrick's University Hospital Research Ethics Committee Standard Operating Procedures

Approval 1: Signed _____ Chairperson

Approval 2: Signed _____ Secretary

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PREFACE

These Standard Operating Procedures (SOPs) are focused on assisting in the ethical review of any area of research within St Patrick's University Hospital Dublin that involves humans or their tissues, biological materials or hazardous substances. The SOPs apply to research carried out by St Patrick's University Hospital Dublin clinical staff, whether permanent staff members, honorary staff members or on fixed-term research contracts of any duration, and either alone or in collaboration with colleagues within the university or in other research institutes (where ethical approval has not been sought in those other institutes).

The aim is to provide complementary support to the *Declaration of Helsinki* and to international Good Practice guidelines currently in use in Europe, taking into account any EU Directives or National legislation pertaining to the ethical conduct of research.

1 OBJECTIVES

The objective of the St Patrick's University Hospital Dublin Research Ethics Committee is to safeguard the health, welfare and rights of human participants and researchers (in the case of hazardous materials) in research studies, and to afford dignity to the handling and treatment of biological materials, taking into account the scientific procedures and concerns of the local community. For any research proposal to gain ethical approval it must be both necessary and of a design that minimises predictable risk to both the research participant and the researcher.

The St Patrick's University Hospital Research Ethics Committee:

1. aspires to provide timely, comprehensive and independent reviews of the ethics of proposed studies, acting in accordance with the *Declaration of Helsink*i, statements of appropriate ethical practice produced by relevant professional organisations, following International Good Practice Guidelines, relevant EU Directives, National Guidelines and National legislation pertaining to the ethical conduct of research, and acting in good faith with respect to both applicants and the community.

2. through its operation, would hope to provide St Patrick's University Hospital research and clinical staff and students with the resources for understanding and addressing ethically significant problems which might arise in their research and to promote responsible research and practice.

3. in carrying out these objectives, respects academic freedom and remembers that research is an important activity within the academic and clinical community, and that care should be taken not to hinder research without good cause.

4. aims to facilitate the development of a culture of audit and research among all grades of clinicians and trainees (including students) and to that end, to promote the timely review of studies which are not interventional and have limited risk for patients. These studies are outlined in section 4.3.

5. does not constitute itself as a body intending or equipped to rule on the use of new medications or the non-standard use of existing medications in the context of clinical trials. Such clinical trials should be referred to an external REC which is equipped to rule on the application and approved for that purpose by the Irish Council for Bioethics.

2 MEMBERSHIP

2.1 Selection and Appointment

The Board of Governors of St Patrick's University Hospital Dublin Research, taking advice as appropriate, shall be responsible for selecting and appointing suitable members to the Ethics Committee from the applications put before it through both internal and external solicitation for members. Membership is on a strictly voluntary basis and selection of members shall be by consensus. (When selecting candidates, the Board of Governors should take into account whether or not by virtue of employment, profession or relationship, the candidate could be construed to have a potential conflict of interest with respect to a majority of proposals reviewed.)

2.2 Composition

It is the responsibility of the Board of Governors to ensure that the Research Ethics Committee shall include:

- A chairperson and vice-chairperson, who shall be from or additional to the other categories of members listed below.
- One or two persons with law qualifications. These must not be from any firm that represents St. Patrick's University Hospital interests.
- One or two members with knowledge of, and current experience in, the areas of research that are regularly considered by the Research Ethics Committee.
- One or two members with knowledge of, and current experience in, the area of social science.
- Two members with knowledge of, and current experience in, the professional care and treatment of people (e.g. practising clinicians, nurses), one of whom shall be a specialist in mental health (e.g. clinical psychologist, psychiatrist, qualified counsellor).
- One member with training in ethics (e.g ethicist, philosopher, moral theologian).
- One or two lay members (The qualifications for lay members are independence from the institution and their non-involvement in scientific, clinical practice and legal work. Those who have no experience in professions associated with research on human beings are more likely to have a truly lay perspective.)
- Committee Administrator.

Where a chairperson or members of the Ethics Committee believe there is insufficient expertise on the committee to assess an application or an issue, the committee may seek additional expert advice. As far as possible, the Board of Governors should strive to achieve gender balance in the membership of the Ethics Committee.

2.3 Term of Appointment

Term of office by REC members is open-ended, although it is expected that a new member will remain on the committee for a minimum of 3 years.

- Should a member wish to resign from the committee, they should inform the chairperson in writing of their intention, allowing at least 1 month from the date of receipt of their letter of resignation in which to find a replacement.
- Disqualification of a member from the Research Ethics Committee is at the discretion of the chairperson, with the approval by the Research Committee. Grounds for disqualification include, but are not confined to, failure to attend the required number of scheduled meetings, disruptive behaviour at meetings, undeclared conflicts of interest, breach of the code of confidentiality and canvassing of other committee members. Members will be informed of their disqualification in writing by the chairperson.

2.4 Alternate Members

The Research Committee may appoint a person to act as an alternate to each member of the committee, where the alternate satisfies the same membership criteria as the member. When alternates substitute for a primary member, the alternate member should have received and reviewed the same material that the primary member received or would have received. An alternate can only vote if the member for whom he/she acts as an alternate is absent. The use of an alternate member does not relieve the primary member from their commitment to attend the minimum number of scheduled meetings.

2.5 Attendance

A member is expected to attend **at least two** scheduled Research Ethics Committee meetings each year. Should a member fail to do so, the chairperson should address this with the member concerned.

2.6 Declarations of interest

- When a committee member or deputy member believes they have an interest in relation to an application for ethical review or any other matter for consideration at the meeting that may compromise their ability to make an impartial decision, they should declare that interest to the Committee. Such a declaration may be made orally at the meeting, prior to the matter being considered, or in writing to the Chairperson (or vice chair as appropriate) prior to the meeting.
- Where the member concerned is the Principal Investigator or another key investigator/collaborator named on the application form, the Committee has the following options:
    - The member should leave the meeting room and take no part in the discussion or the vote on the application.
    - The member may remain in the meeting room in order to provide any relevant information requested by other members, but leave the meeting before the vote.
- In the case of any other declared interest, the Committee should collectively consider whether or not it is appropriate for the member concerned to take any part in the review of the application. Account should be taken of the closeness of the member's interest in the application and the potential for a conflict of interest. In some cases, the declaration of the interest may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced. The Committee has the following options:
    - The member should leave the meeting room and take no part in the discussion or the vote on the application.
    - The member may remain in the meeting room in order to provide any relevant information requested by other members, but may not vote.
    - The member may remain in the meeting room and take full part in the review.
- Failure to declare a known interest in an application for ethical review will result in disqualification of a member from the Committee.

2.7 Training

All members of the committee should receive a copy of the Standard Operating Procedures of the Ethics Committee, documentation that clearly outlines their responsibilities, and the schedule of meetings for each year. Each member must also agree to take part in education and ongoing training appropriate to the role as REC member.

2.8 Confidentiality

Members are expected to treat as confidential all applications, meeting deliberations, information on research participants/volunteers and related matters.

2.9 List of Members

Members must be willing to have their name, profession and affiliation published on the committee's webpage.

2.10 Indemnification of REC members

The REC members are indemnified by the Hospital's insurance policy.

2.11 Chairperson

The Chairperson is appointed by the Chairperson of the Board of Governors. The duties of the Chairperson are:

- Liaise with the Office of the Medical Director
- Chair meetings of the REC
- Ensure that the Standard Operating Procedures are followed
- Ensure an annual report is issued (see p.13)

3 OPERATIONAL MATTERS

3.1 Documentation

The members of the REC shall receive the following documentation, preferably 2 weeks prior to a REC meeting, but no later than 5 working days prior:

- Agenda
- Minutes of previous meeting
- Documentation for each research proposal
- Protocol Review assignments

3.2 Frequency of Meetings

The REC meets 4 times a year. A meeting schedule is published annually.

3.3 Agenda

The REC shall endeavour to conduct its business in accordance with the order of the agenda.

3.4 Minutes

The REC Administrator shall record minutes of the REC meeting which should be checked by the REC Chairperson and the REC Secretary. The minutes should include:

- Members, deputy members and experts present
- List of all applications considered, interests declared and decisions made
- In the case of a favourable opinion, any special conditions or additional advice
- In the case of an unfavourable opinion, the reason for the decision
- In the case of a provisional opinion, the further information requested

The minutes shall be approved and signed at the following REC meeting.

3.5 Quorum Requirements

A minimum of **five** members of the Ethics Committee are required to be present at a meeting held to determine an opinion in relation to an application to the Committee. There must be a reasonable representation of member categories in any quorum, including at least the following:

- The Chairperson, or in their absence, the vice-chairperson.
- One clinician or one scientist
- One lay person

The following may be counted for the purposes of the quorum:

- A deputy member who is attending in place of their 'lead' member
- A co-opted member

The following should not be counted for the purposes of the quorum:

- The REC Administrator
- Members who are yet to arrive at the meeting or who have left early
- Members who submit comments but do not attend
- Deputy members attending alongside the lead member

Where a quorum is not present, the Committee may not commence, continue or conclude any discussion with the purpose of determining the Committees' opinion on an application for ethical review. However, the Committee

may proceed with any other business on the agenda, provided that the Chairperson (or vice-chairperson) is present.

3.6 Other Attendees

Where appropriate, the principal investigator and/or sponsor may be invited to present the proposal or to elaborate on specific issues. The decision to do so will be taken by the Chairperson or, in their absence, the Vice-Chairperson.

4 PROCEDURE FOR SUBMITTING AN APPLICATION

4.1 Applicant

The applicant should be a qualified researcher responsible for the ethical and scientific conduct of the research.

4.2 Obtaining Application Documentation

An applicant wishing to submit a research proposal should log onto the committee's webpage at www.stpatrickshosp.ie/research/research-ethics-committee and download the relevant documentation.

4.3 Type of Application

Clinical Audit – If the study can be described as a clinical audit, it is not necessary to submit a REC application form. Instead, the applicant can contact the Clinical Audit Facilitator for a copy of the Audit Policy and Audit Proposal Form.

Clinical Trials - St. Patrick's University Hospital REC is not authorised to approve clinical trials.

Interventional Studies - Any and all research that involves manipulating or changing the therapeutic interaction of a patient with a treatment or therapist shall be classified as interventional. The use of Psychometric tests shall *not* be considered an intervention, except where the results impact on further interventions or where the results are likely to change a patient's decision about further therapy. The taking of biological samples of any kind shall be considered interventional and requires full St. Patrick's University Hospital REC approval.

Non-Interventional Studies - Any and all research that does not involve manipulating or changing the therapeutic interaction of a patient with a treatment or therapist shall be classified as non-interventional. This includes outcome studies of a particular therapy, even if such studies are prospective in nature, but where there is no randomization or manipulation of the choices available to the patient. Such research shall use the same application form as interventional research. The use of Psychometric tests shall *not* be considered an intervention, except where the results impact on further interventions or where the results are likely to change a patient's decision about further therapy.

4.4 Submissions Deadline

The completed application must be received in full by the REC administrator **five weeks** before the REC meeting.

4.5 Application Requirements

The requirements for the submission of a research project for ethical review are clearly described on the checklist, available for download on the above webpage.

As a summary, the submission should *always* include the following:

- Checklist
- REC Application Form
- Research Protocol
- Declaration and Signatory page
- CV of Principal Investigator – maximum of two pages (dated)

In addition, the following documents should be included, as appropriate:

- Participant Information Sheet
- Participant Consent Form
- Consultant/GP Information Sheet
- Consultant/GP Consent Form
- Sample letters to participants, consultants, and/or GP's
- Questionnaire(s)
- Advertisement(s)
- Arrangements for insurance or indemnity
- Proof of Funding
- Approval from other Ethics Committees
- Request for Chair Approval (see 4.7)
- Any other documentation related to the study

Review of a research study could be delayed if information is missing. When preparing a protocol, it is advisable to contact the REC administrator for assistance in order to ensure an acceptable submission.

4.6 Notification of Receipt

All applications will be acknowledged in writing within 7 days of receipt, including the communication of the incompleteness of an application where this applies. This notification will only be sent once the application has been reviewed by the REC Secretary (currently the Medical Director of St. Patrick's University Hospital) and/or the REC Administrator.

4.7 Chair Approval

If the study is of a non-interventional nature and the next REC meeting is more than 6 weeks away or the study requires urgent approval, the applicant may request that it be considered for chair approval. It will be reviewed by the REC Secretary (Medical Director) and Administrator first, and if approved (see 4.6), it will then be forwarded to the chairman of the committee for his approval. Upon receipt of such approval, the Principal Investigator will be notified by letter that their study has chair approval. All such applications will still be considered by the committee at their next meeting.

4.8 Registration of Applications

The REC Administrator should maintain a database of all applications and this should be updated regularly. When a new application is submitted, this registration procedure should be followed:

- Assign a protocol number to the application for all future correspondence
- Check for the formal completeness of an application
- Arrange for the REC Secretary to review the application
- Notify the applicant of receipt and of amendments that need to be made, if required.
- Enter the new application on the database, including PI details, Title of research, name of supervisor, date received, date checked, date acknowledged.
- Where an application is found to be invalid, the applicant will be informed of the reasons in writing within 1 week of receipt. The application is void and should be deleted from the agenda of the next meeting.

4.9 Revisions to Application

No revisions may be made, prior to the Research Ethics Committee meeting, to an application that has been accepted for review and assigned a protocol number. Where an applicant considers it necessary to revise the application form or supporting documents prior to review, the application should be withdrawn.

4.10 Payment to Participants

No research participants in any study should receive a payment or gift for their involvement in the study.

5 DECISION MAKING

5.1 Before the Meeting

In making decisions on submissions for the ethical review of research, 2 committee members will be assigned in advance of the meeting to lead the discussion for each application. Having reviewed their assigned application carefully in harmony with their review responsibilities (Appendix A), they will have formed a decision in their own mind before attending the meeting.

5.2 During the Meeting

Although 2 committee members are assigned in advance to lead the discussion for each application, all committee members will be given the chance to make comment, as appropriate.

The following should be taken into consideration:

- Decisions should be arrived at through consensus where possible; under this model the proposal will be approved when all members present are willing to allow the proposal to proceed.
- In cases where consensus appears unlikely, the Chairperson may call for a vote with a two-thirds majority required for decision.
- Dissenting members should have an opportunity to append an opinion to the REC decision.
- Members who have conflicts of interest should declare these to the chairperson (or vice chair as appropriate) prior to the review of the application and these should be recorded in the minutes.
- Decisions should only be made at meetings where a quorum is present.
- Advice that is non-binding may be appended to the decision.
- In cases of provisional approval, clear suggestions for revision and the procedure for having the submission re-evaluated should be specified.
- A negative decision on an application should be supported by clearly stated reasons.

5.3 Possible Ethics Committee Decisions

Approval	The applicant may begin the research as outlined in the research proposal submitted to the Research Ethics Committee.
Provisional Approval	Provisional approval may be granted, subject to recommended revisions to the proposal or answers to questions posed to the applicant. In this case the PI should submit a cover letter (along with a modified submission and supplemental information if requested), highlighting any changes in line with REC recommendations/queries. These modified submissions may be reviewed by the Chairperson (or vice chair as appropriate), and he may grant approval subject to the affirmation of the Committee at its next meeting.
Deferral	A deferred research proposal must be reviewed and re-submitted to the Committee as a new proposal.
Approval Declined	Proposals may be rejected by the Committee. This may occur if the protocol has been deferred several times and/or the Committee feels that the proposed research is not justified and/or poses severe or unnecessary risk to the subjects. A rejection should be supported by clearly defined reasons. The Committee may or may not, as it feels appropriate, invite resubmission of a substantially altered proposal for reconsideration.

5.4 Communicating the Decision

The Committee decision should be communicated to the applicant in writing with a copy to the study supervisor within two weeks of the meeting at which the decision was taken and no later than 90 days after acknowledgement of receipt of the application.

The decision is to include, but is not limited to:

- Name and title of applicant
- Protocol number and exact title of the proposal reviewed
- Date and place of the decision
- Name of Chairperson and list of members present when the decision was taken
- A clear statement of the decision taken
- Any additional advice, opinions, requirements or conditions adjoined to the decision by the Ethics Committee, including the timeframe and procedure by which they should act on these
- Clearly defined reasons for the requirements
- Clearly stated reasons for a negative decision
- Signature of the Chairperson (or other authorised person) of the Ethics Committee

In the case of a positive decision (this applies to chair approval and committee decisions), a statement of the responsibilities of the applicant should be laid out, which should include the following standard conditions:

- Adhering to the terms and conditions of their research (which includes the declaration on page 6 of the application form)
- Notifying the committee in the case of material changes to the protocol
- Providing a progress report no later than 12 months subsequent to the approval

In addition, the following conditions should be included, as appropriate:

- Request written confirmation of the destruction of electronic recordings (if used)
- The need to obtain an honorary contract with the hospital through HR in the event that the PI or co-investigators are not employees of the hospital. If this is required, HR should be copied in on the approval letter.

6 REVIEW PROCESSES FOR ONGOING RESEARCH

6.1 Amendments to Approved Studies

In the event of **any** revision to an approved research study, an amendment must be submitted to the REC Administrator, including details of the change(s) and the rationale for such. Amendments may not be implemented until REC approval has been obtained.

The REC reserves the right to determine whether proposed changes are substantive and to request further information or a new research study submission, as appropriate. If the amendment is deemed to be of a non-substantive nature, it may receive chair approval (see 4.7) and be submitted as correspondence at the next REC meeting.

6.2 Transferring Research Study to another Investigator

When an investigator chooses to transfer his status of principal investigator on an approved research study to another investigator, the REC must be notified. This notification must be signed by the new principal investigator, recognising that he/she is now responsible for the research, and their CV must also be submitted. Appropriate changes to other documents (e.g. consent forms, information sheets) must also be submitted.

6.3 Adverse Events

As a condition of approval, investigators must report to the REC at the earliest opportunity any serious or unexpected adverse reaction on subjects or unforeseen events that might affect the benefits/risks ratio of the research study. The REC shall review this and decide whether there are sufficient grounds for changing its initial decision to grant approval to the proposal.

6.4 Reporting Requirements

The Research Ethics Committee is responsible for following the progress of all studies (for which a positive decision has been reached) from the time the research commences through to its termination. As a minimum, the Research Ethics Committee will require an annual report from the Principal Investigator, but the Committee can agree more frequent reporting at the time of approval of the application.

When a study includes audio or video recordings, written confirmation that the recordings have been destroyed needs to be requested and received by the committee.

6.5 Annual Report

The annual report of the investigator should include, but is not limited to:

- Progress to date or outcomes in the case of a completed project
- A statement of compliance with the approved proposal and/or minor amendments to the proposal and a justification for these
- A description of measurements taken to maintain and secure personal information/records pertaining to the research

6.6 Progress Report

If the REC has concerns about a research study, an investigator may be asked to submit a progress report within a stated period for review by the REC.

6.7 Study Termination

In the case of the premature suspension/termination of a study, the applicant should notify the Research Ethics Committee of the reasons for the suspension/termination. This should be accompanied by a summary of results obtained in a study up to the point of being suspended/terminated.

In all cases, the Research Ethics Committee will require a final study report, summarising the main findings.

7 DOCUMENTATION AND ARCHIVING PROCEDURE

7.1 Documents to File

All documentation and communications of the Research Ethics Committee are to be dated, filed and archived by the REC Administrator. Documents to be filed and archived include, but are not limited to:

- Historical documents and SOP of the Research Ethics Committee
- The curriculum vitae of all Research Ethics Committee Members
- The agenda and minutes of all Research Ethics Committee meetings
- All submitted documentation
- All correspondence
- Annual reports
- Final study reports

7.2 Database

The REC Administrator shall maintain a database of all submissions including submission date, study title, PI, Supervisor, date of REC review, follow-up, outcomes.

7.3 When to Archive

Original documents should be kept for a minimum of three years, after which all documentation will be scanned and stored on the computer of the REC Administrator. Once the files get too large, older files shall be stored on CD and kept in a locked cabinet in the Administrator's office.

7.4 Confidentiality

Requested copies of files will be given only to the principal investigator, supervisor, co-investigator(s) listed on the particular research study and members of the REC. Copies will not be given to anyone else unless the principal investigator notifies the REC that it is appropriate to do so.

8 RESEARCH ETHICS COMMITTEE ANNUAL REPORT

Within six months from December 31st, the REC shall prepare an annual report on the activities of the REC during that year. It should contain information relevant to its procedures including, but not limited to:

- Membership and membership changes
- Number and dates of meetings held
- Attendance of members and confirmation of participation by required categories of members
- Substantive changes to the standard operating procedures (SOP)
- List of training undertaken by members
- A list of proposals considered and the decision reached on each
- Time taken from acceptance of application to final decision on each proposal
- List of projects completed or terminated during the year

A copy of the report will be sent to the Board of Governors. Annual reports are public documents and should be available on request.

APPENDIX 1: REC Review Responsibilities

The REC should consider the following when reviewing research proposals:

A) Scientific Design and Conduct of the Study

- The thoroughness and completeness of the information submitted and its ability to respond to ethical questions arising within the context of the study
- The suitability of the protocol and the data collection forms in relation to the objectives of the study (taking into account rules and regulations), the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants/volunteers
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the participants/volunteers and the concerned communities
- Criteria for prematurely withdrawing participants/volunteers from the research
- Criteria for suspending or terminating the research project as a whole
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including data safety
- The adequacy of the site, including the supporting staff, available facilities and emergency procedures, where applicable
- The manner in which the results of the research will be reported and published

B) Recruitment of Research Participants/Volunteers

- The characteristics of the population from which the participants/volunteers will be drawn (including gender, age, literacy, culture, economic status and ethnicity) and the justification for any decisions made in this regard
- The method by which initial contact and recruitment is to be conducted and its appropriateness to the study
- The method by which information is to be conveyed to potential participants/volunteers or their representatives and by which means consent is to be obtained
- Inclusion and exclusion criteria for participants/volunteers

C) Care and Protection of Research Participants/Volunteers

- The safety of any intervention to be used in the proposed research
- The suitability of the investigator for the proposed study in relation to his/her qualifications and experience
- The provisions made for receiving and responding to queries and complaints of participants/volunteers throughout the course of the study
- If applicable, any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action
- If applicable, the adequacy of health and social supervision and psychological support for participants/volunteers during and after the course of the research
- Steps to be followed if participants/volunteers voluntarily withdraw during the course of the research
- If appropriate, the arrangements for informing the participant's/volunteer's GP, including procedure for seeking consent to do so

- The provisions for compensation/treatment in the case of injury/disability/death of a participant/volunteer attributable to participation in the research
- The insurance and indemnity arrangements covering the liability of the investigator
- A description of any grants, payments or other reward to be made to any researchers or research hosts, related to the conduct of the study

D) Protection of Research Participant/Volunteer Confidentiality

- A description of the persons who will have access to personal data of the participants/volunteers, including medical records and biological samples
- The measures taken to ensure the confidentiality and security of personal information concerning research participants
- The extent to which the information with be anonymised
- How samples/data will be obtained and the purposes for which they will be used
- How long samples/data will be kept

Both Research Ethics Committee members and investigators should be aware of the provisions of the Data Protection Acts 1988, and all other legislation and guidelines pertaining confidentiality and their obligations as set out in these acts.

E) Informed Consent Process

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent and the time frame in which it will occur
- The adequacy, completeness, and understandability of written and oral information to be given to the participants/volunteers and, when appropriate, their legally acceptable representative(s)
- The content and the wording of the participant/volunteer information sheet
- The content and the wording of the informed consent form and, when applicable, the provisions made for participants incapable of giving consent personally
- Description of the procedures for disclosure, if appropriate, of relevant information to participants/volunteers which may become available during the course of the research, as well as assurance that such will be given (including rights, safety and well-being)

F) Community Considerations

- The impact and relevance of the research on the local community and on the concerned communities from which the participants/volunteers are drawn
- The manner in which the results of the research will be made available to participants/volunteers and the concerned communities

APPENDIX 2: Glossary

The definitions provided within this glossary apply to terms as they are used in this SOP:

advice

Non-constraining suggestions or considerations adjoined to a decision intended to provide ethical assistance to those involved in the research.

amendment

A written description of changes to a protocol or document.

applicant

A qualified researcher undertaking the scientific and ethical responsibility for a study, either on his/her own behalf or on behalf of a research team or organisation, seeking a decision from an ethics committee through formal application.

community

A group of people understood as having a certain identity due to the sharing of common interests or to a shared proximity.

conflict of interest

A conflict of interest arises when a member (or members) of the Research Ethics Committee holds interests with respect to specific applications for review that may jeopardise his/her ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interest may arise when a REC member has financial, material, institutional or social ties to the research.

principal investigator

A qualified researcher who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organisation, for the scientific and ethical integrity of a research study at a specific site or group of sites. In some instances a coordinating investigator may be appointed as the responsible leader of a team of sub-investigators.

protocol

A document that provides the background, rationale and objective(s) of a research study and describes its design, methodology and organisation, including statistical considerations

Research Ethics Committee (REC)

An independent body constituted of medical professionals and non-medical members, whose responsibility it is to safeguard the welfare and the rights of subjects participating in research studies, taking into account the scientific procedures and the concerns of the local community.

subject

An individual who participates in a research study. The individual may be a healthy person who volunteers to participate in the research study, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person whose condition is relevant to the study and who agrees to participate.

APPENDIX 3: Information Sources

SOP compiled from:

1. Operational Procedures for Research Ethics Committees: Guidance 2004. The Irish Council for Bioethics (www.bioethics.ie). ISBN 1-904890-06-7.
2. Operational Guidelines for Ethics Committees that Review Biomedical Research (2000), World Health Organisation, Geneva (TDR/PRD/ETHICS/2000.1).
3. Guidelines and Recommendations for European Ethics committees (1997). European Forum for Good Clinical Practice.
4. Irish College of General Practitioners Research Ethics Committee Standard Operating Procedures (www.icgp.ie).
5. Guidelines for Research Ethics at Dublin Institute of Technology (www.dit.ie/admin/graduate/ethics/index.html).
6. Research Ethics Committee Guidelines, Royal College of Surgeons of Ireland (2001).
7. UK Central Office for Research Ethics Committees (COREC); Standard Operating Procedures for Research Ethics Committees in the United Kingdom (www.corec.org.uk)
8. Research Ethics Committee Guidelines, University of Limerick.
9. National University of Ireland Galway Research Ethics Committee Standard Operating Procedures 2005 (http://www.nuigalway.ie/research/VPResearch/ethics.htm)
10. St Vincent Hospital Group – Ethics and Medical Research Committee (2004).
11. Research Ethics Committee SOP – Sligo General Hospital (2008)