St Patrick's
Mental Health Services

ST PATRICK'S MENTAL HEALTH SERVICES

RESEARCH ETHICS COMMITTEE

GOVERNANCE &

STANDARD OPERATING PROCEDURES

Approval 1: **Signed** _____ **Chair**

Approval 2: **Signed** _____ **Vice-Chair**

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1 INTRODUCTION

1.1 The St Patrick's Mental Health Services (SPMHS) Research Ethics Committee (REC) is an institutional research ethics committee established by the Board of Governors of SPMHS to ensure that all research conducted by Staff and Students involving human subjects, excluding clinical trials, is conducted according to best ethical practice. Staff include permanent staff members, honorary staff members or those on fixed term research contracts of any duration, either alone or in collaboration with colleagues within Trinity College Dublin, University of Dublin, Ireland, or in other Research Institutes. SPMHS refers to the services provided by St Patrick's Hospital Dublin at St Patrick's University Hospital (SPUH), James Street Dublin, St Edmundsbury Hospital, Lucan Co Dublin, Willow Grove Adolescent Unit SPUH and the network of Dean Clinics in the community in Dublin, Cork and Galway.

1.2 The SPMHS REC is not formally recognised by the Department of Health for the ethical review of clinical trial studies under regulation 7 of the European Communities Regulations (Clinical Trials on Medicinal Products for Human Use (S.I. 190 of 2004))[1-2]. The REC does not review clinical trials of medicinal products and medical devices. All such trials conducted within SPMHS must be submitted to a recognised REC. The SPMHS REC will only review clinical trials to ensure that they conform to the ethos of SPMHS. Further information regarding application for ethical review of clinical trials of medicinal products can be found on the Department of Health website[3] and in the Guide to Clinical Trial Applications published by the Health Products Regulatory Authority[4].

1.3 The purpose of this document is to outline the governance and operating procedures of the SPMHS REC. The governance and operating procedures have been developed based on requirements for ethical review established as best practice in national and international guidelines[5-15]. They also draw on the 2004 guidance document, Operational Procedures for Research Ethics Committees developed by the Irish Council for Bioethics[16]. The aim is to provide complimentary support to the Declaration of Helsinki and to international best practice currently in use in Europe, taking into account any EU legislation or national legislation pertaining to the ethical conduct of research[5-15]. The Economic and Social Research Council's framework for research sets out principles, requirements and standards for Research Ethics Committees[17].

2 OBJECTIVES

2.1 The objective of the SPMHS REC 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.

2.2 The SPMHS REC:

(a) 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.

(b) through its operation, it provides SPMHS 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.

(c) 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.

(d) aims to facilitate the development of a culture of 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 23.3.

(e) 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.

3 SCOPE ROLE AND RESPONSIBILITIES OF RESEARCH ETHICS COMMITTEE (REC)

3.1 The REC is established by the Board of Saint Patrick's Hospital Dublin (the Board) and reports through the Chair to the Board.

3.2 A favourable opinion from an ethics committee does not imply management approval to proceed with the research project, clinical trial or clinical investigation of a medical device, and applications for management approval should be directed to the Chief Executive's Office using the CEO Management Approval and Signature of Research Related Documents Check List. Final management approval to proceed will not issue until a favourable ethical opinion and, where applicable, regulatory approval have been obtained and insurance issues addressed, and any necessary legal documents reviewed, approved and signed by the CEO or delegated person.

3.3 The REC is not recognised as an ethics committee for the purposes of providing ethical opinion in respect of clinical trials pursuant to the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (SI 190 of 2004 as amended) and applications for ethical approval of such trials fall outside the remit of the REC. Approval of a clinical trial by a recognised ethics committee as well as regulatory approval by the HPRA is required. The REC will only review clinical trials to ensure that they conform to the ethos of SPMHS. In addition, before a clinical trial may proceed at SPMHS management approval is required as set out at paragraph 3.2 above. For the avoidance of doubt, it is open to the CEO or delegated person to request the research ethics committee to provide him advice in relation to the appropriateness of a clinical trial, clinical investigation of a medical device to proceed at the SPMHS.

3.4 Subject to paragraph 3.3, the REC will review applications to conduct research in SPMHS. The REC will undertake competent ethical review of research proposals submitted to the REC and an independent, just and timely review of any such proposals and in so doing will act in accordance with applicable laws and Irish, EU and International best practice guidance (including ICH Guideline for Good Clinical Practice and the Declaration of Helsinki) applicable to the approval and conduct of research involving or relating to human participants in force at the relevant time. The overriding responsibility of the REC is to safeguard the rights, safety and well-being of all research subjects.

3.5 In particular, the REC will undertake ethical review of research involving any of the following:-

3.5.1 The service users or staff of SPMHS

3.5.2 The use of or reference to human remains, human organs, tissues, cells or other human biological material whether collected from Service Users or Staff of the SPMHS or held by the SPMHS and accessed for the purpose of the research

3.5.3 Research proposals involving comparison between an established procedure whether therapeutic, non-therapeutic, screening or diagnostic and other procedures which are not recognised as established whether by virtue of their recent development, discovery or use in a new or unfamiliar way or otherwise

3.5.4 Research conducted by students in SPMHS or which seeks access to service users or staff or data or materials held by the SPMHS for the purpose of the research

3.5.5 Access to personal information by means of questionnaires, interviews or other techniques of information gathering involving service users, family of service users, staff or students of SPMHS

3.5.6 Secondary use of data (use of data not collected for that research purpose) if any form of identifier is involved and / or if health information pertaining to individuals is involved

3.5.7 Case studies when a series of subject observations allow possible extrapolation of generalisation of the results from the reported cases and when there is an intention to publish and disseminate the data.

3.5.8 Such other matters as may be referred to the REC for an opinion by either the Board or the Chief Executive from time to time including, without limitation, the appropriateness of any research project or clinical trial proposed to be carried out at SPMHS.

4 ROLE AND RESPONSIBILITIES OF INVESTIGATORS

4.1 The Principal Investigator is the lead researcher who is responsible for the conduct and in many instances the design of the research study. In the case of a multi-site study, the Principal Investigator is the principal researcher who has overall responsibility for the conduct of the multi-site study. The expression Chief Investigator is also used interchangeably with Principal Investigator. In the case of multi-site studies a Lead Co-investigator is appointed for each site. The Lead Co-investigator takes responsibility for the conduct of the study at that site. In addition to the Principal Investigator/ Co Lead investigator there may be a number of other Co-investigators involved in the conduct of the study. The Co-investigators play designated key roles in relation to the conduct of the study. The Co-investigators are identified in the application form and their role in the study is described. If a study is conducted by a team of individuals at a study site, the Principal Investigator is the leader of the team.

4.2 The Principal Investigator may delegate tasks to appropriately qualified persons within the study team but will retain overall responsibility for the proper conduct of the research.

4.3 The Principal Investigator is responsible for the accuracy and completeness of all information and documentation whether written or oral submitted to the REC in support of an application for approval of a research project including all information provided in response to oral questions raised by the committee at a meeting of the REC or in reply to written request(s) for information received from the REC in relation to the application or in relation to an approved study.

4.4 The Principal Investigator is responsible for conducting the research project in compliance with the terms of the approval received from the REC. The Principal Investigator should be aware of and comply with the principles of ICH-GCP, all applicable laws and regulatory requirements relevant to the conduct of the approved study.

4.5 The Principal Investigator is responsible for obtaining and documenting the informed consent of study participants using the participant information leaflet and written informed consent form as approved by the REC prior to the commencement of the research. The participant information leaflet and written

informed consent form may be revised by the Principal Investigator from time to time in which event they must be submitted to and approved by the REC in advance of use.

4.6 The Principal Investigator shall not recruit any human participants to the study prior to the receipt of REC approval for the study and for the participant information leaflet and written informed consent form, and management approval in accordance with paragraph 3.2.

4.7 The Principal Investigator is responsible to ensure that the study is conducted and that any data which could identify individuals is protected in compliance with data protection law and regulatory requirements.

4.8 The Principal Investigator shall ensure that all study information is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

4.9 The Principal Investigator shall ensure that the rights, safety and wellbeing of the study participants are protected paying special attention to any vulnerable subjects or classes of subject.

4.10 The Principal Investigator should have sufficient time to properly conduct and complete the study within the agreed study period.

4.11 The Principal Investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the study to conduct the study properly and safely and ensure that all persons assisting with the study are adequately informed about the study protocol, the study interventions or procedures and their study related duties and functions.

4.12 The Principal Investigator is responsible for notifying the study participant's primary medical practitioner of his his/her participation (as appropriate).

4.13 The Principal Investigator shall ensure that all study related medical decisions are made by an investigator who is an appropriately qualified medical practitioner.

4.14 The Principal Investigator is responsible for the provision of adequate medical care to study participants who experience an adverse event

4.15 The Principal Investigator shall not implement any deviation from or changes to the study as approved without prior review and documented approval from the REC of the amendment. In an emergency where a change is necessary to eliminate an immediate hazard to study participants it is permissible to implement the change or deviation and as soon as possible thereafter notify the REC of the implemented deviation or change, the reason for it and the proposed study amendment should be submitted to the REC for review and approval.

4.16 The Principal Investigator shall comply with the REC requirements for notification of commencement, post approval monitoring, notifications and reporting as set out in the REC approval of the research study and as provided for at paragraph 24 of the REC Governance & Standing Operating Procedures document.

4.17 The Principal Investigator shall ensure that all staff assisting with the study are aware of and orientated to the SPMHS policies that apply to research including those policies set out at Appendices 20-28 as amended and updated from time to time.

5 PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

5.1 In obtaining and documenting informed consent, the Principal Investigator shall comply with applicable law and regulatory requirements and should adhere to ICH-GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

5.2 Prior to the beginning of the study, the Principal Investigator should obtain the REC's written approval of the written informed consent form and written participant information leaflet for study subjects.

5.3 The written informed consent form and other written participant information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form and written participant information leaflet should receive the REC's approval in advance of use.

5.4 It is the Principal Investigator's responsibility to ensure that the subject (or where the subject lacks decision making capacity his or her legal representative) should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the study. The communication of this information should be documented.

5.5 Neither the Principal Investigator nor the study team should coerce or unduly influence a subject to participate or to continue to participate in a study.

5.6 The language used in the oral and written information about the study and the informed consent form should be as non-technical as practical and should be understandable to the subject or to the subject's legal representative where applicable.

5.7 Before informed consent may be obtained the Principal Investigator or a suitably qualified person designated by the Principal Investigator, should provide the subject or the subject's legal representative (if applicable) ample time and opportunity to enquire about the details of the study and to decide whether or not to participate in in the study. All questions about the study should be answered to the satisfaction of the subject or the subject's legal representative (where applicable).

5.8 Prior to the subject's participation in the study, the written informed consent form should be signed and personally dated by the subject or by the subject's legal representative (if applicable) and by the person designated by the Principal Investigator who conducted the informed consent discussion.

5.9 Both the informed consent discussion and the participant information leaflet to be provided to the subject should include explanations of the following:-

5.9.1 That the study involves research

5.9.2 The purpose of the study

5.9.3 The study treatment(s) and where applicable the probability of random assignment to each treatment or study group.

5.9.4 The study procedures to be followed, including all invasive procedures.

5.9.5 The subject's responsibilities.

5.9.6 Those aspects of the study that are experimental.

5.9.7 The reasonably foreseeable risks or inconveniences to the subject and, where applicable to any embryo, foetus or nursing infant.

5.9.8 The reasonably expected benefits. Where there is no intended clinical benefit to the subject, the subject should be made aware of this.

5.9.9 The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their potential benefits and risks.

5.9.10 The compensation and or treatment available to the subject in the event of research related injury.

5.9.11 The anticipated payments (if any) to the subject for participating in the study.

5.9.12 The anticipated expenses (if any) to the subject for participating in the study.

5.9.13 That the subject's participation in the study is voluntary and that the subject may refuse to participate or withdraw from the study, at any time, without penalty or loss of any benefits to which the subject is otherwise entitled and without giving any reason for refusal or withdrawal.

5.9.14 That the REC and any relevant regulatory authorities and any monitors and or auditors will be granted access to the subject's original medical records for verification of study procedures and / or data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legal representative (if applicable) is authorising such access.

5.9.15 That any records identifying the subject will be kept confidential and, to the extent permitted by applicable laws and or regulations will not be made publicly available. If the results of the study are published the subject's identity will remain confidential.

5.9.16 That the subject or the subject's legal representative (if applicable) will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the study.

5.9.17 The identity of the persons to contact for further information regarding the study and the rights of study subjects and to whom to contact in the event of a study related injury or to make a complaint.

5.9.18 The foreseeable circumstances and or reasons under which the subject's participation in the study may be terminated.

5.9.19 The expected duration of the subject's participation in the study.

5.9.20 The approximate number of subjects involved in the study.

5.10 Prior to participation in the study the subject or the subject's legal representative (if applicable) should be given a copy of the signed and dated written informed consent and the participant information leaflet provided to the subjects. During a subject's participation in the study, the subject or the subject's legal representative (if applicable) should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

5.11 When a study, whether therapeutic or non-therapeutic, includes subjects who can only be enrolled in the study with the consent of the subject's legal representative (e.g. minors or adult patients lacking capacity) the subject should be informed about the study to the extent compatible with the subject's

understanding and, if capable, the subject should sign and personally date the written informed consent.

5.12 A non-therapeutic study is one in which there is no anticipated direct clinical benefit to the subject. Non-therapeutic studies may be conducted in subjects with consent of a legal representative provided the following conditions are fulfilled.

5.12.1 The objectives of the study cannot be met by means of a study in subjects who can give informed consent personally.

5.12.2 The foreseeable risks to the subjects are low.

5.12.3 The negative impact on the subject's wellbeing is minimised and low.

5.12.4 The study is not prohibited by law.

5.12.5 The approval of the research ethics committee is expressly sought on the inclusion of such subjects and the written approval covers this aspect.

5.13 The written informed consent form must be consistent with the information provided in the participant information leaflet. A template participant information leaflet and written informed consent form is available to all Principal investigators/Co-lead investigators seeking REC approval from the REC Administrator.

6 MEMBERSHIP COMPOSITION AND TERMS OF APPOINTMENT OF REC

6.1 Selection and Appointment

6.1.1 The Board of St Patrick's Hospital Dublin, taking advice as appropriate, shall be responsible for selecting and appointing suitable members to the REC from the applications put before it. Applications for Membership of the REC will normally be considered by the Chair of the REC prior to application being put before the Board. Membership is on a strictly voluntary basis. When selecting candidates, the Board 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.

6.1.2 It is the responsibility of the Board to ensure that the REC shall include:

(a) One or two persons with law qualifications. These must not be from any firm that represents the interests of SPMHS.

(b) One or two members with knowledge of, and current experience in, the areas of research that are regularly considered by the REC.

(c) One or two members with knowledge of, and current experience in, the area of social science.

(d) 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).

(e) One member with training in ethics (e.g. ethicist, philosopher, moral theologian).

(f) At least one member with data protection qualifications and experience.

(g) Two service users.

(h) 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.

6.2 **Composition and term of appointment**

6.2.1 The members of the REC shall be appointed by the Board and shall consist of expert member and lay members. As far as possible, the Board of Governors should strive to achieve diversity in the membership of the REC.

6.2.2 The REC shall consist of no more than fifteen (15) members of which at least one quarter of members shall be lay members. At least four (4) members of the Research Ethics Committee are not and never have been healthcare professionals. The Board may designate up to two (2) persons as lay members ad hominem even though by virtue of his or her professional training he or she would not ordinarily be regarded as lay members provided he or she is not and never has been a healthcare professional.

6.2.3 The term of membership of a member of the REC shall be for a period of five (5) years unless he or she sooner dies, resigns or is removed from membership of the committee.

6.2.4 A member of the REC whose term of membership expires by effluxion of time shall be eligible for re-appointment as a member at the discretion of the Board for a further period of five (5) years but a member shall not hold office for more than two consecutive periods of five (5) years or a maximum of ten (10) consecutive years.

6.2.5 Notwithstanding paragraph 6.2.4, where the term of office of a member of the REC expires by effluxion of time, that person shall, for so long as he or she consents to act as such member continue in office as a member until either he or she is re-elected (unless he or she is ineligible for re-election having held office for two consecutive periods of five (5) years or a maximum of ten (10) consecutive years) or a successor is elected in his or her place.

6.2.6 Where a member of the REC dies, resigns, or is removed from membership of the REC the Board will appoint a replacement member as soon as possible.

6.2.7 Where a member of the REC wishes to resign from the committee, he or she should inform the Chair in writing of their intention, allowing at least one (1) month from the date of receipt of their letter in which to find a replacement. The Chair shall inform the Board and the Company Secretary of the members resignation as soon as possible following receipt of their letter of resignation.

6.2.8 The REC may act notwithstanding one or more vacancy among its members.

6.2.9 Members of the REC including alternate, deputy and co-opted members are required to comply with and are subject to the policies listed in Appendices 16-19 as amended and updated from time to time.

6.2.10 Any concern or complaint in respect of the conduct of any member of the REC shall be addressed in accordance with the Procedure Adopted by the Board of Saint Patrick's Hospital Dublin to Address Conduct Contrary to the Code of Conduct of the Board of Saint Patrick's Hospital Dublin (the Procedure).

7 CHAIR AND VICE-CHAIR

7.1.1 There shall be a Chair of the REC appointed by the Board from amongst the members of the REC.

7.1.2 There shall be a Vice-Chair of the REC appointed by the Board from amongst the members of the REC.

7.1.3 The members appointed as Chair and Vice-Chair shall be appointed for such period, not exceeding the remainder of his or her term as a member, as the Board may specify on appointing him or her. Any person so appointed may at any time resign from the office of Chair or Vice-Chair by giving notice in writing to the Board.

7.1.4 Where the Chair is not available to perform his or her duties they shall be performed by the Vice-Chair. In the event that neither the Chair nor the Vice-Chair is available to conduct the business of a meeting of the REC then the members of the REC then present at the meeting may elect one of their members to chair the meeting of the REC in the absence of the Chair and the Vice-Chair.

8 DEPUTIES, ALTERNATE AND CO-OPTED MEMBERS

8.1.1 The Board may appoint a person to act as the deputy or alternate of an expert member or a lay member of the REC provided that the person would be eligible for appointment as an expert member or, as the case may be, a lay member.

8.1.2 A deputy or alternate shall hold and vacate office as a deputy member or alternate member in accordance with the terms of the instrument appointing him or her as a deputy or alternate.

8.1.3 A deputy or alternate may attend meetings and vote as a member of the REC only if the member for whom he or she acts as a deputy or alternate is absent.

8.1.4 A deputy or alternate member and the member for whom he or she is deputy or alternate shall count as one member for the purpose of paragraph 6.2.2.

8.1.5 In the event that a deputy or alternate member is subsequently appointed a full member of the REC his or her service as an alternate or deputy shall not be construed in calculating his or her term of office as a full member for the purpose of paragraph 6.2.4 and paragraph 6.2.5.

8.1.6 At any meeting of the REC, the committee may co-opt up to two additional members for the purposes of that meeting.

8.1.7 At any meeting of a sub-committee of the REC, the sub-committee may co-opt an additional member for the purposes of that meeting.

8.1.8 A person shall be eligible to be co-opted as a member only if he or she is or has been a member of an ethics committee.

8.1.9 A co-opted member shall hold office only in relation to the meeting for which he or she is co-opted.

8.1.10 A member co-opted under this paragraph shall not count as a member of the REC for any of the purpose of paragraph 6.2.2.

8.1.11 Where a member is co-opted under paragraphs 8.1.6, the Chair shall notify the Board and the Company Secretary of the details of the appointment at the next meeting of the Board for the purpose of the ratification by the Board of the person as a member of the REC for the occasion on which he or she was co-opted to the committee.

9 COMMITTEES

9.1 The REC may appoint sub-committees consisting of members of the REC and make arrangements for the exercise, on behalf of the REC, of any of its functions by such a sub-committee in accordance with terms of this document and any supplementary procedures adopted for the conduct of business by such sub-committees as may be approved by the Board.

10 QUORUM FOR MEETINGS

10.1 The Quorum for any meeting of the REC shall be five (5) members including at least one (1) lay member and one (1) expert member.

10.2 The Quorum for any meeting of a sub-committee of the REC shall be three (3) members including one (1) lay member and one (1) expert member.

11 CONDUCT OF BUSINESS AND DECISION MAKING

11.1 The Chair of the REC is responsible for the conduct of the business and for ensuring that the REC and subcommittees reach clearly agreed decisions on all matters. Where the Chair is unavailable the meeting should be chaired by the Vice-Chair. In the absence of the Chair and the Vice-Chair the meeting shall be chaired by a member of the REC or subcommittee (as applicable) elected from amongst the members of the REC or subcommittee (as applicable) present at the meeting to act as Chair of that meeting.

11.2 A quorum must be present at each meeting of the REC or subcommittee (as applicable). Subject to paragraph 22.5, in the absence of a quorum the meeting will be adjourned.

11.3 All members present, both expert and lay, should be allowed a reasonable opportunity to express relevant views on matters on the agenda.

11.4 The meeting should reach unanimous decisions by consensus wherever possible and the decision and reasons for the decision should be recorded in the Minutes. Where a consensus is not achievable, a formal vote should be taken by a counting of hands. The decision of the REC or sub-committee (as applicable) should be determined by a simple majority of those members present and entitled to vote. Where there is equality of votes the Chair of the REC, or the Vice-Chair or in the absence of both the Chair and Vice-Chair, the person selected to chair the meeting of the REC or sub-committee (as applicable) shall be entitled to a second or casting vote.

11.5 Where any member wishes to record his or her formal dissent from a decision of the REC or sub-committee (as applicable) this should be recorded in the Minutes and the reasons for the dissent.

12 EXPERT ADVICE

12.1 The REC shall be entitled, at its discretion, to engage suitably qualified experts to provide written advice or to attend at a meeting of the REC in relation to any matter.

13 EXPENSES

13.1 The REC shall not incur expenses in excess of the amounts approved for the Committee by the Board. SPMHS shall provide secretarial and administrative support including an Administrator to the REC to enable it to effectively discharge its role.

14 ATTENDANCE

14.1 A member is expected to attend **at least three out of five** scheduled REC meetings each year. The appointment of an Alternate or a Deputy does not relieve a member of the requirement to attend at least three out of five scheduled REC meetings each year. Should a member fail to do so, the Chair should address this with the member concerned in the first instance. In the event that attendance by a member continues to be an issue of concern the Chair may address the issue of concern in accordance with the Procedure.

15 DECLARATIONS OF INTEREST

15.1 Members of the REC including alternate, deputy and co-opted members are required to comply with the Conflict of Interest and Conflict of Loyalty Policy for Saint Patrick's Hospital Dublin which applies to committee members who are appointed by the Board.

15.2 When a committee member, alternate, deputy or co-opted member is aware or becomes aware that he or she or a connected party has an interest in relation to an application for ethical review or any other matter for consideration at a meeting of the REC or of a sub-committee that may give rise to a conflict of interest or potential or perceived conflict of interest of the committee member, alternate, deputy or co-opted member or of a connected party he or she 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 Chair (or Vice-Chair as appropriate) prior to the meeting.

15.3 Where a member or an alternate, deputy or co- opted member has any declared interest, the REC or sub-committee of the REC (excluding any conflicted member) will ask the member to leave the meeting room and take no part in the discussion or the vote on the application.

15.4 The duty to disclose to the REC or sub-committee of the REC any conflict of interest is a continuing duty and continues to apply where disclosure by the committee member, alternate, deputy of co-opted member did not take place prior to the decision by the REC or sub-committee on the item of business or where knowledge of the conflict or potential or perceived conflict of interest of the committee member, alternate, deputy or co- opted member or of a connected party is gained by the committee member, alternate, deputy or co-opted member after the item of business has been decided or the business has been transacted by the REC or sub-committee.

15.5 Committee members or alternate, deputy or co-opted committee members who have any concerns that a conflict or potential or perceived conflict of interest may arise or has arisen should consult with the Chair and should comply with the reporting requirements.

15.6 Failure to declare a known interest in an application for ethical review or to otherwise comply with the Conflict of Interest and Conflict of Loyalty Policy is a serious matter and a breach or concern that there has been a breach will be addressed in accordance with the Conflict of Interest and Conflict of loyalty Policy and the Procedure and where a breach is established may result in sanctions including the removal from membership of the REC or termination of appointment as alternate or deputy of a member of the REC.

16 TRAINING

16.1 All members of the REC should receive a copy of the Governance and Standard Operating Procedure of the REC, 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. All members will complete the Concise Research Integrity training programme[18-23] and be familiar with Public and Patient Involvement (PPI)[24] in research, GDPR[25] and Health Research Regulations[26]. Ongoing training may include brief 10-15 minute training sessions within each REC meeting on a relevant aspect of the committee's work. All REC members will also be invited and expected to attend, where possible, seminars that are organised by the REC as well as any other relevant conferences recommended by the committee.

17 CONFIDENTIALITY

17.1 The REC conducts its business and meetings in private. Members of the REC do not sit on the committee in a representative capacity. Members of the REC are required to keep confidential all applications, meetings, deliberations, information on research participants/volunteers and related matters, and the business of the REC.

18 LIST OF MEMBERS

18.1 Members will have their name, profession and affiliation published on the committee's webpage.

19 INDEMNIFICATION OF REC MEMBERS

19.1 The REC members are indemnified under and in accordance with the scope of the SPMHS insurance policy. For further information in respect of the policy and scope of cover REC committee members may contact Mr Brendan Power, Company Secretary.

20 CHAIR

20.1 The duties of the Chair include:

- Liaise with the REC administrator
- Ensure that the Governance and Standard Operating Procedures are followed
- Chair meetings of the REC and committees (save where unavailable when the arrangements set out in paragraph 11.1 apply)
- Set the agenda for each meeting
- Ensure the meeting runs to schedule
- Lead questioning on research study under review
- Encourage broad participation from members
- Resolve any conflict that may arise during committee meetings
- End each meeting with a summary of decisions and actions
- Sign the approved Minutes of each meeting of the REC and sub-committees

- Report to the Board throughout the year
- Ensure an annual report is issued to the Board
- Working with the REC administrator and through the sub-committees seek to achieve progression of new applications (where appropriate) and of existing applications and correspondence between meetings of the REC.

21 REC ADMINISTRATOR

21.1 The REC administrator's duties include:

Meetings

- Organise regular meetings of the REC and any other subcommittee meetings
- Promote awareness of these meetings within SPMHS
- Request confirmation of attendance from each REC member or sub-committee member in advance of each meeting of the REC or subcommittees to ensure quorum is met and assign 3 REC members to review each new application
- Prepare agenda and all documentation on Boardpacks at least one week in advance of each meeting and publish meeting for REC members to access
- Take minutes at all meetings and then ensure all action points are followed through

Applications

- Check all new applications for completeness
- Formally acknowledge the application and register it on the REC database
- Correspond with the committee's decision to the Principal Investigator.
- If conditions are specified by the Committee, ensure that these are met and reviewed by the assigned reviewers and seen by the Chair before full approval is granted
- Working with the Chair and through the sub-committees seek to achieve progression of new applications (where appropriate) and of existing applications and correspondence between meetings of the REC.
- Follow-up annually until research is completed, reminding the Principal Investigator as necessary

Correspondence and documentation

- Maintain all REC files securely including database of all research, all REC forms and policy documents, documentation for all research applications as well as all correspondence received/sent, REC committee members contact details and CV
- Inform Chair of all correspondence received relevant to the work of the REC, agree and action next steps, as appropriate
- Formulate and send all correspondence to the Principal Investigator before, during and after the review process

- Keep the REC webpage up-to-date in collaboration with the Communications department SPMHS
- Prepare annual report for Board and any other reports/letters as requested by the Chair

Other matters

- Organise induction and ongoing training for REC members as requested by the Chair
- Provide assistance to all REC members as required in using Boardpacks and MS Teams or other software or platform approved by SPMHS for such communications
- Work on projects as requested by the Chair

22 OPERATIONAL MATTERS

22.1 Documentation

All documentation for meetings of the REC and subcommittees is distributed electronically through Boardpacks. Members of the REC will be notified by automatic emails from Boardpacks that the documentation for the meeting is ready to view. The following documentation will be made available 10 days prior to the REC meeting:

- Agenda
- Minutes of previous meeting
- Documentation for each research proposal
- Protocol Review assignments
- Feedback from previously approved protocols
    - Amendments
    - Extensions
    - Annual Reports
    - End of study reports
    - Publications, papers, posters, theses

22.2 Frequency of Meetings

The REC meets 5 times during the academic year, approximately every 2 months from September through to June. A meeting schedule is published annually.

22.3 Agenda

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

22.4 Minutes

The REC Administrator shall record minutes of the REC meeting which should be checked by the REC Chair and the Vice-Chair. The minutes should include:

- Members, deputy, alternate and co-opted 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 will be approved at the following REC meeting and will be made available on the REC webpage.

22.5 **Quorum Requirements**

A Quorum in accordance with paragraph 10 must be present.

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

- A deputy or alternate 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 REC may not commence, continue or conclude any discussion with the purpose of determining the committee's opinion on an application for ethical review. However, the REC may proceed with any other business on the agenda, provided that the Chair (or Vice-Chair) is present.

22.6 **Other Attendees**

Where appropriate, the sponsor may be invited to present the proposal or to elaborate on specific issues. The decision to do so will be taken by the Chair or is his/her absence the Vice-Chair.

22.7 **REC Webpage**

Details of the REC are maintained and published on a webpage within the SPMHS website, namely: www.stpatricks.ie/research/research-ethics-committee.

The webpage includes the following:

- Contact details for the REC Administrator
- Membership of the committee
- Dates of meetings

- Minutes of meetings
- All documentation and guidance for making a submission
- Links to Governance & Standard Operating Procedures document and relevant data protection regulations
- Links to publications that have been generated by research approved by the REC
- Annual Reports made to the Board (see Section 26)

23 PROCEDURE FOR SUBMITTING AN APPLICATION

23.1 Applicant

The applicant should be the Principal Investigator and must be a qualified researcher responsible for the ethical and scientific conduct of the research in accordance with the role and responsibilities of investigators as set out at paragraph [4] above. In the case of a multi-centre study where the Principal Investigator is not based at SPMHS a Co- Lead Investigator who is based at SPMHS should be appointed and act as joint applicant with the Principal Investigator. They must also be a permanent staff member, an honorary staff member or on a fixed term research contract of any duration, either alone or in collaboration with colleagues within Trinity College Dublin, the University of Dublin, Ireland, or in other research institutes. If not a consultant or senior staff member within SPMHS, the applicant will be required to nominate someone in those roles who can act as an on-site lead co- investigator for the research.

23.2 Obtaining Application Documentation

An applicant wishing to submit a research proposal should log onto the committee's webpage (see [22.7]) and download the relevant documentation.

23.3 Type of Application

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 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.

Epidemiological research – Epidemiology is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out epidemiological investigation; surveillance and descriptive studies can be used to study determinants (WHO).

Health Services research – Health services research is research aimed at improving the effectiveness and efficiency of the health care system through changes to practice and policy. It is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to healthcare, the quality and cost of healthcare, and ultimately health and well-being.

Population Health research – Research with the goal of improving the health of the population or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status or through the identification of effective interventions for improving health status and reducing health inequalities.

Medical Education research – Medical education research includes any investigation related to the education of medical professionals, including research related to undergraduate, postgraduate, and continuing medical education. Medical education research can focus on any number of topics, including curriculum development, teaching methods, student evaluation, teacher evaluation, course evaluation, facility development, admission and preparation of candidates for medical training, factors influencing career choice, research methodology and use of technology in education.

The REC advice might be sought on complex ethical issues of service evaluation or clinical audit (see also Appendix 15) as stipulated by SPMHS policy (CLIN0040 SPMHS Approval and Conduct of Research, Clinical Audit and Service Review).

23.4 **Submissions Deadline**

The completed application must be received in full by the REC administrator **four weeks** before the REC meeting. Deadlines are published along with meeting dates each year and are available on the committee webpage.

23.5 **Application Requirements (see Appendices 5-12)**

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
- Declaration and Signatory page
- Data Protection Impact Assessment (DPIA)
- CV of Principal Investigator (dated)

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

- Participant Information Leaflet
- 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 Action (see 23.7)
- 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.

23.6 **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 Administrator.

23.7 **Chair /Sub-committee / Fast-Track 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 fast-track approval. Chair action involves a review by the REC Administrator first, and if approved (see 23.6), it will then be reviewed by a sub-committee of the REC. This sub-committee meets every 4 weeks, if necessary, and reviews amendment requests and other urgent correspondence. If the sub-committee approves the application, the Principal Investigator will be notified by letter that their study has sub-committee approval and the research can commence subject to management approval (paragraph 3.2). If additional information is required prior to decision or if the sub-committee so decides the study may be referred to the next meeting of the REC for consideration. The REC at the next scheduled meeting will be notified of the outcome of all applications considered by the subcommittee of the REC and of any matters arising.

23.8 **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
- 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.

23.9 **Payment to Participants**

No research subjects in any study should receive a payment for their participation in the study. However, a token may be acceptable in the form of a meal voucher or reimbursement for travel expenses if it is deemed to be appropriate and approved by the REC. Other research participants may be entitled to a payment if their role is categorised as Public and Patient Involvement (PPI) [24].

24 **DECISION MAKING**

24.1 **Before the Meeting**

In making decisions on submissions for the ethical review of research, 3 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 (see Appendix 3), they will have formed a decision in their own mind before attending the meeting. A template form (see Appendix 4) will be completed by each reviewer and returned to the REC administrator at least 24 hours before the scheduled meeting and these opinions will be uploaded to Boardpacks for review at the meeting.

24.2 **During the Meeting**

The completed forms by each reviewer will form the basis for discussion of new research applications. While 3 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:

- Members who have conflicts of interest should declare these to the Chair (or Vice-Chair as appropriate) prior to the review of the application and these should be recorded in the minutes.

- 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 Chair may call for a vote with a simple majority of those present and voting required for decision.

- Where there is equality of votes the Chair of the REC, or the Vice-Chair or in the absence of both the Chair and Vice-Chair, the person selected to chair the meeting of the REC shall be entitled to a second or casting vote.

- Dissenting members should have an opportunity to append an opinion to the REC decision.

- 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.

24.3 **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 Chair and assigned reviewers after which approval may be granted subject to the affirmation of the Committee at its next meeting.

Approval Declined Proposals may be rejected by the Committee. This may occur if 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.

24.4 **Communicating the Decision**

The REC 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 the original application was acknowledged.

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 Chair and list of members present when the decision was taken
- A clear statement of the decision taken
- The approval of any Participant Information, Consent Form, Poster, Advertisement or Communication used in the Recruitment of Participants or Questionnaire to be used in the Study.
- Any additional advice, opinions, requirements or conditions adjoined to the decision by the REC, 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 REC Administrator

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.

- Adhering to data protection regulations (GDPR and Health Research Regulations)
- 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
- 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.
- Requesting copies of all publications, posters and presentations generated by the research and/or link to their thesis which has already been submitted to their institutional repository

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

- The need to make an application to the Health Research Consent Declaration Committee (HRCDC) where it is not deemed possible to obtain explicit consent for the study to go ahead or where the public interest of doing the research significantly outweighs the need for explicit consent. In these cases, the applicant should be directed to the HRCDC website (www.hrcdc.ie)
- Request written confirmation of the destruction of electronic recordings (if used). If audio or video recordings will be made as part of an approved research by SPMHS staff including clinicians and honorary staff, they will adhere to the SPMHS policy (DP0003 Processing of Audio and Visual Data)

25 POST APPROVAL MONITORING NOTIFICATIONS AND REPORTING

25.1 The REC 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 REC 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. In addition the certain events or changes require notification, reporting and approval as set out in the succeeding paragraphs.

25.2 Commencement

25.2.1 It is a standard condition of approval that the Principal Investigator informs the REC in writing that the study has commenced stating the date of commencement**.**

25.3 Amendments to Approved Studies

25.3.1 It is a standard condition of approval that the Principal Investigator shall not implement any deviation from or changes to the study as approved by the REC without prior review and documented approval from the REC of the amendment.

25.3.2 In an emergency where a change is necessary to eliminate an immediate hazard to study participants it is permissible to implement the change or deviation and as soon as possible thereafter notify the REC in writing of the implemented deviation or change, the reason for it and the proposed study amendment should be submitted to the REC for review and approval.

25.3.3 An application for an amendment must be submitted to the REC Administrator, including details of the change(s) and the rationale for such. 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 subcommittee approval (see 23.7) and be notified as an approved amendment at the next REC meeting.

25.4 **Transferring Research Study to another Investigator**

25.4.1 When a Principal Investigator or Co-lead Investigator wishes to transfer his responsibility as principal investigator or co-lead investigator on an approved research study to another investigator, the REC must be notified [6] weeks in advance of the proposed date of the change and its approval obtained in advance of the change. The notification must be signed by the proposed new principal investigator, confirming that he/she is responsible for the research from the proposed date of the change, and their CV must also be submitted for review and approval. Appropriate changes to other documents (e.g. consent forms, information sheets) must also be submitted for approval.

25.5 **Adverse Events**

25.5.1 It is a standard condition of approval that the Principal Investigator will report to the REC immediately any Serious Adverse Event or Serious Adverse Reaction or Unexpected Adverse Reactions of a study subject while participating in a study. The initial immediate report may be made orally to the Chair and if made orally shall be followed up by a written report within 3 working days. The written report should provide a detailed description of the event, assess causation and identify any safety measures which have been taken or which are proposed to mitigate the risks and avoid recurrence. The report should assess the implications of the event for the safety of study participants and whether it alters the risk assessment of the study. The REC shall review the report and may invite the Principle Investigator and / or Lead Co investigator to attend at a meeting of the REC to consider the report and review the approval of the study.

25.6 **Breach of Data Security**

25.6.1 It is a standard condition of approval that the Principal Investigator will report to the REC immediately any breach of data security involving data from which a patient or an individual study participant may be identified or at risk of identification or of any circumstances which place confidential data including sensitive personal data, special category data relating to study participants at risk of unauthorised access, loss, disclosure or destruction. The initial immediate report may be made orally to the Chair and if made orally shall be followed up by a written report within 3 working days. The REC shall review the report and may invite the Principal Investigator and/or Lead Co investigator to attend at a meeting of the REC to consider the report and the implications of the report for the privacy rights of those affected by the data security breach.

25.7 **Monitoring and Audit Procedures**

25.7.1 Research which receives REC approval is subject to continuing ethical review. The frequency of review will be decided by the REC at the time of approval. The decision letter from the REC will notify the Principal Investigator of the committee's requirements in relation to periodic review, notifications and reporting. As a minimum the REC requires the submission of an Annual Progress Report however depending on the risk assessment of the study more regular reporting may be required.

25.8 **Annual Progress Report (Appendix 13)**

25.8.1 It is a standard condition of approval that the Principal Investigator provides an annual progress report to the REC which should include but not be limited to:

(a) a summary of the progress of the study to date or the outcomes in the case of a completed project;

(b) a description of measurements taken to maintain and secure personal information/records pertaining to the research;

(c) a statement of compliance with the approved proposal and/or minor amendments to the proposal and a justification for these;

(d) confirmation that the assessment of risk to study subjects remains unchanged; and

(e) identification of any safety issues which have arisen and how they have been addressed.

25.8.2 The REC Administrator will send a reminder to the Principal Investigator about one (1) month before the report is due. A standard template annual progress report (available for download from the REC webpage) must be completed by the Principal Investigator and submitted to the Research Ethics Committee every 12 months after approval has been granted. Failure to submit the annual progress report within the appropriate timeframe may result in ethical approval being withdrawn.

25.8.3 The REC will consider each report and notify the Principal Investigator of any requirements or concerns which the committee may have or require further information. The REC may invite the Principal Investigator and / or Lead Co investigator to attend at a meeting of the REC to consider the report and review the approval of the study. Where the committee has no requirements or concerns, it will write to the Principal Investigator acknowledging the report.

25.9 **Early Termination or Suspension**

25.9.1 It is a standard condition of approval that the Principal Investigator will report to the REC immediately in the event that the study is prematurely terminated or suspended and provide a detailed written explanation of the reasons for the premature termination or suspension and the implications of the early termination or suspension for study subjects. This should be accompanied by a summary of results obtained in the study up to the point of being suspended/terminated. In all cases, the REC will require an end of study report to be completed, summarising the main findings

25.10 **Additional Progress Reports**

25.10.1 If the REC has concerns about a research study, the Principal investigator may be asked as a condition of approval to submit progress reports within a stated period for review by the REC. The REC will consider each report and notify the Principal Investigator of any requirements or concerns which the committee may have or require further information. The REC may invite the Principal Investigator and/or Lead Co investigator to attend at a meeting of the REC to consider a report and review the approval of the study. Where the committee has no requirements or concerns arising out of a report it will write to the Principal Investigator acknowledging the report.

25.11 **End of Study Report (Appendix 14)**

25.11.1 It is a standard condition of approval that the Principal Investigator informs the REC in writing that the study has completed, stating the date of completion and furnishes the committee with a final report of the study. The final report provides the committee with a synopsis of the study and its findings and conclusions. It should include a statement of compliance with the REC approval of the study and a confirmation of the measures taken

to ensure on going compliance with data protection law and with the informed consent of study participants in relation to the retention of personal data.

25.11.2 A standard template form (available from the REC webpage) is completed and submitted with the following:

(a) Copy of publication(s) / list of publications with links to DOI journal

(b) Copy of full thesis, if applicable, or a link to an institutional repository

(c) Copy of poster presentations, if applicable

(d) When a study includes audio or video recordings, written confirmation by the Principal Investigator that the recordings have been destroyed needs to be received by the REC.

(e) Confirmation of compliance with data protection law/ GDPR.

26 DOCUMENTATION STORAGE AND RETENTION

26.1 The REC will keep proper records of the business conducted by it and its decisions.

26.2 The documentation and communications of the REC will be retained by it in accordance with applicable national and international guidelines as amended from time to time.

26.3 Documents to File

26.3.1 All documentation and communications of the REC are to be filed electronically on the SPMHS server by the REC Administrator and can be accessed at all times by the REC Administrator. Documents to be filed include, but are not limited to:

(a) Historical documents and Governance and SOP of the Research Ethics Committee

(b) The curriculum vitae of all REC Members, deputy, alternate and co-opted members

(c) The agenda and minutes of all REC meetings and sub-committee meetings

(d) All submitted documentation

(e) All correspondence

(f) Annual reports

(g) All approvals, post approval monitoring, notifications and reports including final study reports

(h) Publication database

(i) Publications, presentations, posters and theses generated by research projects

26.4 Database

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

27 RESEARCH ETHICS COMMITTEE ANNUAL REPORT

27.1 No later than June of each calendar year, the Chair of the REC will prepare an annual report on the activities of the REC during the preceding calendar year. It should contain information relevant to its procedures including, but not limited to:

- List of publications, presentations and posters generated from approved research projects
- A list of proposals considered and the decision reached on each
- List of projects completed or terminated during the year
- Membership and membership changes
- Number of meetings held
- Attendance of members
- Changes to the governance and standard operating procedures
- List of training undertaken by members

27.2 A copy of the report will be sent by the Chair to the Board of Governors. Annual reports are public documents and will be published on the website once reviewed by the Board of Governors.

Appendix – Health Research Regulations

1. Control of Clinical Trials Act 1987
2. Control of Clinical Trails and Drugs Act 1990
3. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190/2004))
4. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2004 (S.I. No. 878/2004)
5. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No.2) Regulations 2006 (S.I. No. 374/2006)
6. Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539/2007)
7. European Communities (Control of Placing on the Market) Regulations 2007 (S.I. No. 540/2007)
8. The Health Research Board (Establishment) (Amendment) (No.3) Order 2007 (S.I. No. 305/2007)
9. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2009 (S.I. No. 1/2009)
10. Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I No. 314/2018) as amended by
    a. Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2019 (S.I. No. 188/2019)
    b. Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021)