

TITLE: Research Ethics Committee at SGH, Terms of reference	REFERENCE NO: TBC
AUTHOR: Mette Jensen Kavanagh JOB TITLE: Research Ethics Committee Administrator	REVISION NO: 5
APPROVED BY: Research Ethics Committee at SGH	EFFECTIVE FROM: Sept 2010
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TITLE: Research Ethics Committee at SGH, Terms of reference

AREA: All Areas

REFERENCE NO: TBC

REVISION NO: 5

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JOB TITLE: Research Ethics Committee Administrator

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DATE: 30 September 2010

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1.0 Background/Rationale

The Research Ethics Committee (REC) at SGH is established to give independent advice on the extent to which proposals for research studies undertaken at Sligo General Hospital (SGH) and in the hospital catchment area comply with recognised ethical standards

2.0 Role/Purpose

2.1 The Research Ethics Committee (REC) at Sligo General Hospital (SGH) is charged with the responsibility of independent review and surveillance of Clinical Trials referred to it under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004. The Committee shall act in relation to clinical trials of all descriptions and classes other than those to which Regulation 13 (4) refers (i.e. gene therapy, somatic cell therapy etc.). The REC at SGH was first recognised under regulation 7 by DoHC on September 20th 2005.

The REC will also be available to carry out review of research studies in the SGH catchment area (Counties Sligo, Leitrim, South Donegal and West Cavan) that are not classified as clinical trials and which involve human subjects.

2.2 The REC at SGH is established in accordance with the

- *The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. 190 of 2004)*

The ethical guidelines accepted by the REC are consistent with the *Declaration of Helsinki* of the World Health Organisation and the ICH (International Conference on Harmonisation) guidelines for *Good Clinical Practice* (GCP) 1997.

3.0 Objectives

The REC's objectives include:

- The maintenance of ethical standards of practice in research referred to it for consideration
- The protection of the welfare of research subjects
- The preservation of the rights of research subjects
- The facilitation of ethically informed research.
- The facilitation of research projects onto the Hospitals QPulse Research Register

See appendix A for a detailed list of the REC's responsibilities.

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4.0 Membership

4.1 Composition

The REC shall comprise max 21 members, each of who shall be appointed by the Hospital Manager. The REC shall include:

- Max two thirds expert members (as defined in Schedule 2, Section 2 of S.I. 190 of 2004)
- Min one third lay members (as defined in Schedule 2, Section 2 of S.I. 190 of 2004)

The health professionals shall include those with experience in research and investigation as well as those involved in active clinical care. At least half of the lay members shall be persons who are not and never have been health care professionals. Membership of the REC shall include representatives of both sexes and a range of age groups.

4.2 Deputies and co-opted members

The REC may appoint a person to act as the deputy of an expert members or a lay member provided that the person would be eligible for appointment as an expert member or as the case may be, a lay member. The REC may co-opt up to 2 additional members for the purposes of that meeting.

4.3 Term of office

Term of office by REC members is for an initial period of 3 years. Term of office is renewable, however membership should not normally exceed two consecutive terms.

4.4 Attendance

REC members are expected to attend at least two-thirds of all scheduled REC meetings in each year. Should a member fail to do so, the chairperson should address this with the member concerned.

4.5 Resignation

A member may resign from the REC at any time upon giving notice in writing to the Chairperson.

4.6 Vacancy

The REC shall notify the Hospital Manager of any vacancy, which may arise in its membership, to allow a successor be appointed promptly.

4.7 List of Members

A list of members of the REC shall be made available from year to year to the public upon request. The list of members will indicate the name of each member, the capacity in which they serve on the REC and occupation.

4.8 Chairperson, vice chairperson and alternate vice chairperson

The Hospital Manager shall appoint one of the members of the REC to be chairperson of the Committee, another to be alternate vice chairperson. Where the Chairperson is unable to perform his or her duties as chairperson owing to illness, absence or any other cause, the vice chairperson shall perform the duties of the Chair person. Where the Vice-

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Chairperson is unable to perform his or her duties as chairperson owing to illness, absence or any other cause, the alternate Vice-Chairperson shall perform the duties of the Vice Chairperson. The REC Chairperson will be a member of the Hospital Research Committee.

4.9 Quorum

For the purposes of holding a meeting of the REC, a quorum will be constituted by the presence of the Chairperson and 6 other REC members (including any members co-opted) are present, including at least

- a. one lay member who is not and never has been a health professional or a chairperson, member, director, officer or employee of a health service body; and
- b. one expert member

4.10 Indemnification of REC members

The REC members are indemnified by the Clinical Indemnity Scheme (CIS).

4.11 Sub-committees

The REC may appoint sub-committees consisting of members of the REC and make arrangements for the exercise to any of its functions by such a sub-committee.

4.12 Training

A member must agree to take part in education and ongoing training appropriate to the role as REC member.

5.0 Responsibilities

The REC must review research studies with respect to the following:

- Scientific design and conduct of the study
- Recruitment of research participants/volunteers
- Care and protection of research participants/volunteers
- Protection of confidentiality of participants/volunteers
- Informed consent process
- Community considerations

Appendix A contains a detailed list of REC responsibilities.

6.0 Relationship with other internal Committees +/- external Committees or Organisations

The REC has a functional reporting relationship to the Hospital Research Committee at Sligo General Hospital.

The DoHC is the supervisory body charged with the responsibility of recognising the REC for the purposes of reviewing Clinical Trials as defined by S.I. 190/2004.

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7.0 Authority

7.1 The REC has the authority to undertake independent review and surveillance of Clinical Trials of Medicinal Products for Human Use as defined in S.I. 190/2004. The Committee shall act in relation to clinical trials of all descriptions and classes other than those to which Regulation 13 (4) refers (i.e. gene therapy, somatic cell therapy etc).

7.2 The REC has the authority to undertake independent review and surveillance of Non-Clinical Trials undertaken in the SGH catchment area.

8.0 Accountability

The REC shall be accountable to the General Manager, Sligo General Hospital. For Clinical Trials, the REC is under continuous surveillance by the Ethics Committees Supervisory Body (The Supervisory Body). The Supervisory Body may carry out site visits and audits of the REC's review process, record keeping and general conduct.

9.0 Reporting Lines

The REC reports to the General Manager at Sligo General Hospital. The REC has a functional reporting relationship to the Hospital Research Committee at Sligo General Hospital.

10.0 Mode of Operation

10.1 Administrative support to the REC

The REC Administrator will provide support to the REC. S/he will be responsible for:

- providing support to REC applicants in application process
- circulating the agenda and supporting papers for REC meetings to REC members
- organising the logistics of meetings
- attending the REC meetings to take minutes
- writing up decisions made by the REC and circulating the decisions to applicants and other stakeholders impacted by the decision
- follow up on correspondence with applicants
- liaising with external organisations and committees on national developments in research ethics
- facilitate training opportunities for REC members and the administrator
- keep abreast of legislation and guidelines relating to research ethics
- writing up annual reports and other information requested by the Supervisory Body etc.

10.2 Submissions deadline

Completed applications must be received in full by the secretariat three weeks before the relevant deadline to be considered at the subsequent REC meeting. Upon receipt of the protocol and application form, the Administrator will review the submission for

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completeness and notify the investigator of any apparent deficiencies. Review of a research study could be delayed if further information is required.

10.3 Documentation

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

- Agenda
- Minutes of previous meeting
- Relevant documentation for each research proposal:
 - Application form
 - Protocol
 - Research Subjects Information Sheet
 - Consent Form

All other documentation relevant to the research study shall be available for reference at the meeting.

10.4 Frequency of meetings

The REC meets 6 times per year. A meeting schedule shall be published annually

10.5 Agenda

The REC Administrator in conjunction with the REC Chairman will set the agenda for the REC meetings.

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

10.6 Minutes

The Administrator shall record minutes of REC meeting. A record of each decision of the REC shall be read out and approved by the meeting.

10.7 Annual Report

Within the period of six months from 31 December the REC shall prepare a report on the REC's activities during that year. The report shall include a list of the applications made to the REC and the decisions made by the committee in relation to those applications. A copy of the report will be sent to the Research Ethics Supervisory Body and the General Manager, Sligo General Hospital.

11.0 Research study Submission

11.1 Contents

All submissions must include:

- Standard application form (for non-clinical trials) or DoHC standard application form (for clinical trials). (1 signed original in hard copy & 1 e-copy)
- Study Protocol (1 hard copy & 1 e-copy)
- Principal Investigator CV (1 hard copy & 1 e-copy)

Where applicable the PI must also submit:

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- Application fee of €1,000 (Clinical Trials only)
- Application fee of €600 for industry sponsored studies that fall outside the remit of SI190 (reduced fee of €150 for studies that have already been approved by another recognised REC)
- Consent form (1 hard copy & 1 e-copy)
- Subject information sheet (1 hard copy & 1 e-copy)
- Advertisement for subjects (1 hard copy & 1 e-copy)
- GP/Consultant information letter (1 hard copy & 1 e-copy)
- Interview schedule (1 hard copy & 1 e-copy)
- Letter of invitation to research subjects (1 hard copy & 1 e-copy)
- Questionnaire (1 hard copy & 1 e-copy)
- Investigative brochure or data sheet for IND (1 hard copy)
- Letter of Medical Indemnity (1 hard copy)
- Letter of confirmation of insurance (1 hard copy)
- Irish Medical Board approval for IND (1 hard copy)

All questions on the application form must be addressed. Incomplete forms will be deemed invalid and will not be reviewed by the REC.

REC submissions are accepted in parallel with IMB application

11.2 REC Application Form

All Non-Clinical Trial submissions to the REC must include the Standard Application Form. The Standard Application Form must be completed in full. The Principal Investigator must sign the original. The form is available at www.ref-sligo.ie/ethics.htm. Investigators are reminded that protocols must be made as understandable as possible for lay REC members.

11.3 Request for further information

Where following receipt of a valid application it appears to the REC that further information is required in order to give an opinion on a trial, the REC may send a notice in writing to the applicant requesting that the REC is furnished with that information.

11.4 Notification of receipt of valid application

Upon receipt of valid application with all necessary documentation, the REC shall notify the PI in writing the date of receipt.

11.5 Application Fee

Where a Clinical Trial is sponsored by industry, an administrative fee of €1000 will be charged for an initial application and €200 for an amendment. A fee of €150 will be charged in respect of each trial site to which the initial application relates. For non-sponsored Clinical Trials the fee is €150 for an initial application and €50 for an amendment. The fee will be donated to the Research & Education Foundation.

11.6 Investigator Status

Principal Investigator (PI)

A registered medical practitioner or a registered dentist must sponsor all REC protocols, which fall within the scope of the *The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004*. The REC will consider the suitability of the PI in relation to each specific clinical trial.

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The research study will be listed in the REC files under the PI's name. The PI or other will receive all correspondence from the REC including the annual surveys. Only the PI may submit amendments to the original research study.

Co-investigators

The name of other health professionals part-taking in the research project must be listed as co-investigator.

The REC must be notified in writing when co-investigators are added to or removed from the research study. Only the named and approved PI and the co-investigator may carry out the research described in the research study.

12.0 Decision Making

12.1 Confidentiality

The business of the REC is confidential and members shall be encouraged to raise any matter of concern. The subject of discussions held at REC meetings and the decision-making process shall be treated with discretion by REC members and the REC administrator.

12.2 Declaration of Interest

If any REC member has any interest, financial or otherwise, in a research project or other related matter and is present at a meeting at which that project is to be the subject of consideration, the member shall at the meeting and as soon as practicable declare such interest. He/she shall not participate in the discussion and shall not be entitled to vote on any question with respect to that project. In cases where the nature of the interest declared is such that the Chairperson considers that the member should withdraw from the meeting, the member shall withdraw until the REC's consideration of the relevant application has been completed. All declarations of interest made pursuant to this provision shall be minuted.

12.3 External Advisors

The REC shall be free to consult any person considered by the REC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person providing an undertaking of confidentiality and provided that such person shall not be entitled to vote on any matter.

12.4 Principal Investigator Presence

The Principal Investigator of a Clinical Trial will be invited to attend part of the REC meeting, at which his/her study is being reviewed. The PI should not participate in the deliberations of the REC or the vote/opinion of the REC.

Investigators of non-clinical trial studies may be asked to be present at the REC meeting to provide information on any aspects of the trial, but should not participate in the deliberations of the REC or the vote/opinion of the REC.

12.5 Committee Decision

Decisions of the REC shall normally be arrived at by consensus. If agreement cannot be reached in this manner a majority vote of more than two-thirds of those members present

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and entitled to vote is required. Any significant minority view (ie. two or more members) shall be noted in the minutes.

The Committee can arrive at the following opinions:

Approved

The PI may conduct the research as outlined in the research proposal and the PI may begin the research proposed in the protocol upon receipt of the REC approval letter.

Provisionally Approved

Provisional approval of the research study may be granted, requiring modifications of any of the submitted documentation or responses to specific enquiries from the REC. In this case the investigator should submit a cover letter along with the modified submission with the changes highlighted.

Where provisional approval is granted the Chairperson may review the modified submissions and grant approval subject to the affirmation of the REC at the next REC meeting.

No research may be started until all conditions have been met and full approval has been obtained.

Approval declined

If the research proposal does not meet the appropriate criteria, the REC may decline approval. This may occur if the REC feels that the proposed research is not justified and/or poses severe or unnecessary risk to the subjects. The REC shall provide the PI with detailed written reasons for declining approval, with or without an invitation to resubmit a substantially altered proposal for reconsideration..

12.6 Specified Periods

The REC shall within the specified periods (as outlined in Part 2, section 13 (9) of SI 190), following receipt of valid application, give an opinion in relation to the Clinical Trial to which the application applies.

12.7 Expedited Review

The Chairperson of the REC is responsible for determining whether a research study is eligible for expedited review. Non-clinical Trials only can be granted expedited review. The research should present minimal risk to subjects.

Research Studies submitted for expedited review require a complete submission. Expedited review can take place independently of the scheduled meetings. Investigators will be informed in writing either that the submission has been expedited, or notified by phone that the submission must wait and go through full REC review. Expedited review should be undertaken by the chairperson or by one or more experienced reviewers designated by the chairperson. Reviewers may not disapprove research using expedited review. Research may only be disapproved in accordance with non-expedited procedures.

Research may be initiated as soon as investigators receive expedited approval. Research studies that have been approved by expedited review will be subject to affirmation by the REC at the next REC meeting.

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12.8 Notification of Decisions to PI

The REC decision shall be communicated to the principal investigator in writing within two weeks of the meeting at which the decision was taken. The chairperson shall sign and date all such communication. The notification shall record any significant view, which was held by a minority of the REC. The letter shall contain the following information:

- Date of the meeting
- The opinion of the committee
- Identification of the documents, version numbers, dates etc which were reviewed
- Any special conditions attached to the approval
- Request PI to register on Hospital Research Register
- Clearly stated reasons if approval has been declined
- Whether approval was by expedited review
- A list of REC members present at the REC meeting (for Clinical Trials only)

12.9 Circulation of Minutes

The minutes of REC meetings will be forwarded to the Hospital General Manager.

13.0 Review Process of ongoing studies

13.1 Amendments to Approved Studies

In the event of any revision to an approved research study, an amendment must be filed with the REC using the Amendment Notification Form. The investigator must submit the amendment indicating what changes have been made and the rationale for the change. The investigator should also stipulate if there is IMB approval for the amendment, if relevant.

Amendments to approved research studies may not be implemented until the REC approval has been obtained, except when necessary to eliminate apparent immediate hazards or discomforts to the subject. Amendments require REC approval at a scheduled meeting.

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. At the discretion of the Chairperson, amendments of a non-substantive nature may be acknowledged by a letter sent to the principal investigator and recorded in the REC's correspondence.

The REC shall within the period of 35 days from the date of receipt of a valid notice of amendment give an opinion to the sponsor.

13.2 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. Occasionally, investigators may be invited to attend a REC meeting to resolve outstanding issues.

13.3 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

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notification must be co-signed by the new principal investigator, recognising that he/she is now responsible for the research. Appropriate changes to other submission documents e.g. consent forms etc. must also be submitted to the REC, when transferring a research study.

13.4 Annual Review

The REC conducts an annual survey of all active research studies. It is the responsibility of the PI to forward an Annual Review form to the REC administrator. The REC Annual Review form must be completed in full and received by the REC within one month of the date one year after the original approval was granted. Failure to forward a review form may result in termination of the research study. New submission of the research study will be required if the study is to continue.

The annual review form shall include information on progress to date, a statement of compliance with the approved proposal and a description of measures taken to maintain and secure personal information pertaining to the research.

13.5 Adverse Reactions

Investigators must report to the REC 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 information and decide whether there are sufficient grounds for changing its initial decision to grant approval to the proposal.

13.6 Suspension of a research study

In unusual circumstances, if it appears to the REC that an apparent risk to human subjects is increased significantly in an approved research study or new knowledge concerning risk becomes known to the REC, the research study may be suspended. In such a situation upon written notification, the investigator must immediately stop all research involving the particular research study.

13.7 Termination of the Research study

Investigators should terminate a research study when subjects are no longer being followed or studied. When research has been terminated, the principal investigator must complete a termination report and forward it to the REC.

14.0 Research Ethics Committee Records

The REC keeps records of:

- Written procedures incl. forms, sample information sheets etc. for making applications for ethical approval
- List of REC members with occupation, status and contact details
- Agenda and minutes of meetings
- All correspondence
- All submitted documentation
- Annual reports
- Operating procedures
- Income and expenditure of REC

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The REC shall maintain a database of all submissions including submission date, study title, PI, Sponsor, date of REC review, outcome and final outcome.

The REC retains records for a period of 3 years after completion of the research study. Hereafter the REC will submit all documents to the SGH archives.

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

The members of the REC shall treat as and keep confidential all information and documents, which relate to research projects referred to them (which are not already in the public domain) and shall not disclose the same to any third party.

15.0 References

Department of Health & Children, Clinical Trials on Medicinal Products for Human Use Regulations (2004) (S.I. 190 of 2004)

European Commission, Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use, 2006

ICH Topic E6 Guideline for Good Clinical Practice, The European Agency for the Evaluation of Medicinal Products, 1997 (GCP)

The Declaration of Helsinki: The World Medical Association Inc. 2008

The Irish Council for Bioethics, Operational procedures for Research Ethics Committees: Guidance 2004.

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APPENDIX A

REC Review Responsibility (The Irish Council for Bioethics)

The REC should consider the following when reviewing research proposals

Scientific design and conduct of the study

- (a) the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation) and the potential for reaching reliable conclusions with the smallest number of research participants/volunteers
- (b) the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants/volunteers and the concerned communities
- (c) the justification for use of control arms in trials (whether placebo or active comparator), and the randomization programme to be used
- (d) criteria for withdrawing participants/volunteers prematurely
- (e) criteria for suspending or terminating research
- (f) the adequacy of conditions made for the monitoring and auditing the conduct of the research
- (g) the adequacy of the site including the supporting staff, facilities and emergency procedures
- (h) the form in which the results will be reported and published

Recruitment of research participants/volunteers

- (a) the characteristics of the population from which the participants/volunteers will be drawn (including gender, age, ethnicity) and the justification for any decisions made in this regard
- (b) the method by which initial contact and recruitment are to be conducted
- (c) the method by which information is to be conveyed to participants/volunteers or their representatives and by which means consent is to be obtained
- (d) inclusion and exclusion criteria for research participants/volunteers

Care and protection of research participants/volunteers

- (a) the safety of any intervention to be used in the proposed research
- (b) the suitability of the investigator for the proposed research in relation to his/her qualifications and experience
- (c) any plans to withdraw or withhold standard therapies or clinical management protocols for the purpose of the research, and the justification for such action
- (d) the adequacy of health and social supervision and psychological support for the research participants/volunteers
- (e) the adequacy of medical supervision and follow-up concerning the participants/volunteers
- (f) steps to be followed if participants/volunteers decide to withdraw during the course of the research
- (g) the arrangements, if appropriate, for informing the participant's/volunteer's GP, including procedure for seeking consent to do so
- (h) a description of any scheme to make the study product available to the participants/volunteers following the research
- (i) a report of the expenses (if any) payable to participants/volunteers

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- (j) the provisions for compensation/treatment in the case of the injury/disability/death of a participant/volunteer connected to participation in the study
- (k) the provisions made for receiving and responding to queries and complaints of participants/volunteers throughout the course of the study
- (i) the insurance and indemnity agreements covering the liability of the investigator by the sponsor
- (l) a description of any grants, payments or other reward to be made to any researchers or research hosts
- (m) a description of possible conflicts of interest which might affect the independent judgement of the researcher(s)

Protection of confidentiality of participants/volunteers

- (a) a description of the persons who will have access to personal data of the participant/volunteer including medical records and biological samples
- (b) a description of provisions to ensure the confidentiality and security of personal information concerning participants/volunteers
- (c) the extent to which the information will be anonymised
- (d) how samples/data will be obtained, and the purposes for which they will be used
- (e) how long samples/data will be kept
- (f) to which countries (if any) the samples/data will be sent

Both REC members and investigators should be aware of the provisions of the Data Protection Acts 1988 and 2003 and their obligations as set out in those Acts.

Informed consent process

- (a) description of the procedures for obtaining informed consent, including the identification of those responsible for obtaining consent and the time frame in which it will occur
- (b) the adequacy, comprehensiveness and understandability of written and oral information given to the participants/volunteers, their relatives/guardians and, if necessary, their legal guardians
- (c) the content and wording of the informed consent form and, when applicable, the provisions made for participants incapable of giving consent personally
- (d) clear justification for the intention to include participants/volunteers who cannot consent and a full account of the arrangements for obtaining consent or authorisation for the participation of such individuals
- (e) description of the procedures for disclosure, if appropriate, of relevant information to participants/volunteers which may become available during the study

Community considerations

- (a) the impact and relevance of the research on the local community and on the concerned communities from which the participants/volunteers are drawn
- (b) a description of procedures to consult with the concerned communities during the course of designing the research
- (c) the extent to which the research contributes to e.g. the enhancement of local healthcare, research and the ability to respond to public health needs
- (d) a description of the availability and affordability of any successful study product to the concerned communities following the research
- (e) the manner in which the results of the research will be made available to participants/volunteers and the concerned communities