Standard Operating Procedures for Research Ethics Committees
Version 1.0

20 February 2012
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1. Introduction

Fundamentals

1.1. The Health Authority - Abu Dhabi (HAAD) was established as a governmental authority by the Emirate of Abu Dhabi under Law No. 1 of 2007. HAAD’s mandate is to ensure quality health services in the Emirate of Abu Dhabi and HAAD’s mission includes the regulation of health research conducted within the emirate.

1.2. The HAAD Research Ethics Committee (REC) Standard Operating Procedures (SOPs) described in this document provide guidance for compliance with relevant laws and HAAD policies regulating health research in the Emirate of Abu Dhabi. The HAAD REC SOPs meet the obligations of HAAD under UAE Federal Law No. (10) of 2008 regarding Medical Liability and HAAD policies regulating health research in the Emirate of Abu Dhabi for the operation of the Abu Dhabi Research Ethics Committee (ADREC) and institutional Research Ethics Committees (RECs) to oversee the conduct of clinical trials and other human health research. These policies include the following:

a) Abu Dhabi Health Research Council - HAAD/PHR/R01
b) Licensing Requirements for Institutional Human Subjects Research - HAAD/PHR/R02
c) Policy Governing the Ethical Conduct of Human Subjects Research – HAAD/PHR/R03

Scope

1.3. The HAAD REC SOPs apply to research conducted in all licensed Healthcare Facilities.

1.4. The HAAD REC SOPs apply to:

a) Clinical Trials of Investigational Medicinal Products (CTIMPs).
b) Any research involving vulnerable persons (see Statutory definitions Annex B).
c) All other research involving human participants

d) Research that does not involve human participants but has ethical considerations

1.5. The HAAD REC SOPs currently do not apply to:

a) CTIMPs for gene therapy
b) Phase I CTIMPs
c) Any research exclusively involving animal subjects

1.6. Procedures for CTIMPs for gene therapy, Phase I CTIMPs, and clinical investigations involving medical devices or ionising radiation will be added to the SOPs in the future.

Implementation

1.7. This version of HAAD SOPs came into effect on 20 February 2012. All institutional RECs authorised by HAAD must comply with these SOPs.
1.8. HAAD Medical Research Section will monitor compliance with these SOPs through REC coordinators established under the Abu Dhabi Research Ethics Committee (ADREC).

**Standard approval conditions**

1.9. The standard ethics approval conditions for CTIMPs and all other research are laid out in Annex C. They apply to all research being conducted with a favourable opinion from the ADREC and/or institutional REC.

**Authorities**

1.10. HAAD is empowered under UAE Federal Law No. (10) of 2008 regarding Medical Liability to regulate health research involving human subjects. The Abu Dhabi Health Research Council provides guidance to HAAD in setting standards for health research in Abu Dhabi.

1.11. Under the powers delegated to HAAD by law, HAAD may from time to time amend, update and/or revise these SOPs.

1.12. These SOPs have been approved by the Health Authority-Abu Dhabi (HAAD).

1.13. Facility REC members have been authorised by HAAD to carry out ethical review of research proposals within the scope described in paragraphs 1.5 - 1.7.

1.14. Facilities engaging in research involving human subjects must be licensed research institutions under HAAD’s policy on Licensing Requirements for Institutional Human Subjects Research - HAAD/PHR/R02.
2. New applications for ethical review

General requirements

2.1. An application for ethical review of a research proposal shall be made by the Principal Investigator for that study.

2.2. Applications shall be submitted to the REC-Coordinator using the Facility REC application form.

2.3. The REC-Coordinator shall validate the application within 5 days and shall inform the applicant of any missing information or documentation.

2.4. Every valid application shall receive a unique REC reference number.

2.5. The REC must give an ethical opinion within 60 days upon receipt of a valid application by the REC-Coordinator.

2.6. Institutions that are not licensed research institutions and investigators engaged in research through these institutions may submit applications for ethical review directly to the ADREC.

2.7. All applications submitted to the ADREC should be made using the approved ADREC application form (available upon request from medical.research@haad.ae)

Allocation and review of applications

2.8. Only valid applications that satisfy all of the necessary information and documentation will be allocated for review by the REC.

2.9. The period of 60 days, within which an ethics opinion must be given, begins when a complete and valid application is received. The validation date is the working day on which an application has been confirmed valid by the REC Coordinator (refer 2.3 above).

2.10. Should there be any omissions in the application; the applicant will be contacted before further action is taken. The review process will not be initiated in these cases. The 60 day time period for review does not start until a complete and valid application is received.

Rejection of applications

2.11. The REC will not accept applications for review if:

   a) The field of research falls outside the scope of the HAAD SOPs. Research will not be permitted in a domain for which the REC is unauthorised to conduct ethical review. The REC may retain the application where arrangements have been agreed with the appointing authorities for the REC’s scope to be extended beyond its own domain (see paragraph 1.5).

   b) One of the members of the REC is named as the Principal Investigator or another key investigator/collaborator in the research, unless the named member signs to be a non-voting member of the REC for the relevant application.

Revision of applications following submission

2.12. In general, revisions to applications that have been validated and allocated for review by the REC should not be accepted.
2.13. Where the applicant considers it necessary to make revisions the following applies.

2.14. Revisions prior to review by the REC:
   a) Major revision – the applicant should withdraw the application
   b) Minor revisions – the applicant should inform the Chair of the REC and revisions may be discussed at the applicant’s meeting with the REC or included in the applicant’s response to requests made by the REC for further clarification (see paragraph 2.15).

2.15. Revisions following review by the REC but before a final ethical opinion has been given:
   a) Include revisions in the response to the request made by the REC for further information or clarification (see paragraph 4.6-4.9). At the discretion of the Chair, the revisions may then be reviewed in accordance with the procedures agreed for considering further information from the applicant.

2.16. Revisions made after a favourable opinion has been given:
   a) Refer to the procedures for review of amendments in section 5.

**Withdrawal and retrospective applications**

2.17. If an applicant withdraws an application at any time, it shall be treated as no longer valid. If the applicant wishes to re-submit the application, it will be treated as a new submission and the review period of 60 days commences when the application is re-submitted and validated.

2.18. Retroactive applications shall be considered invalid, and the REC is not obliged to proceed with any form of ethical review. An ethical opinion cannot be given retroactively.
3. Meetings of a Research Ethics Committee

Quorum requirements and meeting attendance

Committee

3.1. The quorum for meetings of the REC is seven members, including the following:
   a) The Chair or, if unavailable, the vice-Chair; and
   b) At least one expert member, with relevant clinical and/or methodological expertise; and
   c) One lay member; and
   d) At least one other member who is independent of the institution or specific location where the research is to take place.

3.2. A member who is unable to attend in person can join the meeting via telephone or video link. This member shall also be counted for the purpose of the quorum. Signatures of quorum members attending via telephone or video link can be obtained retrospectively.

3.3. A member can appoint a deputy member who shall be counted for the purpose of the quorum if he/she attends in place of the lead member. Deputy members are subject to formal appointment procedures.

3.4. A member who is unavailable to attend a meeting may submit comments in writing on any agenda item.

3.5. The following shall not be counted for the purpose of the quorum:
   a) Advisers or referees
   b) Members who are yet to arrive at the meeting, or who have left early
   c) Members who submit written comments but do not attend
   d) Deputy members attending alongside the lead member
   e) Committee Secretariat/Coordinator

3.6. Where a quorum is not present, the Committee must not commence, continue or conclude any discussion with the purpose of determining the Committee’s opinion on an application for ethical review.

3.7. A Committee meeting, or part of the meeting, at which a quorum of members is not present, may proceed with any other business on the agenda, provided that the Chair or Vice Chair and at least one other member is present.

Sub-Committee

3.8. An extraordinary Sub-Committee can be formed to consider the following:
   a) Further information or clarification on an application
   b) Written advice from a referee
   c) Substantial amendments
   d) Monitoring of research studies (review of reports)
e) Any other business that requires urgent action

3.9. The Sub-Committee shall consist of no less than two people approved of by the whole Committee.

3.10. A Sub-Committee has delegated authority to take decisions on behalf of the REC on the matters listed in paragraph 3.8 above. Decisions taken by the Sub-Committee should not require ratification at the Committee meeting, unless the Sub-Committee specifically decides to refer a matter for further consideration and decision by the Committee. Decisions made by a Sub-Committee on behalf of the REC cannot be subsequently reversed by the REC.

Delegation of responsibility by the REC

3.11. The Committee should decide at its meeting that the Chair alone (or together with selected members) makes a decision under the circumstances laid out in paragraph 3.8.

Attendance of Non-REC members

Principal Investigator

3.12. The Principal Investigator, or another key investigator, shall be invited to attend the meeting at which his/her application is to be reviewed in order to respond directly to requests from the Committee for further information, clarification or reassurance.

3.13. It is not compulsory for the Principal Investigator to attend.

3.14. The REC may offer the Principal Investigator the alternative of being available via telephone or video link at the time of the review.

3.15. It is not the purpose of the Principal Investigator’s attendance to make a formal presentation of the study and this shall not be permitted.

Referees

3.16. Referees are not voting members of the REC and shall not be involved in the business of the Committee other than that related to the application on which their advice is sought.

Observers

3.17. Observers may be invited to attend Committee meetings, subject to written invitation setting out the terms under which observer status is permitted, the signing of a confidentiality agreement, disclosure of any conflict of interest, and the agreement of the Committee.

3.18. Meetings, or parts of meetings, may also be attended from time to time by representatives of appointing authorities and auditors. Arrangements for attendance should be discussed and agreed beforehand with the Chair, and should be subject to the signing of a confidentiality agreement.

3.19. If an observer is present, the Chair shall verbally inform any investigator who attends the meeting. The investigator shall be given the opportunity to object to the presence of any observer. If there is an objection, the observer shall be asked to leave the meeting room for that item.
Meeting schedules

3.20. The REC shall hold meetings as required for the purposes of primary ethical review of new applications. A minimum of four meetings per year is recommended.

3.21. Additional meetings may be held where necessary in one of the following ways:
   a) In person at the regular meeting location, with the same quorate requirements
   b) Via email correspondence or telephone or video conference, with the same quorate requirements
   c) As an extraordinary Sub-Committee (see paragraphs 3.8 – 3.10)
   d) Chair’s delegated responsibilities should be decided by the Committee (see paragraph 3.11)

3.22. The closing dates for applications shall be no later than 14 days prior to each REC meeting.

Declaration of interest

3.23. Members shall declare to the Committee any interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting.

3.24. Such a declaration may be made orally at the meeting, prior to the matter being considered or in writing to the Chair prior to the meeting.

3.25. The Committee Chairman shall decide to what extent a member may contribute to the issues discussed in the meeting.

Confidentiality of proceedings

3.26. REC members do not sit on the Committee in any representative capacity and need to be able to discuss freely the applications submitted to the committee. For this reason, REC meetings shall be held in private and members shall be encouraged to raise any matters of concern.

3.27. The terms and conditions of appointment for members include requirements to keep confidential the business of the REC.

Conduct of business and decision making

3.28. The Chair is responsible for the conduct of the business and for ensuring that the Committee reaches clearly agreed decisions on all matters. Where the Chair is unavailable, the meeting shall be chaired by the vice-Chair.

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

3.30. The meeting shall reach unanimous decisions by consensus wherever possible. Where a consensus is not achievable a formal vote shall be taken by a counting of hands. The decision of the Committee shall be determined by a simple majority of those members present and entitled to vote.

3.31. Where any member wishes to record his/her formal dissent from the decision of the Committee, this shall be recorded in the minutes.
Administration

3.32. For details on preparing the meeting agenda, distribution of papers, minutes and responsibilities of the Coordinator, see Annex D.
4. Giving an ethical opinion

General policy

4.1. A REC is required to give an ethical opinion on an application relating to a CTIMP within 60 calendar days of the receipt of a valid application (except where paragraph 4.2 applies). Where the REC considers that further information is required in order to give an opinion, the REC may make one request in writing for further information from the applicant. The period of 60 days will be suspended pending receipt of this information.

4.2. In the case of a clinical trial involving a medicinal product for somatic cell therapy, the normal statutory time limit for review is extended to 90 days. This may be extended by a further 90 days (i.e. to 180 days in total) where the REC needs to consult a specialist group or Committee about the application. Except for this difference in the time limit for review, SOPs apply to such trials in the same way as any other CTIMP.

4.3. These requirements will also apply to all other research reviewed by the REC.

4.4. The following section of the SOPs set out the procedures to be followed in communicating decisions made at meetings, requesting further information from applicants and issuing the REC’s opinion. It does not in any way constrain the independence of the REC in considering the ethics of individual research applications and deciding whether or not to give a favourable opinion.

Decisions available to the REC

The Chair shall ensure that one of the following decisions is made on every application considered at a REC meeting:

Final opinion

4.5. The final opinion may be either:

a) Favourable: The Principal Investigator shall be notified within 10 days and the trial shall commence within 12 months (see paragraphs 7.3-7.4). The Principal Investigator shall receive a copy of the Standard Approval Conditions together with the final opinion letter. Any additional approval conditions specified by the REC for a particular application, for example a requirement for more frequent progress reports, should be included in the letter.

b) Unfavourable: The applicant shall be given a full explanation of the REC’s reasons and may re-submit a new application taking due account of the REC’s concerns (see also paragraphs 4.14-4.15).

Provisional opinion with request for further information

4.6. The Committee may decide that an opinion cannot be issued until further information or clarification has been received from the applicant.

4.7. The 60 day time period shall be suspended from the date on which the request for further information was sent to the applicant. It should be re-started on the date when a complete response is received in the REC office (“the re-start date”).
4.8. The applicant shall be allowed a period of four months to respond to the request for further information.

4.9. Further information required to issue a final opinion may be considered at an additional meeting (see paragraph 3.21).

No opinion and request for advice from a referee

4.10. The Committee may decide that no opinion can be given until a referee has been consulted.

4.11. The Coordinator or Chair shall contact the referee within 5 days of the meeting. The referee shall be asked to respond in writing within a further 10 days. The written advice received shall then be considered promptly at an additional meeting (see paragraph 3.21).

4.12. Once the referee’s advice has been considered, the REC may issue a provisional opinion and request further information from the applicant and the same procedures as above apply (see paragraphs 4.6-4.9).

4.13. The REC shall not disclose the nature of the referee’s advice to the applicant. The opinion it reaches on the application is its own. It shall not disclose the identity of the referee except with his/her expressed permission.

Further review of research given an unfavourable opinion

4.14. When the final opinion is unfavourable the applicant may submit a new application together with additional documentation addressing the RECs concerns raised at first review (see Application Guidance Notes).

4.15. New applications of research proposals previously reviewed shall be ethically reviewed according to standard procedures.

4.16. New applications shall be assigned a new REC reference number.

Additional considerations

Regulatory approval

4.17. Applications for regulatory approval may proceed in parallel with the ethical review.

4.18. It is not necessary for evidence of regulatory approval to be provided to the REC before it confirms the final ethical opinion.

4.19. Where a favourable ethical opinion is given before regulatory approval and the regulator requires significant changes to be made to the terms of the REC application or the supporting documentation, a Notice of Substantial Amendment form shall be submitted to the REC for review (see section 5).

Insurance, indemnity and compensation

4.20. In accordance with best practice as described by the International Conference for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP), the REC must ensure that there is sufficient provision for indemnity or compensation in the event of injury or death attributable to a CTIMP, and insurance or indemnity to cover the liability of the investigator and sponsor(s).
4.21. Before confirming a favourable opinion on any research (including both CTIMPs and non-CTIMPs), the REC shall assure itself that the sponsor and investigators have appropriate insurance or indemnity cover for the potential legal liability arising from the research. Applicants must show that:

a) the financial arrangements, including insurance or indemnity, cover the research study concerned

b) the sponsor, protocol authors, investigators/collaborators and, where applicable, Site Management Organisations will all be protected by insurance or indemnity arrangements

c) the arrangements will provide adequate cover to meet the potential liability assessed by the sponsor

4.22. RECs are not expected to undertake detailed expert scrutiny of insurance policies. The responsibility for ensuring that cover is adequate lies with the research institution, investigators and sponsors themselves.

**Safety of CTIMP**

4.23. The Committee is not required to undertake its own expert scientific or safety assessment of CTIMP or seek advice on safety issues from scientific referees. The quality and safety of CTIMP is the responsibility of the institution and investigator. The Committee should make an ethical assessment of the information provided in the application about the potential risks and benefits to participants and any measures in place to minimise the risks. The ethical review must also ensure that the potential risks and benefits of the trial are fully and clearly explained in the participant information sheet.

**Statement of compliance**

4.24. Per International Conference for Harmonisation Guidelines for Good Clinical Practice (ICH GCP), sponsors of CTIMPs should obtain a statement from the Research Ethics Committee issuing the ethical opinion on the trial that it is organised and operates according to ICH GCP. The REC standard letter SL3 issuing ethical opinions on a CTIMP includes an appropriate statement of compliance with the conditions and principles of ICH GCP.

**Approval to proceed with research**

4.25. A favourable opinion from a REC does not imply authorisation from the regulatory authority to proceed with the research.
5. Amendments to research given a favourable opinion

General requirements

5.1. An “amendment to a clinical trial authorisation” is defined broadly as an amendment to any of the following:
   a) the terms of the request for clinical trial authorisation from the regulatory authority or the REC
   b) the terms of the REC application
   c) the protocol
   d) any other particulars or documents submitted with the applications to the regulatory authority or the REC

5.2. A “substantial amendment” is defined as an amendment that is likely to affect to a significant degree any of the following:
   a) the safety or physical or mental integrity of the subjects of the trial
   b) the scientific value of the trial
   c) the conduct or management of the trial
   d) the quality or safety of any investigational medicinal product used in the trial

5.3. It is the responsibility of the sponsor to decide whether a substantial amendment to a CTIMP requires authorisation or an ethical opinion, or both (guidance can be found in Annex E).

5.4. For research other than a CTIMP, the REC has the discretion to decide whether or not a proposed amendment is substantial and requires ethical review. The Coordinator has the discretion to make this decision on behalf of the REC in straightforward cases. Where the Coordinator is in any doubt about the designation of an amendment, he/she should invite the Chair to review the documents. Other members may be consulted where necessary, or exceptionally the documents may be considered at a meeting.

5.5. Depending on the nature of the trial for submission of notices of amendment, the forms SF1 (or equivalent) shall be used.

5.6. Where changes are made to a research study that the sponsor (or Principal Investigator) considers minor rather than substantial amendments, there is no requirement to obtain an ethical opinion.

Review of substantial amendments

5.7. Substantial amendments shall be reviewed by the whole REC or a Sub-Committee (see paragraphs 3.1 – 3.10) but not by the Chair acting alone.

5.8. An ethical opinion shall be issued according to the procedures described in section 4 with the exception that an ethical opinion for a substantial amendment shall be given within 35 days.

5.9. Where an unfavourable opinion is given, the sponsor or Principal Investigator may modify the amendment.
5.10. The REC shall give an opinion on a modified amendment within a further 14 days. Responsibility may be delegated to the Chair.

5.11. There is no provision for appeal against a decision of the REC to give an unfavourable opinion of a substantial amendment.

Amendments requiring submission of a new application

5.12. Where a proposed amendment would fundamentally alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants, the REC may give an unfavourable opinion and instead request submission of a new application for full ethical review.

5.13. Amendments involving the submission of a separate protocol shall always require the submission of a new application.

Urgent safety measures

5.14. The sponsor, Principal Investigator or any Key Investigator may make changes to the conduct of a study for urgent safety-related reasons without first giving notice to the REC or obtaining a favourable opinion. The REC and the regulatory authority must be notified within three days of taking urgent safety measures, the reasons why the measures were taken, and the plan for further action. Procedures relating to urgent safety measures are described in paragraph 8.15 and Annex C.
6. Expedited review

General policy

6.1. There is no statutory provision for the expedited review of applications. The REC shall give an opinion on any valid application within a period of 60 days, which may be suspended once pending receipt of further information from the applicant.

7. Exempt research

General policy on research exempt from full REC review

7.1. Six specific categories of human subject research listed in section 7.7 may be declared exempt from further REC review. This determination is made by the REC itself, not the investigator.

7.2. All proposals for non-exempt human subject research must receive full review by a Research Ethics Committee under HAAD jurisdiction. While a REC may determine that a human subject research proposal is exempt from further REC review, the research must comply by all other research ethics requirements.

Procedures for exempting research from full REC review

7.3. A complete REC application with Standard Form SF5 cover (or equivalent) must be submitted for the research to be considered for exemption from full REC review. The REC Chairman, or one or more experienced reviewers designated by the Chairman from among the REC members, must review the completed research ethics application.

7.4. The REC shall keep a record of all declarations of exemption citing specific exemption category (A-F) under section 7.7 of this chapter, notifying the applicant using Standard Letter SL6 (or equivalent), and advising all REC members of research proposals that have been declared exempt from further REC review requirements.

7.5. In conducting review for exemption, the REC reviewers may exercise all of the authorities of the REC except that they may not disapprove the research. A research activity may be disapproved only after full REC review.

7.6. Changes to the research proposal may disqualify the research from exempt status. Therefore, any proposed changes to an exempt study must be submitted to the REC for review and approval prior to implementation.

7.7. The following research categories may be declared exempt from the requirements for full REC review:

a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

7.7.a.1. research on regular and special education instructional strategies; or

7.7.a.2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:

7.7.b.1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

7.7.b.2. any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.

c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (I)(B) of this policy, if:

7.7.c.1. UAE or Abu Dhabi law(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

e) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs;

7.7.e.1. procedures for obtaining benefits or services under those programs; or

7.7.e.2. possible changes in or alternatives to those programs or procedures; or

7.7.e.3. possible changes in methods or levels of payment for benefits or services under those programs.

f) Taste and food quality evaluation and consumer acceptance studies,

7.7.f.1.1. if wholesome foods without additives are consumed; or

7.7.f.2.2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Abu Dhabi Food Control Authority or Abu Dhabi Environment Agency.

7.8. The exemptions specified in section 7.7 do not apply to research involving prisoners.

7.9. The exemptions specified in Section 7.7(a), (c), (d), (e) and (f) apply to research involving children.

7.10. The exemption specified in Section 7.7(b) only applies to research involving children if the investigator does not participate in the public activities being observed. The exemption does not apply to research involving children where the research involves survey or interview procedures or any direct interaction with participants under observation.
8. Monitoring of research given a favourable opinion

General policy on monitoring research

8.1. The REC shall keep under review the favourable ethical opinion given to any research study in the light of regular progress reports and significant developments in the research.

8.2. Other than by means of the reports that the sponsor and investigators are required to submit; the REC has no responsibility for proactive monitoring of research studies. The accountability for this lies with the sponsor and the employing organisation.

Commencement of the research

8.3. Research shall normally commence within 12 months of the date on which a favourable ethical opinion is given by a REC.

8.4. Should the study not commence within 12 months, the Principal Investigator shall give the REC a written explanation for the delay in the first annual progress report. It is open to the Chair to allow a further period of 12 months within which the trial should commence.

8.5. Should the study not commence within 24 months, the matter shall be discussed at a meeting of the REC. At the discretion of the REC, the favourable ethical opinion may be terminated and the Principal Investigator required to submit a new application. Alternatively, a further period may be allowed.

Duration of the favourable ethical opinion

8.6. The favourable ethical opinion of the REC applies for the duration of the research, except where action is taken to suspend or terminate the opinion. Where the duration of the study is to be extended beyond the period specified in the application form, the REC should be notified by letter, giving reasons for the extra time needed to complete the research. (Annual progress reports should continue to be submitted if the study duration is extended in this way). Extension of the study period is not in itself a substantial amendment, except where it is related to other amendments that would be substantial, such as an increase in target recruitment, addition of new procedures or extension of follow-up. It is not necessary to obtain formal approval for extension of the study period, though the REC may review its favourable opinion of the study at any time.

Reviewing reports

8.7. The following paragraphs list the responsibilities for review of reports submitted to the REC. Details on reporting formats, timelines and contents are described in Annex C.

8.8. The primary responsibility for monitoring the safety of research participants lies with the trial sponsor and/or investigators.

The REC shall receive the following reports from the Principal Investigator:

Annual progress reports

8.9. Annual progress reports and the final report shall be reviewed at least by the Chair or, at the Chair’s discretion, by one or more members of the Committee or a Scientific Officer.
**Periodic safety reports**

8.10. Periodic safety reports should be reviewed at least by the Chair and, unless the Chair has appropriate expertise, by an expert member or referee.

8.11. The purpose of the review of periodic safety reports is to:

a) Check the accuracy of the risk/benefit analysis as described in the patient information sheet

b) Consider the possible need for new information to be given to patients and their consent sought to continue in the study

c) Consider any other issue that may be relevant to the ethics of the trial.

8.12. Where concerns arise about any of the above, the REC may contact the Principal Investigator or sponsor to express its concerns, and may request further information. The Principal Investigator may be requested to attend a meeting of the Sub-Committee or Committee to discuss the concerns of the REC.

8.13. Where findings and recommendations from Data Monitoring Committees are received by the REC, they should be reviewed in the same way as periodic safety reports.

**Final report**

8.14. See paragraph 8.9

**Urgent safety measures and expedited reports**

8.15. Notifications of urgent safety measures should be reviewed at a meeting of the REC or Sub-Committee but not by the Chair acting alone. The REC should consider whether the measures taken are appropriate in relation to the apparent risk to participants, and what further action the sponsor and investigator(s) propose to take, for example the submission of amendments to the protocol. Where any concern arises about the safety or welfare of participants or the conduct of the research, the REC should address these with the sponsor or Principal Investigator in writing.

8.16. Expedited reports of SUSARs or other occurrences should be acknowledged and filed by the Coordinator. They do not need to be seen by the Chair. There is no requirement for the Committee to be notified routinely of the receipt of expedited reports, or for any review to be carried out, as the overall safety of the trial cannot be assessed on the basis of such limited data.

**Serious breaches of Good Clinical Practice or the protocol**

8.17. The REC should be notified of serious breaches of the protocol or of the conditions or principles of Good Clinical Practice (ICH GCP) as set out in the Regulations. Any such report should be considered at a meeting of the Committee or Sub-Committee.

8.18. There is no statutory provision for the Committee to approve proposed deviations from the protocol for individual subjects. It is the responsibility of the sponsor and/or investigator to consider whether protocol amendments should be made in such cases. Where the amendment is substantial, it should be notified.
Review of a favourable ethical opinion

8.19. The REC may review its favourable ethical opinion of a study at any time. In particular, this might be prompted by safety reports, progress reports or any other information received about the conduct of the study. The Principal Investigator or sponsor may ask the REC to review its opinion, or seek advice from the REC on any ethical issue relating to the study.

Review of opinion on a CTIMP

8.20. The REC has no power to legally withdraw the ethical opinion given previously. However, the REC may review its opinion in the light of new ethical concerns following any new information received about the trial. It may also notify the regulatory authority and the ADREC that it no longer has a favourable opinion of the trial. Any such notification should be based on a decision taken at a quorate meeting of the full Committee.

8.21. Where the REC decides that it no longer has a favourable opinion of a trial, the Chair should write to the regulatory authority and the ADREC. The REC may recommend that consideration is given to suspending or terminating the trial authorisation. Any such recommendation should relate to serious concern about one or more of the following:
   a) The scientific validity of the trial
   b) The health or safety of participants
   c) The competence or conduct of the investigator(s)
   d) A delay of at least 2 years in the commencement of the trial leading to doubts about the continuing validity of the ethical opinion given on the original application
   e) The adequacy of the site or facilities.

Suspension or termination of opinion on a non-CTIMP

8.22. A favourable ethical opinion on a non-CTIMP may be suspended or terminated by the REC due to serious concern about one of the following:
   a) The scientific validity of the study
   b) The health or safety of participants
   c) The competence or conduct of the investigator(s)
   d) Serious or repeated breach of approval conditions
   e) A delay of at least 2 years in the commencement of the study leading to doubts about the continuing validity of the ethical opinion given on the original application
   f) The adequacy of the site or facilities
   g) Suspension or termination of regulatory approval for the study.

8.23. A decision by the REC to suspend or terminate a favourable ethical opinion should be taken only at a quorate meeting of the full Committee. Before taking this course the REC should weigh carefully the implications for any research participants already recruited. The Principal Investigator should be notified of the decision by the Chair.
Research-related fraud and misconduct

8.24. Where a REC receives information suggesting that any kind of fraud or misconduct may have occurred in relation to an application for ethical review or the conduct of research, the Chair or Coordinator should pass the information confidentially to the appointing authority.

8.25. It is for the REC to consider whether any action needs to be taken in relation to the ethical opinion for the research, in particular where there could be an immediate risk to the safety of participants. The opinion on a non-CTIMP may be suspended pending the outcome of further investigation by other bodies. Such a decision should only be taken after careful consideration of the implications for research participants already recruited.

8.26. A member of a REC who becomes aware of possible fraud or misconduct in research should report this to the Chair and Coordinator of the REC, who will be responsible for reporting the matter.

8.27. Where a REC receives information suggesting that a criminal offence may have been committed, it should proceed as in paragraph 7.24.

Non-compliance in CTIMPs

8.28. RECs should draw serious concerns about compliance issues in CTIMPs to the attention of the appointing authority under the procedures for notifying possible fraud or misconduct (see paragraph 7.24).

8.29. The authorities should always be notified where one of the following is suspected:
   a)  Conduct of a trial without regulatory authorisation or favourable REC opinion.
   b)  Provision of false or misleading information to the REC in relation to an application for ethical opinion or notification of substantial amendment.
   c)  Implementation of a substantial amendment without authorisation and/or a favourable opinion as appropriate.
   d)  Failure to notify SUSARs occurring in a trial in an expedited manner or to provide an Annual Safety Report.
   e)  Failure to notify urgent safety measures.
   f)  Failure to notify the early termination or conclusion of the trial.
   g)  A serious breach of ICH GCP or the protocol.
   h)  Any other fraud or serious misconduct.
   i)  A breach of the conditions and principles of ICH GCP or the protocol should be regarded as “serious” if it is likely to affect to a significant degree the safety or physical or mental integrity of the participants or the scientific value of the trial.

8.30. Consideration should also be given to notifying the authorities where a pattern emerges of repeated minor breaches of ICH GCP or the protocol.
9. Research involving human tissue

Annex F provides guidance to applicants on research involving human tissue that requires ethical review and circumstances for projects-based applications or Research Tissue Bank (RTB) applications. Research involving human tissue is regulated under the provisions of Federal Law No. (10) of 2008 regarding Medical Liability.

General policy

9.1. The Facility REC shall:
   a) Provide ethical review of research using human tissue collected, stored and used at the Facility.
   b) Undertake ethical review in a proportionate way, taking account of any material risk of harm or distress to donors, their families and other research participants.
   c) Facilitate valuable research using human tissue of benefit to society, within the legal framework of the UAE.

Options for ethical approval

9.2. There are two possible routes to obtaining ethical approval for research involving storage or use of human tissue or analysis of DNA:
   a) Application for approval of a specific project. These shall be made using the normal Facility REC application form. Such approval lasts only for the duration of the project as described in the protocol and the application form. Project-based applications shall be reviewed in line with HAAD policy and standards. The standard approval conditions described in Annex C apply.
   b) Application for approval of a RTB. This may confer generic ethical approval prospectively for a range of research to be carried out by the establishment responsible for the bank and/or by other researchers to whom tissue is released by the bank within the conditions of the ethical approval. The model standard approval conditions in Annex G apply.

General guidance on ethical review of RTB applications

9.3. RECs undertaking the ethical review of RTBs should note the following general guidance:
   a) The review should focus particularly on the following ethical issues:
      • arrangements for the collection of new samples
      • requirements to seek consent from new donors, further consent from previous donors, or consent from relatives where the donors are deceased
      • the terms of informed consent as set out in information sheets and consent forms
      • justification for storage and use of tissue for research without specific consent where not legally required
      • the policy for provision of tissue to researchers, including arrangements for ensuring adequate scientific critique of projects and the conditions under which samples will be released
• any plans to provide donors with feedback of any clinically significant information obtained in research using their samples.

b) Ethical review should be proportionate, balancing the need to protect the safety, rights and well being of donors with the need to facilitate research of value to society as a whole.

Process of ethical review for RTBs

9.4. The process of ethical review will generally be the same as for project-based applications. All references to the “Principal Investigator” in the SOPs should be read as applying to the person submitting the application.

9.5. Where an unfavourable opinion is issued, the usual options for further review will apply.

9.6. Substantial amendments to the terms of ethical approval for a RTB shall be dealt with in the same way as substantial amendments to specific research projects.

9.7. The model standard approval conditions in Annex G apply.
Annex A: Glossary

ADREC
Abu Dhabi Research Ethics Committee constituted under the Abu Dhabi Health Research Council.

Adverse reaction
In a CTIMP, any untoward and unintended response in a subject to an IMP which is related to any dose administered to that subject. See also SSAR and SUSAR.

Amendment
A change made to the terms of the REC application, the protocol or any other supporting documentation after the study has started. A study is normally considered to start with the commencement of any protocol procedures.

Appointing Authority
A body responsible for the approval of the REC.

Approval conditions
Conditions to be observed by the applicant in the conduct of the research.

Care organisation
The organisation(s) responsible for providing care to patients and/or users and carers participating in the study. Care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.

Chair
The head of a Committee, carrying ultimate responsibility for all actions and decisions taken by the Committee. Note: all references in the SOPs to “the Chair” should be interpreted as referring also to the vice-Chair when acting in place of the Chair.

Principal Investigator (PI)
The investigator with overall responsibility for the research. All applications for ethical review should be submitted by the PI.

Clock
The period allowed for the ethical review of a new application or substantial amendment. The clock starts on receipt of a valid application. See “60 day clock” and “35 day clock”.

CTIMP
Clinical trial of an investigational medicinal product. (Any other type of research is known as a non-CTIMP).

Committee
The Research Ethics Committee

Domain
Local area of responsibility of REC.

Employing organisation
An organisation employing the Principal Investigator, other investigators or research collaborators. Employers remain liable for the work of their employees.
Facility
Organisation licensed by HAAD to conduct medical research

HAAD
Health Authority - Abu Dhabi

HRC
Health Research Council, the governing body for health research in the Emirate of Abu Dhabi.

ICH GCP
International Conference on Harmonisation Guideline for Good Clinical Practice (ICH GCP), a set of standards used internationally for the conduct of clinical trials, delineating the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors and ethics committees. ICH GCP sets internationally accepted standards for monitoring, reporting and archiving of clinical trials. (See Efficacy Guidelines; Good Clinical Practice E6; at [http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html](http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html)).

IMP
Investigational medicinal product

Investigator’s brochure
A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects.

Minor amendment
An amendment which is not a substantial amendment, not requiring review by a REC.

Modified amendment
Following the issue of an unfavourable opinion on a substantial amendment, the re-submission of the amendment in modified form.

Non-CTIMP
Any research study that is not a CTIMP.

Participant
Patient, service user, carer, relative of the deceased, professional caregiver, other employee, or member of the public, who consents to take part in a study.

Phase 1 trial
A clinical trial to study the pharmacology of an investigational medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.

Principal Investigator (PI)
The investigator responsible for the research site in a multi-site study. There should be one PI for each research site. In the case of a single-site study, the PI and the key investigator will normally be the same person.

Protocol
A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study.
Provisional opinion
A decision reached by a REC on an application, subject to the receipt of further information or clarification from the applicant. The 60 day time period is suspended until the information is received.

REC
Research Ethics Committee

REC reference number
Reference number assigned by the REC when accepting the application for review. This includes a REC local identifier, specific project number and year.

Referee
A person or body who gives expert advice to a REC on an application or any related matter.

Regulatory Authority
A body responsible for the approval, regulation and monitoring of CTIMPs and non-CTIMPs.

Research site
The organisation or unit responsible for conducting any of the research procedures in a study at a particular locality.

Revision of application
Any changes made to the terms of an application following the meeting or, following issue of an opinion, before the research has started. Revision is not permitted prior to the REC meeting once the application has been validated.

SAE
Serious Adverse Event (see Statutory definitions Annex B)

60 day clock
The period of 60 calendar days allowed for the issue of an ethical opinion on a new application. The clock may stop once while awaiting a complete response from the applicant to one written request from the REC for further information or clarification.

SOPs
Standard Operating Procedures

Sponsor
See Statutory definitions Annex B

SSAR
Suspected Serious Adverse Reaction (see Statutory definitions Annex B).

Substantial amendment
Amendments to the trial are regarded as ‘substantial’ where they are likely to have a significant impact on the safety or physical or mental integrity of the clinical trial participants, or the scientific value of the trial (See Appendix E). A significant amendment to a CTIMP must be notified to both the ethics Committee and the competent authority; and requires a favourable opinion from the REC and/or a notice of no objection from the regulatory authority before it can be implemented. In the case of non-CTIMPs, a substantial amendment always requires the issue of a favourable opinion from the REC.

SUSAR
Suspected Unexpected Serious Adverse Reaction (see Statutory definitions Annex B).
35 day clock
The period of 35 days allowed for the issue of an ethical opinion on a substantial amendment. The clock does not stop while awaiting any further information.

Validation
An administrative check carried out by a REC Coordinator to verify that an application is complete and may be accepted for review. Decisions on validation should be made within 5 working days of receipt.

Validation date
The date on which a valid application is received by the REC.

Vulnerable persons
See Statutory definitions Annex B
Annex B: Statutory definitions

Note: The following is a selection of relevant definitions relating to clinical trials of investigational medicinal products.

Authorised health professional

a. a doctor  
b. a dentist  
c. a nurse  
d. a pharmacist  

Note: The Principal Investigator and any investigator at a site in a CTIMP must be one of the above.

Principal Investigator

a) In relation to a clinical trial conducted at a single trial site, the investigator for that site, or

b) In relation to a clinical trial conducted at more than one trial site, the authorised health professional,  
whether or not he is an investigator at any particular site, who takes primary responsibility for the  
conduct of the trial.  

Note: The formulation in (b) means that, in a multi-site study, it is lawful for the Principal Investigator to  
be an employee of a pharmaceutical sponsor company rather than one of the site investigators. The  
ethical review would need to ensure that he or she had appropriate professional qualifications and  
expertise to take responsibility for the conduct of the trial.

Clinical trial

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

a. to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more  
medicinal products  
b. to identify any adverse reactions to one or more such products  
c. to study absorption, distribution, metabolism and excretion of one or more such products with the  
object of ascertaining the safety or efficacy of those products.

Clinical trial protocol

A document that describes the objectives, design, methodology, statistical considerations and  
organisation of a clinical trial.

Conducting a clinical trial

a. Administering, or giving directions for the administration of, an investigational medicinal product to  
a subject for the purposes of that trial; or

b. Giving a prescription for an investigational medicinal product for the purposes of that trial; or

c. Carrying out any other medical or nursing procedure in relation to that trial; or
d. Carrying out any test or analysis:
   
   • to discover or verify the clinical, pharmacological or other pharmacodynamic effects of
     the investigational medicinal products administered in the course of the trial
   
   • to identify any adverse reactions to those products, or
   
   • to study absorption, distribution, metabolism or excretion of those products.

It does not include activity undertaken prior to the commencement of a trial which consists of making
such preparations for the trial as are necessary or expedient.

**Investigational medicinal product**

A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be
used, as a reference in a clinical trial, and includes a medicinal product which has a marketing
authorisation but is, for the purposes of the trial:

a. used or assembled (formulated or packaged) in a way different from the form of the product
   authorised under the authorisation

b. used for an indication not included in the summary of product characteristics under the
   authorisation for that product

c. used to gain further information about the form of that product as authorised under the
   authorisation

**Investigator**

The authorised health professional responsible for the conduct of a clinical trial at a trial site, and if the
trial is conducted by a team of authorised health professionals at a trial site, the investigator is the
leader responsible for that team.

**Investigator’s brochure**

A document containing a summary of the clinical and non-clinical data relating to an investigational
medicinal product which are relevant to the study of the product in human subjects.

**Non-Interventional trial**

A study of one or more medicinal products which have a marketing authorisation, where all of the
following conditions are met:

a. the products are prescribed in the usual manner in accordance with the terms of that authorisation

b. the assignment of any patient involved in the study to a particular therapeutic strategy is not
   decided in advance by a clinical trial protocol

c. the decision to prescribe a particular medicinal product is clearly separated from the decision to
   include the patient in the study

d. no diagnostic or monitoring procedures are applied to the patients included in the study, other than
   those which are ordinarily applied in the course of the particular therapeutic strategy in question

e. epidemiological methods are to be used for the analysis of the data arising from the study.
**Phase 1 trial**

A clinical trial to study the pharmacology of an investigational medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.

**Serious adverse event**

An untoward occurrence that:

- results in death
- is life-threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect
- is otherwise considered medically significant by the investigator

**Sponsor of a clinical trial**

The person who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial.

Note: Two or more persons may take responsibility for the functions of the sponsor. Where this applies, one of the sponsors should take responsibility for each of the following group of functions:

- communications relating to substantial amendments, modified amendments and the conclusion of the trial
- communications relating to urgent safety measures
- pharmacovigilance reporting

The Principal Investigator is considered the sponsor if he/she independently plans, conducts and is totally responsible for a clinical trial.

**Substantial amendment to a clinical trial authorisation**

An amendment to the clinical trial authorisation which is likely to affect to a significant degree:

- the safety or physical or mental integrity of the subjects of the trial
- the scientific value of the trial
- the conduct or management of the trial, or
- the quality or safety of any investigational medicinal product used in the trial

Note: A substantial amendment is defined in relation to the regulatory authorisation rather than the terms of the REC application or the protocol. However, where the sponsor proposes to make a substantial amendment to an authorised research protocol which consists of, or includes, an amendment to the terms of the REC application or the supporting documentation, the amendment may be made only if the REC has given a favourable opinion.
Suspected serious adverse reaction (SSAR)

An “adverse reaction” is any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered to that subject.

An adverse reaction is “serious” if it:

a. results in death
b. is life-threatening
c. requires hospitalisation or prolongation of existing hospitalisation
d. results in persistent or significant disability or incapacity
e. consists of a congenital anomaly or birth defect.

A “suspected serious adverse reaction” (SSAR), therefore, is any event which is suspected of meeting the above criteria.

Suspected unexpected serious adverse reaction (SUSAR)

A “suspected unexpected serious adverse reaction” (SUSAR) is a SSAR which is also “unexpected”, meaning that its nature and severity are not consistent with the information about the medicinal product in question set out:

a. in the case of a product with a marketing authorisation, in the summary of product characteristics for that product
b. in the case of any other investigational medicinal product, in the investigator’s brochure relating to the trial in question

A serious adverse reaction is an untoward and unintended response to an IMP at any does that:

a. results in death
b. is life threatening
c. requires hospitalisation or prolongation of existing hospitalisation
d. results in persistent or significant disability or incapacity, or
e. consist of a congenital anomaly or birth defect.

An adverse reaction is considered to be “unexpected” if its nature and severity are not consistent with the information about the medicinal product set out in the trial documentation.

Vulnerable persons

Vulnerable persons include, but are not limited to:

a. the mentally ill
b. prisoners and young offenders
c. children under 18
d. those in an overtly dependent situation (for example those in care)
e. those with learning disabilities.
Annex C: Standard approval conditions

The standard approval conditions apply to CTIMPs and all other research. All paragraphs relating to authorisation for clinical trials, Investigational Medicinal Products (IMPs) and Suspected Unexpected Serious Adverse Events (SUSARs) apply to CTIMPs only.

Further communications with the Research Ethics Committee

Further communications during the trial with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as “the Committee”) are generally the responsibility of the lead sponsor. However, the sponsor may delegate responsibility to the Principal Investigator or another representative.

Where there is more than one sponsor for the trial, it is recommended that the lead sponsor or its representative takes responsibility for all communications with the Committee. However, one of the co-sponsors may take responsibility for each of the following group of functions:

a) Substantial amendments, modified amendments and the conclusion of the trial
b) Urgent safety measures
c) Pharmacovigilance reporting.

Commencement of the trial

It is assumed that the trial will commence (i.e. the initiation of any protocol procedures) within 12 months of the date of the favourable ethical opinion.

The sponsor will obtain authorisation from the regulatory authority before the commencement of the clinical trial. Evidence of the authorisation should be forwarded when available (if not already provided to the Committee). Where the regulatory authority requests significant changes to the protocol before confirming authorisation, or attaches any other condition requiring substantial amendments to be made to the terms of the REC application or the supporting documentation, a Notification of Substantial Amendment form should be submitted to the Committee.

Should the trial not commence within 12 months, the sponsor should give the Committee a written explanation for the delay. It is open to the Committee to allow a further period of 12 months within which the trial must commence.

Should the trial not commence within 24 months, the Committee may review its opinion and may recommend to the regulatory authority that the authorisation should be suspended or terminated.

Duration of ethical opinion

The favourable opinion generally applies for the duration of the trial. If it is proposed to extend the duration of the trial as specified in the application form, the Committee should be notified.

Progress reports

Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the trial. A progress report should be submitted to the
Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter until the end of the trial is declared.

Progress reports shall be submitted using Standard Form SF2 or equivalent (see Annex J).

The Committee should be kept informed of any significant findings or recommendations by an independent Data Monitoring Committee or equivalent body established for the trial.

The Principal Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the trial.

**Amendments**

If the sponsor proposes to make a substantial amendment to the clinical trial authorisation, a Notification of substantial amendment form should be submitted to the Committee and the regulatory authority.

A substantial amendment is any amendment to the terms of the request for clinical trial authorisation, or to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee, that is likely to affect to a significant degree:

a. the safety or physical or mental integrity of the trial participants
b. the scientific value of the trial
c. the conduct or management of the trial
d. the quality or safety of any investigational medicinal product used in the trial.

Notifications of a substantial amendment shall be submitted using Standard Form SF1 (or equivalent).

The form should be signed by the person submitting the notice.

A substantial amendment on which an ethical opinion has been requested should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the trial are urgent safety measures. The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

Amendments that are not substantial amendments (“minor amendments”) may be made at any time and do not need to be notified to the Committee.

**Changes to sites**

Where it is proposed to make important changes in the management of a site (in particular, the appointment of a new PI), a Notification of substantial amendment form should be submitted to the Committee (and to the regulatory authority for information), together with the CV of the new PI if applicable.

The Committee should be notified when a site is closed or withdrawn prematurely.

**Urgent safety measures**

The sponsor or the Principal Investigator at a trial site may take appropriate urgent safety measures in order to protect the trial participants against any immediate hazard to their health or safety.
The Committee and the regulatory authority must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

**Pharmacovigilance**

Reporting of adverse events or any other pharmaceutical, medicinal and/or device related problems must be in accordance with the HAAD Policies on ‘Reporting Adverse Reactions’ and ‘Reporting Medication Errors’.

**Periodic safety report**

For each IMP being tested in the trial, the sponsor should provide the REC with an annual report on the safety of subjects. The report, which should be no longer than 10 pages excluding line listings, should:

a. give a concise description and analysis of all new and relevant findings that could have a significant impact on the trial population
b. analyse the safety profile of the IMP and its implications for subjects’ exposure, taking into account all safety data including drop-outs for safety reasons
c. take into account supporting results of non-clinical studies or other experience with the IMP that are likely to affect the subjects’ safety
d. provide an updated risk-benefit evaluation for the trial
e. describe any measures taken or proposed to minimise risks
f. consider the need to amend or update the protocol, participant information sheet, consent form and investigator brochure.

Periodic reports should be accompanied by a line listing of all Suspected Serious Adverse Reactions (SSARs) occurring in relevant trials during the year, including both expected and unexpected reactions.

Periodic reports should be sent to the REC as soon as practicable after the end of the reporting period, and within 60 days at the latest (use Standard Form SF3 or equivalent as cover sheet).

**Expedited safety reporting**

**Suspected Unexpected Serious Adverse Reactions**

Suspected Unexpected Serious Adverse Reactions (SUSARs) occurring during the trial must be notified to the Committee and the regulatory authority in expedited fashion. (See Annex H: SF3 and HAAD Adverse Reaction Reporting Form).

A SUSAR which is fatal or life-threatening must be reported as soon as possible and in any event within 24 hours after the sponsor becomes aware of the event. Any additional relevant information must be reported within 8 days of sending the first report. A SUSAR which is not fatal or life-threatening must be reported as soon as possible and in any event within 15 days after the sponsor first becomes aware of the event.

In the case of double-blinded trials, all reports of adverse reactions must be unblinded.

Pharmacovigilance reports may be provided to the Committee by either the sponsor, or the sponsor’s representative, or the Principal Investigator. All submissions should be accompanied by the cover sheet for safety reports Standard Form SF3 (or equivalent).
The Principal Investigator and representatives of the sponsor may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of trial participants arising from pharmacovigilance reports.

Other events

HAAD mandates reporting of adverse events or any other pharmaceutical, medicinal and/or device related problems in accordance with the HAAD Policies on ‘Reporting Adverse Reactions’ and ‘Reporting Medication Errors’. The following occurrences should be reported to the REC and regulatory authority within 15 days:

a. An increase in the rate of occurrence or a qualitative change of an expected serious adverse reaction, which is judged to be clinically important

b. Post-study SUSARs that occur after the patient has completed a trial and are reported by the investigator to the sponsor

c. A new event, related to the conduct of the trial or the development of the IMP, that is likely to affect the safety of subjects, such as:
   
   (1) a serious adverse event which could be associated with the trial procedures and which could modify the conduct of the trial (for example a SAE occurring during the run-in period)

   (2) a significant hazard to the subject population such as lack of efficacy of an IMP used for the treatment of a life threatening disease

   (3) a major safety finding from a newly completed animal study (such as carcinogenicity)

   (4) any anticipated end or temporary halt of a trial for safety reasons where the trial is conducted with the same IMP by the same sponsor in another country.

d. The conclusions or recommendations of a Data Monitoring Committee, where relevant for the safety of subjects.

Any information that materially alters the current risk/benefit assessment of the IMP or merits changes in the way the IMP is administered or the overall conduct of the trial shall also be reported to the REC and regulatory authority. (See Annex H: SF3 and HAAD Adverse Reaction Reporting Form).

**Serious Adverse Events (Non-CTIMP research only)**

A Serious Adverse Event (SAE) is an untoward occurrence that:

a. results in death

b. is life-threatening

c. requires hospitalisation or prolongation of existing hospitalisation

d. results in persistent or significant disability or incapacity

e. consists of a congenital anomaly or birth defect

f. is otherwise considered medically significant by the investigator

A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Principal Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.
Reports of SAEs should be provided to the Committee within 24 hours of the Principal Investigator becoming aware of the event (use Standard Form SF3 or equivalent as cover sheet). If applicable, the regulatory authority should also be notified. (See Annex H: SF3 and HAAD Adverse Reaction Reporting Form).

**Conclusion or early termination of the trial**

The sponsor should notify the Committee and the regulatory authority in writing that the trial has ended within 90 days of the conclusion of the research. Unless otherwise specified in the protocol, the conclusion of the trial is normally defined as the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol. Any change to the definition of the conclusion of the trial should be notified to the Committee and the regulatory authority as a substantial amendment.

If the trial is terminated early, the sponsor should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.

Declarations of conclusion or early termination shall be made using Standard Form SF4 (or equivalent).

**Final report**

The sponsor or Principal Investigator should provide the Committee and the regulatory authority with a summary of the clinical trial report within 12 months of the conclusion of the trial. The Committee should also be notified of the arrangements for publication or dissemination of the research including any feedback to participants.

For non-CTIMP research the final report should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

**Further reporting after the conclusion of the trial**

If after the conclusion or early termination of a trial the risk/benefit analysis is considered to have changed, the sponsor or Principal Investigator should notify the main REC in case this affects the planned follow-up of trial participants. The plan for further action to inform or protect participants should be described.

**Review of ethical opinion**

The Committee may review its opinion at any time in the light of any relevant information it receives. It has no power to legally withdraw the opinion it has given but may draw the attention of the regulatory authority to any serious concerns and may recommend that consideration is given to suspending or terminating the regulatory authorisation.

The sponsor or Principal Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the trial.
Serious breaches of Good Clinical Practice or the protocol

The Committee should be promptly notified of any serious breach of the conditions or principles of International Conference on Harmonization Good Clinical Practice (ICH GCP) or of the protocol. A breach should be regarded as serious if it is likely to affect to a significant degree the safety or physical or mental integrity of the subjects of the trial, or the scientific value of the trial. The sponsor should notify the Committee and the regulatory authority in writing within 7 days of the matter coming to their attention. There is no requirement to notify minor breaches of ICH GCP or the protocol.

A minor deviation from the protocol to deal with unforeseen circumstances is not considered to be a serious breach of the protocol provided that it is approved by the Principal Investigator, either in advance or after the event. However, if the deviation would meet the criteria for a substantial amendment it should be notified to the Committee.

Breach of approval conditions

These approval conditions are not legally binding but they set out important guidance which Principal Investigators and sponsors are expected to follow. Failure to comply with the conditions may lead to a change of the Committee’s opinion and a recommendation to the regulatory authority that the authorisation should be suspended or terminated.
Annex D: Administration of REC meetings

Agenda

1. It is recommended that the REC Coordinator prepares the agenda for the meeting, which shall include at least the following:
   a) The date, time and venue of the meeting
   b) Declarations of interest relating to items on the agenda
   c) Minutes of the previous Committee meeting
   d) Matters arising at the previous meeting(s) that the Committee specifically indicated that it wished to consider again
   e) Applications for ethical review to be considered at the meeting
   f) Report by the Coordinator.

2. The agenda may also include discussion of the following where appropriate:
   a) General ethical issues, for example arising from new guidelines or recent publications
   b) Matters relating to the establishment or membership of the REC
   c) Matters relating to Committee procedures
   d) Training issues

Distribution of papers

3. The REC Coordinator shall arrange for distribution of the agenda and papers for review at the meeting 7 days prior to the meeting.

4. Written comments by a member who is unable to attend shall be made available to members at least 1 working day prior to the next meeting.

5. All members shall receive the application form for each new application, together with all supporting documentation.

Minutes

6. The minutes of the REC meeting shall be prepared by the secretary to the meeting or the REC Coordinator. It is not mandatory for the minutes to be formally approved by the Chair before letters are issued to applicants giving the Committee’s decision. The Coordinator shall check the drafting of technical or sensitive issues with the Chair and/or other relevant members if in doubt.

7. In relation to applications for ethical review or notices of substantial amendment, the minutes shall contain a record of the following:
   a) The members, deputy members, referees and observers present for the review
   b) Attendance of members via telephone or video link
   c) Any interests declared, and the decision of the Committee on the participation of the member or deputy member concerned
d) The submission of written comments by members or deputy members

e) The substance of any advice given by a referee

f) The decision of the REC on the application

g) A summary of the main ethical issues considered

h) In the case of a favourable opinion, any special approval conditions or additional advice to be given to the applicant

i) In the case of an unfavourable opinion, the reasons for the decision

j) In the case of a provisional opinion, the further information requested by the REC and the arrangements for considering the information and issuing the final opinion of the REC

k) Where no opinion is given, the issues on which further advice is required from a referee

l) Where an unfavourable opinion is given on a notice of amendment, the reasons for the decision, and any delegation of responsibility for giving the opinion of the REC on a modified amendment

m) The outcome of any vote taken

n) Any formal dissent from the decision of the REC by a named member, with reasons

8. Except where (n) applies, the minutes shall be presented as the outcome of collective discussion, and shall not attribute particular statements to individual members or deputy members attending the meeting.

9. The minutes shall be submitted to the following meeting of the REC for ratification as a true record. The final version shall be signed and dated by the Chair and by the Coordinator. Minutes can be distributed to members by email but a signed hard-copy shall be kept.

10. The minutes shall be treated as confidential to the REC and not routinely disclosed to applicants, sponsors or care organisations. For the purposes of REC governance, copies of minutes shall be made available on request to the appointing authority for the REC.

Responsibilities of the Coordinator

REC meetings

11. The responsibilities of the Coordinator or Assistant Coordinator in relation to REC meetings are as follows:

   a) Publishing the schedule of REC meetings

   b) Preparing the agenda

   c) Distributing the agenda and papers

   d) Inviting Principal Investigators and, where appropriate, supervisors to attend and making the necessary arrangements

   e) Recording apologies for absence prior to the meeting
f) Recording attendance by members, deputy members, referees and observers for the discussion of each application for ethical review

g) Advising the meeting as necessary on compliance with standard operating procedures

h) Making a written record of the meeting

i) Preparing the minutes of the meeting for review and approval at the following meeting

j) Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary

**Report by the Coordinator**

12. Members shall be notified in writing of business undertaken outside REC meetings, including at least the following:

   a) Decisions or actions taken by Committee members under delegated authority
   
   b) Progress reports on research with a favourable opinion
   
   c) Receipt of annual safety reports on CTIMPs, and reports of Data Monitoring Committees
   
   d) Notification of the conclusion or early termination of research
   
   e) Receipt of final study reports
   
   f) The ethical opinion given on the application
   
   g) The members that were involved in considering further information
   
   h) Where an unfavourable opinion was given, it may be of interest to members to have a brief summary of the applicant’s response, highlighting the points that failed to meet the Committee’s requirements.
Annex E: Substantial amendments to CTIMPs

1. The following changes shall normally be regarded as substantial:
   a) Changes to the design or methodology of the study, or to background information affecting its scientific value
   b) Changes to the procedures undertaken by participants
   c) Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study
   d) Changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers
   e) A change of sponsor(s) or sponsor’s legal representative
   f) Appointment of a new Principal Investigator or key collaborator, or temporary arrangements to cover the absence of a PI
   g) A change to the insurance or indemnity arrangements for the study
   h) Appointment of a new Principal Investigator at a research site
   i) A change to the definition of the end of the study
   j) Any other significant change to the protocol or the terms of the REC application.

2. There will, however, be changes to the details of research that have no significant implications for participants or for the conduct, management or scientific value of the study and can be regarded as non-substantial or minor amendments. Examples might be as follows:
   a) Correction of typographical errors in the protocol or other study documentation
   b) Other minor clarifications of the protocol
   c) Changes to the Principal Investigator’s research team (other than appointment of key collaborators)
   d) Changes to the research team at particular trial sites (other than appointment of a new Principal Investigator)
   e) Changes in funding arrangements
   f) Changes in the documentation used by the research team for recording study data
   g) Changes in the logistical arrangements for storing or transporting samples
   h) Extension of the study beyond the period specified in the application form
   i) Issue of an updated Investigator’s Brochure or Summary of Product Characteristics relating to an investigational medicinal product.

3. Amendments normally requiring authorisation only:
   a) Amendments related to the quality of the IMP
   b) Changes to non-clinical pharmacology and toxicology data
   c) Changes to clinical trial and human experience data.
4 Amendments normally requiring a favourable ethical opinion only
   a) Amendments to patient information sheets, consent forms, letters to GPs or their clinicians, letters to relatives/carers, etc (whether generic to the whole study or specific to a particular trial site)
   b) Change of insurance or indemnity arrangements for the trial
   c) Change of the Principal Investigator or appointment of a key collaborator
   d) Change of Principal Investigator at a trial site
   e) Change to the definition of a trial site
   f) Any other significant change to the conduct or management of the trial at particular trial sites
   g) Any other amendments to the terms of the REC application.

5 Amendments normally requiring both authorisation and a favourable ethical opinion
   a) Amendments related to the protocol (except those relating only to patient information sheets, consent forms, etc)
   b) Amendments related to the safety of the IMP
   c) Any other amendments related to the safety or physical or mental integrity of trial participants, or change to the risk/benefit assessment.
   d) Change of the sponsor or sponsor’s legal representative
   e) Change of the CRO assigned significant tasks
   f) Change of the definition of the end of the trial.

6 Where the amendment requires authorisation or ethical opinion only, the notice of amendment form must be sent to the other agency for information.

7 The issue of an updated Investigator’s Brochure for the IMP is not itself regarded as a substantial amendment unless there is a change to the risk/benefit assessment for the trial. There is no requirement to provide the regulatory authority or REC with updated versions of the Investigator’s Brochure routinely or to seek authorisation or an ethical opinion.
Annex F: Research involving human tissue

Research requiring ethical review

1. Researchers require favourable opinion from the facility Research Ethics Committee and explicit approval from the regulatory authority in order to conduct the following activities:
   i) Storing or using the tissue of living or deceased persons for a research project
   ii) Storing or using tissue from the living for a research project without consent where the samples are anonymised to the researcher, i.e. in circumstances where the researcher is unable to identify the tissue donor and not likely to be able to do so in future.
   iii) Analysing human DNA in material from the body of a living person (or using the results of DNA analysis) without consent, in circumstances where they are unable to identify the tissue donor and not likely to be able to do so in future.
   iv) Storing or using tissue for a research project where consent is required.

Project-based applications

2. Project-based applications should be made in the following cases
   a) CTIMPs involving storage or use of human tissue.
   b) Research involving removal of human tissue or other bodily material from the living as part of the protocol (i.e. primarily for research purposes).
   c) Research involving the use of stored tissue or data in circumstances where the researcher is able, or could be able, to identify the donor(s).
   d) Research involving any contact with donors or relatives to seek consent, obtain further data or undertake any other research procedure.
   e) Research involving use of stored tissue from a research tissue bank which does not have ethical approval from a REC.
   f) Research involving use of stored tissue from a research tissue bank, which has ethical approval from a REC, but (a) the terms of the approval do not extend to generic approval for projects receiving tissue from the bank, or (b) the tissue bank manager requires the researcher to obtain project-specific approval before agreeing to release tissue.
   g) Research involving stored tissue from a clinical diagnostic archive that is not licensed to store tissue for use in research and is not ethically approved.

3. Ethical approval for project-specific applications is confined to the specific project described in the protocol and the application form. It is permitted to seek approval for a project to be undertaken in several stages provided that these are clearly defined in the protocol and relate to the same set of research questions. It is not acceptable to use the project-specific application form to seek open-ended approval for use of stored tissue in future research programmes (although the terms of the consent itself may be generic and open-ended, allowing for future approved research using the same samples). Applications not relating to specific projects with a study protocol may be invalidated by Coordinators. Nor is it acceptable to submit substantial...
amendments to approved projects in order to use tissue for another project with a different set of research questions.

**Extended tissue storage**

4. Where a researcher makes a specific project-based application but also plans to store the tissue beyond the life of the project for use in further projects, the following options are available:

a) At the end of the project, the researcher may make a further project-based application. If the second application is also granted a favourable opinion, continued storage of the tissue for use in this project will be lawful without a licence. At the end of the second project the options set out in this paragraph apply in the same way.

b) At the end of the project the researcher may make an application for review of a RTB, including details of the plans for further research. The RTB will require a storage licence.

c) The researcher may hold on to the tissue without a licence under the original REC approval provided it is being held as a record of the completed research project, for example to verify research data. Storage for this purpose without a licence should continue for no longer than necessary. If the tissue continues to be stored without a licence for the purpose of any other research project, further ethical approval should be sought using either the project-specific or RTB application process.

**Research Tissue Bank applications**

5. Organisations responsible for the management of research tissue banks (RTB) must apply for a license from the regulatory authority and must seek a favourable opinion from the facility Research Ethics Committee reviewing the arrangements for collection, storage, use and distribution of tissue. A “research tissue bank” (or “biobank”) is defined for the purpose of these SOPs as:

a) A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval.

b) Tissue banks storing human tissue for use in as yet unspecified research must obtain a licence.
Annex G: Research Tissue Bank model approval conditions

1. Ethical approval is given to the Research Tissue Bank (“the Bank”) by the Research Ethics Committee (“the Committee”) subject to the following conditions.

Communications with the Committee

2. Further communications with the Committee are the personal responsibility of the applicant.

Duration of approval

3. Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the Bank since the original approval together with any proposed new developments.

Licensing

4. A copy of the health facility license and regulatory authorization letter issued by the Health Authority – Abu Dhabi (HAAD) should be provided when available (if not already submitted).

5. The Committee should be notified if the Authority renews the health facility licence and regulatory authorization, varies the licensing conditions or revokes research authorization or facility licence. If the health facility licence is revoked, ethical approval is terminated.

Generic ethical approval for projects receiving tissue

[Note: Use Option A or B, depending on whether the Bank has applied for and received generic approval for projects receiving tissue]

[Option A: For Banks receiving generic approval]

6. Samples of human tissue or other biological material may be supplied and used in research projects to be conducted within the establishment responsible for the Bank and/or by researchers and research institutions external to the Bank within Abu Dhabi] and in other countries in accordance with the following conditions.

   a) The research project should be within the fields of medical or biomedical research described in the approved application form.

   b) The Bank should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add to existing knowledge.

   c) Where tissue samples have been donated with informed consent for use in future research (“broad consent”), the Bank should be satisfied that the use of the samples complies with the terms of the donor consent.

   d) All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e., anonymised or linked anonymised).
e) Samples must not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.

f) A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with all federal and Abu Dhabi laws and regulations, Health Authority – Abu Dhabi policies and standards, the terms of the ethical approval and any other conditions required by the Bank.

7. A research project in Abu Dhabi using tissue provided by a Bank in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval. This means that the researcher will not require a licence for storage of the tissue for use in relation to this project.

8. The Bank may require any researcher to seek specific ethical approval for their project.

9. A Notice of Amendment form should be submitted to seek the Committee’s agreement to change the conditions of generic approval.

**Ethical approval for specific projects**

[Option B: For Banks where the applicant has not applied for generic ethical approval for projects receiving tissue or such approval has not been given by the Committee]

10. The approval for the Bank does not confer generic ethical approval for specific research projects using tissue supplied by the Bank. Where project approval is required under Health Authority – Abu Dhabi (HAAD) policies, a specific application should be made by the researcher. Such applications should normally be made to the Research Ethics Committee.

11. To request generic ethical approval for projects to which tissue is supplied, the Bank should submit a new application rather than a Notice of Amendment.

**Records**

12. The Bank should maintain a record of all research projects to which tissue has been supplied. The record should contain at least the full title of the project, a summary of its purpose, the name of the Principal Investigator, the sponsor, the location of the research, the date on which the project was approved by the Bank, details of the tissue released and any relevant reference numbers.

13. The Committee may request access to these records at any time.

**Annual reports**

14. An annual report should be provided to the Committee listing all projects for which tissue has been released in the previous year. The list should give the full title of each project, the name of the Principal Investigator, the sponsor, the location of the research and the date of approval by the Bank. The report is due on the anniversary of the date on which ethical approval for the Bank was given.

15. The Committee may request additional reports on the management of the Bank at any time.
Substantial amendments

16. Substantial amendments should be notified to the Committee and ethical approval sought before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the Bank as described in the application to the Committee and supporting documentation.

17. The Notice of Amendment form should be used to seek approval.

18. The following changes should always be notified as substantial amendments:
   a) Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the Bank.
   b) Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.
   c) Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.
   d) A change to the conditions of generic approval. *(Omit if not applicable).*
   e) Any other significant change to the governance of the RTB.

Serious adverse events

19. The Committee should be notified as soon as possible of any serious adverse event or reaction, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the tissue. The criteria for notifying the Committee will be the same as those for notifying the Health Authority – Abu Dhabi (HAAD) of serious adverse events as described in Annex C.

Other information to be notified

20. The Committee should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for communication with the Committee to another person at the establishment.

Closure of the Bank

21. Any plans to close the Bank should be notified to the Committee as early as possible and at least two months before closure. The Committee should be informed what arrangements are to be made for disposal of the tissue or transfer to another research tissue bank.

22. Where tissue is transferred to another research tissue bank, the regulatory authorization and ethical approval for the Bank are not transferable. Where the second bank is ethically approved, it should notify the responsible Research Ethics Committee. The terms of its own ethical approval would apply to any tissue it receives.

Breaches of approval conditions

23. The Committee should be notified as soon as possible of any breach of these approval conditions.
24. Where serious breaches occur, the Committee may review its ethical approval and may, exceptionally, suspend or terminate the approval.
## Annex H: Standard letters and forms

### Standard letters

| SL1  | Acknowledgement of valid application |
| SL2  | Request for advice from referee      |
| SL3  | Ethical opinion after review         |
|      | Option 1: Favourable opinion at first review |
|      | Option 2: Unfavourable opinion at first review |
|      | Option 3: Provisional opinion with request for further information |
|      | Option 4: No opinion pending consultation with external referee |
|      | Option 5: Provisional opinion with request for further information following consultation with referee |
|      | Option 6: Favourable opinion following consideration of further information |
|      | Option 7: Unfavourable opinion following consideration of further information |
| SL4  | Acknowledgement of notice of a substantial amendment for ethical review |
| SL5  | Ethical opinion of substantial amendment |
|      | Option 1: Favourable opinion of substantial amendment |
|      | Option 2: Unfavourable opinion of substantial amendment |
| SL6  | Determination of Exemption from Requirements for Full REC Review |
|      | Option 1: Exemption Approved |
|      | Option 2: Exemption Rejected |

### Standard forms

| SF1  | Notification of substantial amendment |
| SF2  | Progress report form                  |
| SF3  | Safety report form                    |
| SF4  | Declaration of the end of a trial/study |
| SF5  | Request for review of research involving human subjects (Exemption request) |

### Appointment letters

| AL1  | Terms and conditions of appointment as a member of the Facility REC |
| AL2  | Confidentiality Agreement with Observer at a Facility REC meeting |
| AL3  | Terms and conditions of appointment for a deputy member of the Facility REC |
Standard Letter 1
Acknowledgment of a Valid Application

Date:

Research Ethics Committee (REC):
Address:
Tel:
Fax/Email:

Principal Investigator:
Address:
Tel:
Fax/Email:

REC Reference:
Title of Project:

Dear [Name]:

I hereby acknowledge receipt of your application for ethical review on [Date].

I confirm that your application is valid and will be reviewed by the Research Ethics Committee at the meeting scheduled for [Date].

The Committee will issue an ethical opinion on this application within a period of 60 days from the date of acknowledgement of a valid application. Therefore, a decision will be reached by [Date].

You will be informed of the decision within 5 working days of the date on which it is made.

Yours sincerely,

Committee Secretary

E-mail:
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear 

The Research Ethics Committee has received the enclosed application, which will be reviewed at the meeting to be held on .

In order to give its opinion, the Committee seeks your views as an external expert on this application. Please review this application and forward any comments that you consider relevant to the review by this Research Ethics Committee.

In particular, the Committee will be interested in your views regarding the following issues:

In order to comply with its obligation to prepare an opinion within 60 days of acknowledgement of a valid application, the committee would appreciate a response from you no later than . If you are unable to respond, please inform me at your earliest possible convenience.

Please declare if you have any personal interest in relation to this research study.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 3: Ethical Opinion after Review
Option 1: Favorable Opinion at First Review

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear :

The Research Ethics Committee has reviewed the above application at its meeting held on .

The Committee has given a favourable ethical opinion for the above project based on the application form, protocol and supporting documentation that comply with the conditions and principles established by the International Conference on Harmonisation - Good Clinical Practice (ICH GCP).

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear [Name]:

The Research Ethics Committee has reviewed the above application at its meeting held on [Date].

The Committee was unable to give a favourable ethical opinion for the above project, for the following reasons:

You are NOT authorised to continue with this research.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear :

The Committee is unable to give an ethical opinion based on the information and documentation received thus far. Before giving its opinion, the Committee requests that you provide further information.

The time period for review has been suspended as of and will recommence on the day the Committee acknowledges receipt of the requested information.

Please address the following questions, including any required revisions to the application or supporting documentation:

Please forward revised documentation highlighting significant changes and resubmit the application with a new version number and date.

You will be informed of the outcome of the ethical review within 5 working days of its decision.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear [Name]:

The Committee is unable to give an ethical opinion based on the information and documentation received thus far. Before giving its opinion, the committee must first consult with the external referee.

The time period for review has been suspended as of [Date] and will recommence on the day the Committee acknowledges receipt of the report from the external referee.

You will be informed of the outcome of the ethical review within 5 working days of its decision.

Yours sincerely,

Committee Chair/Secretary

E-mail:

Enclosure: Copy of application documentation
Standard Letter 3: Ethical Opinion after Review  
Option 5: Provisional Opinion / Request for Further Information Following Consultation with Referee

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear [Name],

The Committee is unable to give an ethical opinion following consultation with the external referee. Before giving its opinion, the Committee requests that you provide further information.

The time period for review has been suspended as of [Date] and will recommence on the day the Committee acknowledges receipt of the requested information.

Please address the following questions, including any required revisions to the application or supporting documentation:

Please forward revised documentation highlighting significant changes and resubmit the application with a new version number and date. You will be informed of the outcome of the ethical review within 5 working days of its decision.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear : The Research Ethics Committee has reviewed the above application and supplementary information at its meeting held on . The Committee has given a favourable ethical opinion for the above project based on the application form, protocol and supporting documentation that comply with the conditions and principles established by the International Conference on Harmonisation - Good Clinical Practice (ICH GCP).

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 3: Ethical Opinion after Review
Option 7: Unfavourable Opinion Following Consideration of Further Information

Date:

Research Ethics Committee (REC):
Address:
Tel:
Fax/Email:

Principal Investigator:
Address:
Tel:
Fax/Email:

REC Reference:
Title of Project:

Dear [Name],
The Research Ethics Committee has reviewed the above application and supplementary information at its meeting held on [Date].

The Committee was unable to give a favourable ethical opinion for the above project, for the following reasons:

You are NOT authorised to continue with this research.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 4  
Acknowledgment of Notice of a Substantial Amendment for Ethical Review

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear [Name]:

I hereby acknowledge receipt of your application and substantial amendment for ethical review on [Date].

I confirm that your application with amendment is valid and will be reviewed by the Research Ethics Committee at the meeting scheduled for [Date].

The Committee will issue an ethical opinion on this application and substantial amendment within a period of 60 days from the date of acknowledgement of a valid application. Therefore, a decision will be reached by [Date].

You will be informed of the decision within 5 working days of the date on which it is made.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 5: Ethical Opinion of Substantial Amendment
Option 1: Favourable Opinion of Substantial Amendment

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear [Name]:
The Research Ethics Committee has reviewed the above application and substantial amendment at its meeting held on [Date].

The Committee has given a favourable ethical opinion for the above project with amendment based on the application form, protocol and supporting documentation.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear 

The Research Ethics Committee has reviewed the above application and substantial amendment at its meeting held on .

The Committee was unable to give a favourable ethical opinion for the above project with amendment based on the application form, protocol, and supporting documentation, for the following reasons:

You are NOT authorised to continue with this research.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 6: Determination of Exemption from Requirements for Full REC Review

Option 1: Exemption Approved

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Dear :

The Chairman of the Research Ethics Committee (or his designee) has reviewed the above application and has determined that it is exempt from the requirements for full REC review per HAAD research policies and standards.

The exemption category is .

The research project may proceed but must comply by all other research ethics requirements, such as solicitation of informed consent and protection of subject confidentiality and privacy.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Letter 6: Determination of Exemption from Requirements for Full REC Review

Option 1: Exemption Rejected

Date:

Research Ethics Committee (REC):
Address:
Tel:
Fax/Email:

Principal Investigator:
Address:
Tel:
Fax/Email:

REC Reference:

Title of Project:

Dear : 

The Chairman of the Research Ethics Committee (or his designee) has reviewed the above application and has determined that it is NOT exempt from the requirements for full REC review per HAAD research policies and standards.

The research proposal will be submitted for review by the full Research Ethics Committee.

Yours sincerely,

Committee Chair/Secretary

Enclosure: Copy of application documentation
Standard Form 1
Notification of Substantial Amendment

Research Ethics Committee (REC):

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Please indicate the type of amendment:

|   | Amendment to information previously given.  
|   | If yes, please attach a summary of the main changes and their significance to the study. |
|   | 1. Yes □  No □ |

|   | Amendment to protocol.  
|   | If yes, please submit the revised protocol highlighting changes in bold. |
|   | 2. Yes □  No □ |

|   | Amendment to consent form(s)  
|   | If yes, please submit revised documents highlighting changes in bold. |
|   | 3. Yes □  No □ |

Please list attached documents (if any):

1.

2.

3.

I confirm that the information in this document is accurate to the best of my knowledge.

Signature of Principal Investigator:

Date:
Standard Form 2
Progress Report Form

Research Ethics Committee (REC):

Principal Investigator:

Address:

Tel:

Fax/Email:

REC Reference:

Title of Project:

Actual Start Date of Study (YYYY/MM/DD):

Expected Completion Date (YYYY/MM/DD):

Please list the major accomplishments of the study to-date:

1. 
2. 
3. 

I confirm that the information in this document is accurate to the best of my knowledge.

Signature of Principal Investigator

Date:
# Standard Form 3

## Safety Report Form

**Research Ethics Committee (REC):**

**Principal Investigator:**

**Address:**

**Tel:**

**Fax/Email:**

**REC Reference:**

**Title of Project:**

Please complete all questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have any participants dropped out of the study for safety reasons?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Have any participants experienced a Serious Adverse Event; death, disability, life threatening condition, or hospitalization?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Has the event been reported to the regulatory authority? (See HAAD Adverse Reaction Reporting Form: <a href="http://www.haad.ae/haad/tabid/900/Default.aspx">http://www.haad.ae/haad/tabid/900/Default.aspx</a>)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please describe any new and relevant findings that may have a significant impact on the trial population and steps to mitigate risks:

4.  
5.  
6.  

I confirm that the information in this document is accurate to the best of my knowledge.

**Signature of Principal Investigator:**

**Date:**
Health Authority Abu Dhabi
Pharmacovigilance Center

Adverse Reaction Reporting Form
Suspected to be related to Medical Products
(Please complete as much as possible, but do not be put off reporting because some details are missing)

A. Patient Details (See Confidentiality section)

Name: ___________________________ Age/O.B: ___________________________
Sex: M F Weight (kg): ___________________________ Medical Record No: ___________________________
Patient Contact Details: ___________________________

B. Medical products used:

<table>
<thead>
<tr>
<th>Medical product Name “Generic &amp; Brand” (Manufacturer and Batch No. if known)</th>
<th>Dose, Route and Frequency</th>
<th>Therapy starting Date</th>
<th>Therapy stopping Date</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Others:

| 1 | 2 | 3 |

Please Check In case of: ☐ Medication Error ☐ Drug Abuse ☐ Self Medication ☐ Poisoning

C. Adverse Reaction

Description of the reaction(s): ___________________________

Onset date of reaction: ___________________________ End date of reaction: ___________________________

Action taken towards Adverse Reaction:
☐ Drug withdrawn ☐ Dose reduced ☐ Dose Increased
☐ Dose not changed ☐ Unknown ☐ Not applicable

Reaction abated after use stopped or dose reduced: ___________________________

Reaction reappeared after reintroduction:
☐ Yes ☐ No ☐ Not applicable

Treatment of Adverse Reaction:
☐ No ☐ Yes, (medications and/or other therapy) include dates

Relevant tests / laboratory data including dates: ___________________________

Other relevant History, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking, renal dysfunction etc): ___________________________

D. Outcome of Adverse Reaction

☐ Recovered ☐ Recovering ☐ No Improvement ☐ Unknown

E. Seriousness of Adverse Reaction (Tick all applicable)

☐ Death (Include date) ☐ Life threatening ☐ Permanent Disability
☐ Hospitalization ☐ Prolonged hospitalization more than 24 hr ☐ Congenital Anomaly
☐ Required intervention to prevent permanent/ impairment/ damage ☐ Others: ___________________________

F. If this is a follow up report of an already reported AR case, please place an ‘X’ in this box: ☐

G. Reporter Details.

(Name and complete address) ___________________________
Profession (Specialty): ___________________________ Date of filling report: ___________________________

Phone: ___________________________ Fax: ___________________________ E-mail: ___________________________ Signature: ___________________________ Report No: ___________________________
Adverse Reaction (AR) Reporting Guidelines

- Pharmacovigilance
  Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. The scope of Pharmacovigilance also covers safety monitoring of herbal medicines, traditional and complementary medicines, blood products, biologicals, vaccines and medical devices.

- An Adverse Reaction is a harmful and unintended response to drugs. This includes any undesirable patient effect suspected to be associated with drug use. Unintended effect, drug abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.

- A serious Adverse Reaction is any untoward medical occurrence that at any dose:
  - results in death
  - requires hospitalization or prolongation of existing hospitalization
  - causes congenital malformation
  - results in persistent or significant disability/incapacity
  - is life-threatening

- The value of reporting AR to Pharmacovigilance Center is to
  - Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
  - Improve public health and safety in relation to the use of medicines.
  - Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use; and
  - Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

- What to Report
  Report all suspected Adverse Reactions from:
  - Pharmaceutical products (Prescription and non-preservation drugs)
  - Herbal Medicines
  - Traditional and complementary Medicines
  - Vitamins and Minerals
  - Blood derived products

- Reporting by Whom
  Health care professionals including but not limited to medical doctors, pharmacists, nurses, dentists, allied health professionals, midwives, etc. are the preferred sources for reporting an AR. But anyone including consumers, patients, caregivers, etc. can also report an adverse reaction (preferably through their health care professional).

- When to report
  Expedited reporting of serious ARs is required as soon as possible, but in no case later than 24 hours of initial receipt of information by health care professional. All other ARs should also be reported at the earliest, but not later than 15 calendar days.

- How to Report
  - Fill out HAAD AR reporting form
  - Attach additional information, if needed
  - Use a separate form for each patient.
  - Report directly to Pharmacovigilance Center, or by fax/email.

- Confidentiality
  Any information related to the identity of the patient and/or the reporter of the Adverse Reaction will be protected to the fullest extent of law and will not be used in any way against him.

For submitting the completed AR forms or for more information on reporting, please contact:

Health Authority Abu Dhabi
Pharmacovigilance Center

Telephone: 02 4193 586 / 348 / 580
Facsimile: 02 4496879
Email: pv@haad.ae
# Standard Form 4
## Declaration of the End of a Trial/Study

<table>
<thead>
<tr>
<th>Research Ethics Committee (REC):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Tel:</td>
</tr>
<tr>
<td>Fax/Email:</td>
</tr>
<tr>
<td>REC Reference:</td>
</tr>
<tr>
<td>Title of Project:</td>
</tr>
<tr>
<td>Actual Start Date of Study (YYYY/MM/DD):</td>
</tr>
<tr>
<td>Expected Completion Date (YYYY/MM/DD):</td>
</tr>
<tr>
<td>Actual Completion Date (YYYY/MM/DD):</td>
</tr>
</tbody>
</table>

1. **Did this study terminate prematurely?**
   - Yes
   - No

2. **Is a final report stating the research outcomes attached with this form?**
   - Yes
   - No

   2a. If no, please specify when will this report be submitted?

   *Please note that the report date should be within one year of the end of study.*

<table>
<thead>
<tr>
<th>DATE (YYYY/MM/DD):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

3. **What is the reason for the early termination of the study?**

4. **Are there any potential implications for research participants resulting from the termination?** If yes, please describe the action planned to address these implications.

   Signature of Principal Investigator:

   Date:
Standard Form 5
Request for Exempt Review of Research Involving Human Subjects

(Request for Exemption from Requirement for Full REC Review)

INSTRUCTIONS: Please complete the research ethics application and append this form as a cover sheet to request review of human subject research that may be exempt from full Research Ethics Committee review per HAAD REC SOP section 7.7. If the research involves a survey or questionnaire, please include the survey or questionnaire in the application.

The completed research ethics application and this form (with required signatures) must be reviewed and approved by a Research Ethics Committee with jurisdiction over the research site.

Research Ethics Committee (REC):

Principal Investigator:

Address:

Tel:

Fax/Email:

Title of Project:

Signature of Principal Investigator:

Date:
Standard Form 5 (page 2)
Request for Exempt Review of Research Involving Human Subjects

Exemption Categories (A-F)

<table>
<thead>
<tr>
<th>Category</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Is the research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>B</td>
<td>Does the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? (i) If so, is the collected information recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects? (ii) If subjects CAN be identified, is there NO reasonable risk of criminal or civil liability or damage to the subjects' financial standing, employability, or reputation if responses are disclosed?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>C</td>
<td>Does the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (B) above? (i) Do UAE or Abu Dhabi emirate laws require without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter? (ii) If this research involves any interviews, participant/observation by the researchers or interaction with the subjects in any way, are children excluded as subjects of this research?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>D</td>
<td>Does the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, from publicly available sources or is the collected information recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>E</td>
<td>Is this research or demonstration project conducted by or subject to the approval of HAAD department or agency heads and designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>F</td>
<td>Is this research a taste or food quality evaluation or consumer acceptance study where (i) wholesome foods without additives are consumed or (ii) food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Abu Dhabi Food Control Authority or Environment Agency-Abu Dhabi?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Appointment Letter 1

Terms and Conditions of Appointment as a Member of the Facility REC

Date:

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Name of Member:

Address:

Tel:

Fax/Email:

Dear 

I hereby acknowledge that you have been appointed as a member of the REC from until .

Information provided to the committee is provided in confidence and shall be regarded as confidential. It shall not to be disclosed to any third party or outside REC deliberations.

REC appointees shall familiarize themselves with relevant policies and procedures issued by the REC and Health Authority – Abu Dhabi and shall comply with all relevant policies and privacy laws.

Thank you for your participation as a member of the REC.

Yours sincerely,

Committee Chair/Secretary
Appointment Letter 2
Confidentiality Agreement with Observer at a Facility REC Meeting

Research Ethics Committee (REC):

Address:

Tel:

Fax/Email:

Name of Member:

Address:

Tel:

Fax/Email:

As an observer / member of the above named REC, I hereby certify that I will not disclose any information disclosed at REC meetings, specifically:

1. I will protect confidential information in a reasonable manner;
2. I will use confidential information only to perform the obligations of reviewing proposals received by the REC;
3. I will not reproduce information disclosed during REC deliberations.

Signature:

Date (YYYY/MM/DD):
Appointment Letter 3  
Terms and Conditions of Appointment for a Deputy Member of the Facility REC

Date:

Research Ethics Committee (REC):

Address:

Tel: Fax/Email:

Name of Member:

Address:

Tel:

Fax/Email:

Name of Deputy:

Address:

Tel:

Fax/Email:

Dear : 

I hereby acknowledge that you have been appointed as a deputy member for the above named REC to substitute for the above named REC member for purpose of reviewing proposals submitted to the REC.

Information provided to the committee is provided in confidence and shall be regarded as confidential. It shall not to be disclosed to any third party or outside REC deliberations.

REC appointees shall familiarize themselves with relevant policies and procedures issued by the REC and Health Authority – Abu Dhabi and shall comply with all relevant policies and laws.

Yours sincerely,

Committee Chair/Secretary