

Health Authority – Abu Dhabi		هيئة الصحة - أبوظبي
HAAD Facilities Title: Policy Governing Research Involving Human Subjects	Reference Number: PHP/PHR/R03 Issue Date: February 2010 Next Review Date: February 2012	

CHAPTER I: INTRODUCTION

1 Purpose

- 1.1 This Policy sets out the ethical framework governing Human Subjects Research in the Emirate of Abu Dhabi.

2 Background

- 2.1 The Health Authority - Abu Dhabi (**HAAD**) is responsible for regulating all aspects of Human Subjects Research.
- 2.2 Human Subjects Research involves a range of interactions with individuals which may raise ethical concerns. This Policy therefore establishes a framework for ethical conduct in Human Subjects Research.
- 2.3 This Policy is not intended to be an exhaustive direction on the ethical conduct of Human Subjects Research. Where other standards, guidelines and codes of practice in particular research fields are consistent with this Policy, Institutions, Investigators and members of ethical review bodies should draw on them when necessary to clarify the ethical obligations in particular contexts.

3 Scope

- 3.1 This Policy introduces a requirement for all Human Subjects Research to be granted ethical approval by a Research Ethics Committee (**REC**). It also sets out the key principles which should guide the REC's decision whether to grant approval.
- 3.2 Research ethics is only one element of an Institution's responsibilities for research governance. Compliance with legal obligations governing research forms another part, which is not within the scope of this Policy.

4 Related Policies

- 4.1 The following HAAD Policies are closely related to this one –
- 4.1.1 *“Licensing Requirements for Institutional Human Subjects Research”* (Ref PHP/PHR/R02).
- 4.1.2 *“Abu Dhabi Health Research Council”* (Ref PHP/PHR/R01).

5 Interested Parties

- 5.1 This Policy is of relevance to all individuals or institutions involved or wishing to engage in Human Subjects Research in the Emirate of Abu Dhabi.

CHAPTER II: ESTABLISHMENT OF RESEARCH ETHICS COMMITTEES

6 The Abu Dhabi Research Ethics Committee

- 6.1 The Abu Dhabi Health Research Council (**the Council**) shall establish a committee known as the Abu Dhabi Research Ethics Committee (**ADREC**).
- 6.2 The ADREC shall be constituted in accordance with this Chapter, and shall establish and follow the procedures and carry out the functions that are in each case set out in Chapters II and III.
- 6.3 The validity of any decision or approval issued by the ADREC shall not be affected by any defect in the constitution of the ADREC or by any failure on its part to establish and follow procedures or to carry out functions in accordance with Chapters II and III.

7 Institutional Research Ethics Committees

- 7.1 An Institution may establish its own Research Ethics Committee.
- 7.2 A committee established by an Institution shall be referred to as an Institutional REC.
- 7.3 Each Institution which establishes an Institutional REC must ensure that it is constituted and operated in accordance with relevant HAAD policies and the [*HAAD Standard Operating Procedure for Research Ethics Committees.*]
- 7.4 A decision or approval of an Institutional REC shall not be valid, and will be treated as having no effect, if there is a defect in the constitution of the Institutional REC or if it does not establish and follow the procedures or carry out the functions in accordance with Chapters II and III.

8 The REC Coordinator

- 8.1 The ADREC shall establish a function known as the REC Coordinator.
- 8.2 The role of the REC Coordinator shall be to:
 - 8.2.1 maintain a list of all the members of all Institutional RECs and their qualifications;
 - 8.2.2 maintain a database of all Research Proposals reviewed by each Institutional REC, and of all decisions and approvals of that REC;

CHAPTER III: DUTIES OF INSTITUTIONS

9 Requirement for Ethical Approval

- 9.1 An Investigator may not carry out Human Subjects Research unless that Research is in accordance with a Research Proposal that has been submitted to and has obtained the approval of:
- 9.1.1 His/her Institutional REC; or
 - 9.1.2 The ADREC, where an Institutional REC has not been established.
- 9.2 An Investigator wishing to submit a Research Proposal to a REC must do so using the Research Application Form available at (www.haad.ae).
- 9.3 An Investigator must disclose fully to the REC when submitting its Research Proposal any financial or other conflict of interest that may exist in relation to any of the proposed Investigators. The circumstances that must be disclosed include, but are not limited to, the existence of:
- 9.3.1 any agreement between an Investigator and any person (including the Institution) under which the value of compensation paid to the Investigator for conducting the Research could be influenced by its outcome;
 - 9.3.2 any proprietary interest held by an Investigator in any product which is a subject of the Research;
 - 9.3.3 any financial interest held by an Investigator in a company or body which may benefit from the outcome of the Research (not including his or her employment status with the Institution);
 - 9.3.4 any non-financial benefits which may be available to an Investigator depending on the outcome of the Research.
- 9.4 An Investigator must provide the REC with such additional documentation or information as the REC considers necessary in order to review the Research Proposal.

10 Authorised Research Proposals

- 10.1 In carrying out Human Subjects Research which is the subject of an Authorised Research Proposal, an Investigator must at all times:
- 10.1.1 act in accordance with the terms of the Authorised Research Proposal (including any revisions or conditions specified by the REC when approving the Proposal);
 - 10.1.2 act consistently with the Key Ethical Principles set out at Chapter IV;
 - 10.1.3 comply with its duties under Chapters V to IX;

- 10.1.4 permit the REC to observe, or have a third party observe on its behalf, the conduct of the Research; and
- 10.1.5 permit the REC to audit, or have a third party audit on its behalf, the Research facilities, files, and progress reports.
- 10.2 An Investigator must promptly notify the REC of any:
 - 10.2.1 material change in circumstances occurring after the approval of a Research Proposal; or
 - 10.2.2 inaccuracy, of which it has since become aware, in any information provided to the REC in support of the Authorised Research Proposal.
- 10.3 An Investigator must promptly notify the REC of any suspension or premature termination of its Research, and of the reasons for that suspension or termination.
- 10.4 An Investigator must immediately restrict, suspend or terminate Research where it is directed by the REC to do so.
- 10.5 In carrying out Human Subjects Research which is the subject of an Authorised Research Proposal, an Investigator must submit to the REC:
 - 10.5.1 progress reports including written summaries of the progress of the Research, as often as the REC may specify;
 - 10.5.2 a safety report immediately upon the occurrence of any serious adverse event; and
 - 10.5.3 a final report upon the completion of the Research, to be submitted no later than ninety (90) days following the date of completion.

CHAPTER IV: KEY ETHICAL PRINCIPLES

11 Conformity with international ethical principles

11.1 Human Subjects Research must conform to generally accepted international principles and values of ethical conduct in research, as described in:

11.1.1 the Nuremberg Code¹;

11.1.2 the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects²; and

11.1.3 the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research³.

11.2 In particular, Human Subjects Research must be:

11.2.1 justifiable by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing;

11.2.2 designed or developed using methods appropriate to achieving the aims of the Research Proposal;

11.2.3 based on a thorough study of the literature and where appropriate preceded by adequate laboratory and/or animal studies;

11.2.4 conducted with integrity and carried out with a commitment to search for knowledge;

11.2.5 undertaken with a commitment to disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding;

11.2.6 just, in that the selection, exclusion and inclusion of categories of Subjects or Donors and recruitment and distribution of benefits of participation is fair, the process is accurately described in its methods and results, and there is no exploitation of Subjects or Donors;

11.2.7 respectful of the privacy, confidentiality and cultural sensitivities of the Subjects or Donors and, where relevant, their communities;

11.2.8 respectful of the right of Subjects and Donors to make their own decisions;

¹ Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.. Washington, D.C.: U.S. Government Printing Office, 1949.

² World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects 2008: Sixth revision, 59th Meeting, Seoul.

³ The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1991.

- 11.2.9 where Subjects or Donors are unable to make their own decisions, or have diminished capacity to do so, designed to empower them where possible and to provide for their protection as necessary; and
- 11.2.10 conducted in an impartial and transparent manner unless there are specific and justifiable reasons preventing it.

12 Risk Assessment

- 12.1 Human Subjects Research can be ethically acceptable only if its potential benefits outweigh its risks, following an assessment which involves:
 - 12.1.1 identifying any risks;
 - 12.1.2 gauging their probability of occurrence and likely severity;
 - 12.1.3 assessing the extent to which they can be minimised;
 - 12.1.4 determining whether they are justified by the potential benefits of the Research; and
 - 12.1.5 determining how they can be managed.

13 Investigators

- 13.1 Human Subjects Research must always be conducted by competent Investigators who:
 - 13.1.1 have qualifications, education, training and experience that is adequate to their degree of responsibility for the proper conduct of the Research;
 - 13.1.2 are familiar with current HAAD policies relating to the Research;
 - 13.1.3 are both independent and impartial;
 - 13.1.4 treat the human body and Human Tissue with respect; and
 - 13.1.5 are aware of cultural or religious differences in the meaning and significance attached to the body or specific parts of it before approaching potential Subjects or Donors.
- 13.2 Prior to participating in human subjects research, all investigators and research personnel shall receive HAAD certification by successfully completing a research ethics training course accredited by HAAD, such as the “Basic Course for the Protection of Human Research Subjects” provided by the Collaborative Institutional Training Initiative (CITI) and available online at <https://www.citiprogram.org/>.
- 13.3 Each investigator shall be required to renew HAAD certification at least every three (3) years by taking a refresher course in research ethics, such as the CITI “Refresher Course for the Protection of Human Research Subjects.”.

CHAPTER V: INFORMED CONSENT

14 Informed Consent of Human Subjects

- 14.1 An Investigator must obtain Informed Consent to Human Subjects Research from each individual who is a Subject of that Research or from his or her legally authorised representative.
- 14.2 An Investigator must ensure that the Informed Consent of each Subject is documented by the use of a written Consent Form approved by the REC.
- 14.3 The Consent Form must either:
 - 14.3.1 set out in full the Elements of Informed Consent; or
 - 14.3.2 truthfully state that the Elements of Informed Consent have been presented orally to the Subject (or his or her legally authorised representative).
- 14.4 The Consent Form must be written in terms that can be readily understood by Subjects participating in the Research.
- 14.5 The Consent Form must be signed and dated by the Subject (or the Subject's legally authorised representative) and by the Investigator who obtained the consent.
- 14.6 A signed and dated copy of the Consent Form must be given to the Subject, or to the Subject's legally authorised representative if he or she has signed the Form.

15 Elements of Informed Consent

- 15.1 The Elements of Informed Consent are the matters that must be communicated to a Subject before Informed Consent is given, and must always include:
 - 15.1.1 a statement of the purpose of the Human Subjects Research, the expected duration of the Subject's participation, a description of any procedures to be followed, and an identification of any procedures that are experimental;
 - 15.1.2 a description of any treatment included in the Research, and the probability of random assignment to each treatment;
 - 15.1.3 a description of any foreseeable risks and benefits to the Subject;
 - 15.1.4 if the Research involves a risk of harm to the Subject, an explanation of whether any compensation or medical treatment is available if injury occurs to the Subject and if so, what that compensation or treatment will be;
 - 15.1.5 a disclosure of any appropriate alternative procedures or courses of treatment;
 - 15.1.6 a statement of the Subject's responsibilities with respect to the Research;
 - 15.1.7 a statement describing how confidentiality will be maintained or private information identifying the Subject will be dealt with;

- 15.1.8 a statement concerning the access to the Subject's records that the REC, the auditors, HAAD (and any of their agents) will have for the verification of the procedures and data associated with the Research;
 - 15.1.9 the name and contact details of a person the Subject may contact for further information regarding the Research,
 - 15.1.10 a statement of the Subject's rights, and the name and contact details of a person the Subject should contact in the event of injury arising in conjunction with the Research; and
 - 15.1.11 a statement that the Subject's participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the Subject is otherwise entitled, and that the Subject may stop participating at any time without penalty or loss of benefits to which he or she is entitled.
- 15.2 To the extent that is relevant, the Elements of Informed Consent must also include:
- 15.2.1 a statement addressing any cultural or religious concerns of the Subject;
 - 15.2.2 a description of any foreseeable risks to an unborn foetus carried by the Subject or to an infant being nursed by the Subject;
 - 15.2.3 a statement that the Research may involve risks to the Subject (or an embryo or foetus carried by the Subject, if the Subject is or may become pregnant) that are currently unforeseeable;
 - 15.2.4 a statement of any anticipated circumstances under which the Subject's participation in the Research may be terminated by the Investigator without the Subject's consent;
 - 15.2.5 a statement of any costs to the Subject that may result from participation in the Research;
 - 15.2.6 a statement of the consequences of a Subject's decision to withdraw from the Research and a description of the procedures for an orderly termination of participation by the Subject; and
 - 15.2.7 a statement that any significant new findings developed during the course of the Research, if they may relate to the Subject's willingness to continue participation, will be provided to the Subject.

16 Vulnerable Subjects

- 16.1 An Investigator which seeks to obtain Informed Consent from vulnerable individuals, including (but not limited to):
 - 16.1.1 those with impaired mental capacity;
 - 16.1.2 children;
 - 16.1.3 those who do not speak English; and

16.1.4 those who are illiterate,

must provide additional elements of protection, both with regard to obtaining and documenting Informed Consent, where that is necessary for the welfare of the Subject.

17 Exception to the Requirement for Informed Consent

17.1 The duty of an Investigator to obtain Informed Consent in accordance with the requirements of this Chapter shall not apply in the case of an individual Subject where all of the following conditions are satisfied:

17.1.1 the Subject is confronted by a life-threatening situation necessitating the use of an unproven treatment, medical device or product that is the subject of the Research;

17.1.2 the Subject is incapable of communicating with the Investigator due to his or her medical condition;

17.1.3 there is insufficient time to obtain Informed Consent from the Subject's legally authorised representative;

17.1.4 there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the Subject; and

17.1.5 both the Investigator and a physician who is not otherwise participating in the Research certify in writing that all of the above conditions are met and submit that certificate to the REC within five (5) working days.

18 Scope of this Chapter

18.1 An Institution may have its own policies in relation to Informed Consent to the extent that they provide additional protections and benefits to Subjects and are otherwise consistent with the requirements of this Chapter.

18.2 The requirements in this Chapter are not intended to limit the applicability of the "*HAAD Consent Policy*" (Ref PPR/HCP/P0003/09).

18.3 Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent that he or she is permitted or required to do so under other legal provisions.

CHAPTER VI: CONDUCT OF HUMAN SUBJECTS RESEARCH

19 Suspension or Early Termination of Research

19.1 An Institution must promptly suspend or terminate Human Subjects Research where:

19.1.1 it becomes (or should be) apparent to the Institution that the risks to Subjects are greater than were anticipated at the time at which the Research Proposal was approved, to the extent that they are no longer justified by the benefits arising from the research; or

19.1.2 the Research causes unexpected serious harm to any one or more Subjects.

19.2 An Institution must establish procedures to be followed in the event of suspension or premature termination of Human Subjects Research. These procedures must include provision:

19.2.1 for the prompt notification of the suspension or termination to Subjects; and

19.2.2 for appropriate therapy and follow-up care for Subjects.

20 Use of a Placebo

20.1 An Investigator may, in carrying out Human Subjects Research, withhold from Subjects a therapy that is known to be superior to an intervention being tested only in cases where there either is no established effective therapy or where:

20.1.1 withholding an established effective therapy would expose the Subjects to no more than temporary discomfort or delay in the relief of symptoms;

20.1.2 the use of an established effective therapy as a comparator would not yield scientifically reliable results; and

20.1.3 the use of a placebo would not increase any risk of serious or irreversible harm to the Subjects.

21 Treatment of Personal Information

21.1 Human Subjects have a right to know individual research results that affect their interests, but should be able to choose whether to exercise that right.

21.2 Investigators should set out at the beginning of a project what information about the results of Research done should be available to the Human Subjects, and agree these plans with the REC.

21.3 If research results have immediate clinical relevance to a Subject, there is a strong presumption that the Subject should be informed.

CHAPTER VII: USE OF HUMAN TISSUE

22 Informed Consent

- 22.1 Where Human Subjects Research involves the use of Human Tissue, an Investigator must ensure that Informed Consent is obtained from the Donor or from his or her legally authorised representative:
- 22.1.1 whenever a new sample of Human Tissue is taken wholly or partly for use in the Research; and
 - 22.1.2 for storage and potential future use of samples of Human Tissue, in which case the Donor should be told who will be responsible for custodianship of the sample and of any personal or confidential data related to the sample.
- 22.2 The provisions of Chapter VI shall apply in relation to this duty to obtain Informed Consent as if:
- 22.2.1 references in that Chapter to Subjects were references to Donors; and
 - 22.2.2 references in that Chapter to the participation of Subjects were references to Donors' Human Tissue being made available for or used in the Research.
- 22.3 For the purposes of this Chapter, the Elements of Informed Consent:
- 22.3.1 must also include a statement of the use to which the sample of Human Tissue is to be put and of how the Research might affect the interests of the Donor;
 - 22.3.2 where samples of Human Tissue are to be stored for potential future use, must include a statement as to who will be responsible for custodianship of the sample and of any personal or confidential information related to the sample.
- 22.4 Wherever it is practical to do so, and in any event where the results of Research could affect the patient's interests, an Investigator must obtain the Informed Consent of the Donor (or his or her legally authorised representative) to the use of a sample of Human Tissue which has been in storage.

23 Use of Surplus Material

- 23.1 Patients' informed consent should always be sought when material left over following diagnosis or treatment (described as surplus to clinical requirements) might be used for Research. The provisions of Informed Consent that apply to Donors and the use of Human Tissue are particularly relevant. .

24 Ethical Considerations and Remuneration

- 24.1 An Investigator must treat Human Tissue obtained for use in Human Subjects Research as a gift, and must ensure that the wishes of the Donor (or his or her legally authorised representative) are respected in the use of samples of that Tissue.
- 24.2 An Investigator must not:

24.2.1 sell for a profit any Human Tissue which has been collected for the purposes of Human Subjects Research; or

24.2.2 offer or provide any financial inducement (except the payment of reasonable expenses) to Donors (or their legally authorised representatives) to donate Human Tissue.

25 Treatment of Personal Information

25.1 Donors have a right to know individual research results that affect their interests, but should be able to choose whether to exercise that right.

25.2 Investigators should set out at the beginning of a project what information about the results of Research done on Human Tissue should be available to the Donors, and agree these plans with the REC.

25.3 If research results have immediate clinical relevance to a Donor, there is a strong presumption that the Donor should be informed.

CHAPTER VIII: CONFIDENTIALITY AND RECORDS

26 Confidentiality

- 26.1 An Investigator must treat as confidential any personal information provided by (or on behalf of) Subjects and Donors for the purposes of Human Subjects Research.
- 26.2 Wherever it is possible to do so, an Investigator must obtain the consent of each Subjects and Donor (or his or her legally authorised representative) to the recording, storing and proposed use his or her personal information.
- 26.3 If an Investigator is unable to obtain this consent from a Subjects or Donor (or his or her legally authorised representative) it must notify this fact to the REC.

27 Disclosure of Confidential Information

- 27.1 An Investigator must not disclose any personal information obtained for the purposes of Human Subjects Research without the express consent of the Subjects or Donor to whom it relates (or his or her legally authorised representative), except where:
 - 27.1.1 disclosure is necessary to eliminate any apparent immediate risk of harm to the or Donor or to any other person; and
 - 27.1.2 the disclosure is the minimum necessary for the purpose of eliminating such harm.
- 27.2 If personal information relating to a Subject or Donor is, or is likely to be, disclosed without consent, an Investigator must immediately inform that Subject or Donor (or his or her legally authorised representative):
 - 27.2.1 of the disclosure and of its purpose and extent; and
 - 27.2.2 that any person given access to the information will be required by the Investigator to be subject to a duty of confidentiality,and the Investigator must ensure that it agrees with any person to whom the information is disclosed that he or she will be subject to a legally binding duty of confidentiality.

28 Data and Record Keeping

- 28.1 An Investigator must ensure that all information related to Human Subjects Research is recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification per HAAD policies and standards relevant to document retention and information management; “Medical Record / Health Information Retention and Disposal Policy” (Ref PPR/HCP/0009/07).
- 28.2 All documentation and records that an Investigator is required to produce in relation to Research, whether under this Policy, under the Authorised Research Proposal (including any revisions or conditions specified by the REC when approving the Proposal), or otherwise by the REC:

- 28.2.1 must be retained by the Investigator for at least seven (7) years after completion of the Research to which it relates; and
 - 28.2.2 must be made accessible by the Investigator to HAAD, the REC and the REC Coordinator for the purpose of auditing and review.
- 28.3 An Investigator must ensure that its security policies and procedures are sufficient to prevent any breach of confidentiality in respect of information relating to Research.

CHAPTER IX: COMPLIANCE AND SANCTIONS

29 Compliance

29.1 An Institution must:

29.1.1 allow HAAD employees or agents to monitor compliance with this Policy by undertaking an on-site inspection on either a random or scheduled basis; and

29.1.2 implement a plan to rectify any deficiencies identified on inspection and report on its implementation to HAAD.

30 Sanctions

30.1 Where HAAD is satisfied that any Investigator or Institution has failed to comply with any of the requirements of this policy, it may take such disciplinary action as it deems appropriate, including the imposition of sanctions.

30.2 Grounds for disciplinary action include, but are not limited to:

30.2.1 a failure to correct identified deficiencies established by HAAD inspections;

30.2.2 the provision of any fraudulent or misleading information to HAAD or to a REC;

30.2.3 a failure to report against required data standards; and

30.2.4 conducting Human Subjects Research without the required approval or outside the terms of the Authorised Research Proposal (including any revisions or conditions specified by the REC when approving the Proposal).

30.3 Sanctions may include, but are not limited to:

30.3.1 temporary or permanent restrictions or conditions on a licence;

30.3.2 financial fines the value of which is determined by HAAD;

30.3.3 the refusal to renew a licence;

30.3.4 the revocation of a licence;

30.3.5 Criminal prosecution and/or civil action.

CHAPTER X: DEFINITIONS

In this Policy the following terms shall have the meanings given to them below:

Abu Dhabi Health Research Council (the Council)	has the same meaning as in the policy “ <i>Abu Dhabi Health Research Council</i> ” (Ref PHP/PHR/R01).
Abu Dhabi Research Ethics Committee (ADREC)	means the REC established by the Council in accordance with Chapter II.
Authorised Research Proposal	means, in respect of a specific Institution and a specific REC, a Research Proposal made by an Investigator and authorised by that REC in accordance with this Policy.
Consent Form	means a form which documents in writing the existence of Informed Consent.
Donor	means an individual (whether living or dead) from whom Human Tissue has been taken.
Elements of Informed Consent	has the meaning given in Chapter V.
Human Subjects Research (Research)	means any activity falling within one or more of the following categories: <ul style="list-style-type: none">• Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or in patients or on Human Tissue.• Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalisable response to these measures against a background of individual biological variation.• Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures.• Studies concerning human health-related behaviour in a variety of circumstances and environments.
Human Tissue	means any part of the human body which has been separated from a human being (whether living or dead).
Informed Consent	means the freely-given agreement of a Subject to participate in Human Subjects Research, or of a Donor to allow Human Tissue to be used in Research, based on an understanding of

all relevant information.

Institution	means the holder of an Institutional Research Licence in accordance with the HAAD Policy <i>“Licensing Requirements for Institutional Human Subjects Research”</i> (Ref: PHP/PHR/R02).
Investigator	means any person who carries out Human Subjects Research.
Principal Investigator	means, in relation to a specific Human Subjects Research project, the Investigator who has management responsibility for all other Investigators carrying out that Research.
REC Coordinator	means the committee established by the Abu Dhabi Research Ethics Committee to collate and maintain information on the work of the Institutional RECs.
Research Ethics Committee (REC)	means either the ADREC or an Institutional REC.
Research Proposal (Proposal)	means a detailed description of proposed Human Subjects Research submitted to a REC for approval in accordance with this Policy.
Standard Operating Procedures (SOPs)	means the procedures adopted by a REC in accordance with Chapter II.
Subject	means an individual who is the subject of or a participant in Human Subjects Research.