



RESEARCH REGULATION

REGULATION NUMBER (6) OF 2013

STATEMENT

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Part One: Preliminary and Key Provisions

1 Title

This Regulation is to be referred to as the DHCC Research Regulation No. (6) of 2013 (the "Research Regulation").

2 Issue of Regulation

This Research Regulation is issued in accordance with the Law.

3 Repeal of Regulation

This Research Regulation repeals and replaces the DHCC Research Regulation No. (6) of 2008.

4 Hierarchy

- (1) If there is any conflict between the provisions of this Research Regulation and the Governing Regulation, the provisions of the Governing Regulation shall prevail.
- (2) In the event of any inconsistency between an earlier version of a Regulation and an amended version of the same Regulation, the most recently amended version of the Regulation shall prevail.

5 Commencement

This Research Regulation comes into force on the date of its issuance by the Chairperson.

6 Background

The vision of DHCC is to be the internationally recognized location of choice for quality Healthcare Services and an integrated center of excellence for clinical and wellness services, medical education and research. To oversee the development of research capabilities within DHCC and to actively promote research to advance human health care. To assist in achieving this vision, there needs to be a strong and transparent governance framework relating to the regulation of Research within DHCC. The protection of human research subjects is always paramount. No Entity or person may undertake research activities within DHCC without a Research Permit issued in accordance with this Research Regulation and the applicable Rules, Standards and Policies.

7 Purpose

The purpose of this Research Regulation is to:

- (1) govern all Entities and Approved Research Operators conducting or intending to conduct research activities in DHCC.
- (2) set out the framework under which research activities may be carried out within DHCC.

8 Requirement to comply with Regulation

- (1) This Research Regulation applies to the undertaking of research activities within DHCC.
- (2) All Entities undertaking or intending to undertake research activities in DHCC shall comply with all of the applicable requirements of this Research Regulation, and the applicable Rules, Standards and Policies.
- (3) Before an Entity is permitted to undertake research in DHCC, it shall obtain a Research Permit in accordance with Part Four of this Research Regulation.

9 Amendment of Regulation

The Chairperson may, from time to time, approve amendments to this Research Regulation in accordance with the provisions of the Governing Regulation.

10 Provision of services in accordance with Regulations

- (1) No person or Entity may operate as an Approved Research Operator conducting research activities within DHCC unless it is an Entity and has obtained and maintains a Research Permit, in accordance with this Research Regulation and the applicable Rules, Standards and Policies.
- (2) No person or Entity may conduct research activities within DHCC except in accordance with this Research Regulation and any other applicable Regulations, Rules, Standards and Policies.
- (3) Any research involving patients and the provision of Healthcare Services shall be provided in accordance with this Research Regulation and the applicable Regulations and in particular the Healthcare Professionals Regulation, the Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
- (4) Failure to comply with subsections (1), (2) or (3) may result in:
 - (a) a Penalty being imposed as provided by the Regulations;
 - (b) the imposing of conditions, suspension, revocation, refusal to renew, or termination of the Approved Research Operator's Research Permit within DHCC as provided by the applicable Regulations; or
 - (c) eviction of the person or Entity operating within DHCC without a License.

11 Research Regulation to be read in conjunction with other Regulations

This Research Regulation shall be read in conjunction with the following Regulations and any amendments to such Regulations:

- (1) Commercial Services Licensing Regulation;
- (2) Company Regulation;
- (3) Complementary and Alternative Medicine Professionals Regulation
- (4) Education Regulation;
- (5) Governing Regulation;
- (6) Health Data Protection Regulation;
- (7) Healthcare Operators Regulation;

- (8) Healthcare Professionals Regulation;
- (9) Medical Liability Regulation; and
- (10) Any other Regulation approved by the Chairperson under the Law.

12 Responsibility for administration of the Regulation

The DHCC Board of Directors and the Executive Body of the DHCA are responsible for ensuring proper administration of this Research Regulation and any Rules, Standards and Policies made under this Research Regulation.

13 Savings and Transitional Provisions

- (1) Every person and Entity who is licensed under the repealed DHCC Research Regulation No. (6) of 2008 immediately before the date upon which this present Research Regulation comes into force shall upon that date be deemed to be licensed under the provisions of this Research Regulation.
- (2) This Research Regulation shall not apply to any investigation, inquiry, review, appeal or other similar proceedings commenced before the date upon which this present Research Regulation comes into force and the repealed DHCC Research Regulation No. (6) of 2008 shall continue to apply to that investigation, inquiry, review, appeal or proceedings as if this Research Regulation has not been enacted.
- (3) Where on the date upon which this present Research Regulation comes into force, any investigation, inquiry, review, appeal or other similar proceedings is in process, the relevant committee or panel carrying out that investigation, inquiry, review, appeal or proceedings shall continue to exist to complete the investigation, inquiry, review, appeal or other similar proceedings and may make such order, ruling or direction as it could have made under the powers of the repealed DHCC Research Regulation No. (6) of 2008.
- (4) A person who was appointed as a member of any Agency, committee or panel before the date upon which this present Research Regulation comes into force, and whose term has not expired by that date, shall continue to be a member of such Agency, committee or panel until the expiry of his term.

Part Two Interpretation

14 Definitions

Capitalized terms not defined in this Research Regulation shall have the meanings ascribed to them in the Governing Regulation.

Words in the singular include the plural and words in the plural include the singular.

Unless it is specifically stated otherwise in another Regulation, or unless the context otherwise requires:

Academic and Research Council means the Academic and Research Council established by Part Five of the Governing Regulation;

Agency means each or any of the boards, councils, registries and similar Entities established under the Governing Regulation and includes the Appeals Board, Central Governance Board, Licensing Board, Planning Council, Quality Council, Academic and Research Council, Professionals Council, Registry of Companies and CPQ;

Animal Care and Use Committee means the Animal Care and Use Committee established under section 27;

Animal Research means any systematic investigation, including research development, testing and evaluation that involves the use of animals in research, with the objective of developing or contributing to generalizable knowledge;

Animal Research Application means the initial application for Animal Research that shall be submitted to the Academic and Research Council for in-principle approval;

Appeals Board means the Appeals Board as established by Part Six of the Governing Regulation;

Applicant means the applicant as defined in the specific Regulations that submits an Application;

Application means an application for a License, a Provisional Approval Letter, or a Miscellaneous Permit made under the specific Regulations;

Approved Continuing Healthcare Education Program means a Continuing Healthcare Education Program that has been approved by the Registry of Companies;

Approved Continuing Medical Education Program means a Continuing Medical Education Program that has been approved by the Registry of Companies;

Approved Education Operator means an Entity licensed by the Registry of Companies to conduct Education Programs in accordance with the Education Regulation and the applicable Rules, Standards and Policies;

Approved Non-Degree Granting Healthcare Program means a Non-Degree Granting Healthcare Program that has been approved by the Registry of Companies;

Approved Professional Indemnity Insurance means professional indemnity insurance that shall be obtained and maintained by a Licensee in accordance with the applicable Regulations, Rules, Standards and Policies;

Approved Research Activity means a research activity for which a Research Permit has been granted;

Approved Research Operator means an Entity licensed by the Registry of Companies to conduct research activities in accordance with this Research Regulation and the applicable Rules, Standards and Policies;

Approved Use means the use of a drug, biologic or medical device that has been approved for one or more specific indications by a duly constituted regulatory agency in a jurisdiction recognized for this purpose by the Academic and Research Council;

Associated Person means with regard to an Applicant, any other person, including an Entity, that is Closely Linked with such Applicant;

Audit means a systematic and independent evaluation of a research and documents to determine whether the research was conducted in accordance with the requirements of the Research Regulation, any applicable Rules, Standards and Policies, and the Protocol approved for such research;

Branch means the branch of a company or any other Entity or body formed outside DHCC under the laws and regulations applicable in its place of incorporation and authorized to conduct business through this branch inside DHCC;

Building Regulations means those laws, regulations, rules or standards of general applicability to the design, construction and safety of buildings in DHCC, whether clinical in nature or not, enforced in DHCC from time to time;

Business Category means a line of clinical business, as determined in accordance with Schedule One of the Healthcare Operators Regulation in at least one of which a Licensed Healthcare Operator engages in DHCC;

Central Governance Board means the Central Governance Board established under Part Five of the Governing Regulation;

Chairperson means the Chairperson of the DHCA appointed under Article (8) of the Law;

Clinical Affairs Department means the department set up within CPQ to monitor and improve the quality of Healthcare Services within DHCC, and to oversee the accreditation processes of healthcare institutions within DHCC.

Clinical Operating Permit is the authorization issued by the Registry of Companies to a healthcare operator allowing it to conduct one or more Clinical Activities;

Closely Linked, with reference to the relationship between a person and an Applicant, means that such person:

- (1) directly or indirectly, is a Controller of such an Applicant;
- (2) directly or indirectly, is controlled by such an Applicant;
- (3) directly or indirectly, is under common control with such an Applicant; or
- (4) is a person in accordance with whose directions or instructions the directors of the Applicant are accustomed to act;

Commercial Services means services provided by a Licensed Commercial Company;

Commercial Services Licensing Regulation means the DHCC Commercial Services Licensing Regulation No. (9) of 2013, as in force from time to time;

Commissioning means the process of verifying and documenting that the Provisional Approval Letter Holder and all of its systems and assemblies are planned, designed, installed, tested, operated and maintained to meet the required Standards so that a License may be granted;

Committee means the committees established under this Research Regulation;

Company Regulation means the DHCC Company Regulation No. (8) of 2013, as in force from time to time;

Complaints Panel means the Complaints Panel established by Part Eight of the Governing Regulation;

Complementary and Alternative Medicine means a diverse group of medical and healthcare therapies and systems that may be separate from or integrated with conventional medical therapies. A common factor shared with all Complementary and Alternative therapies is a holistic and individualistic approach to health and healing, an appreciation of the whole human being, comprising of physical, emotional, mental and spiritual dimensions. Complementary and Alternative Medicine may include ayurveda, homeopathy, naturopathy, osteopathy, traditional Chinese medicine, and others;

Complementary and Alternative Medicine Professionals Regulation means the DHCC Complementary and Alternative Medicine Professionals Regulation No. (3) of 2013, as in force from time to time;

Conflict of Interest means a divergence between an individual's private interest and his professional obligations. A potential or actual Conflict of Interest, either financial or non financial, exists when a significant interest could affect the design, conduct, or reporting of research or educational activities;

Continuing Healthcare Education Program means a program of continuing education for Licensed Healthcare Professionals but does not include a Continuing Medical Education Program;

Continuing Medical Education Program means a program of continuing education for Licensed Healthcare Professionals;

Controller, with reference to the relationship between a person and an Applicant, means a person who, either alone or with any of its Associated Persons:

- (1) holds more than 50 percent (%) of the economic interests in the Applicant or of another person of which the Applicant is a subsidiary company;
- (2) is entitled to exercise, or control the exercise of, more than 50 percent (%) of the voting power of the Applicant or of another person of which the Applicant is a subsidiary company; or
- (3) is able to exercise significant influence over the management of the Applicant or of another person of which the Applicant is a subsidiary company, with such influence being manifested by such indicia as the Controller being a person in accordance with whose directions or instructions the directors of the Applicant are accustomed to act.

CPQ means the Center for Healthcare Planning and Quality established by Part Four of the Governing Regulation;

CPU means the Customer Protection Unit, a department set up within CPQ to manage and investigate complaints against Licensees as set out in Part Eight of the Governing Regulations and other applicable Regulations;

Data Safety Monitoring Board or **DSMB** means an independent data monitoring committee that a Sponsor or a Principal Investigator may establish to assess at intervals the progress of Human Biomedical Research and the associated safety data and critical efficacy endpoints and to recommend to the Sponsor or Principal Investigator whether to continue, modify, or stop a study;

Degree Granting Healthcare Program means an Education Program that refers to the period of didactic and if appropriate clinical experience in a healthcare setting culminating in certification, certificate, diploma or degree;

Design and Construction Guidelines means, as of the applicable time, (1) the then most current edition of the American Institute of Architects' Guidelines for Design and Construction of Hospital and Health Care Facilities, (2) DHCC Healthcare Facility Projects – The Planning, Design and Construction Guidelines and such other guidelines of general professional acceptance that apply to specific Business Categories, provided that any such additional guidelines have been specifically identified as applicable by the Registry of Companies and adequate advance notice is provided that such guidelines may no longer be applicable;

DHCA means the Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body;

DHCA Services means the services provided by the DHCA in carrying out the objectives and functions of the DHCA and include the services provided by the Agencies, and any Entity established by the DHCA for the purposes of providing such services;

DHCC means the Dubai Healthcare City established in the Emirate of Dubai under Resolution No. (9) of 2003;

DHCC Board of Directors means the board established under Article (10) of the Law;

Document and **Documentation** means information stored in any form of writing, code or visual depiction and the manner in which such information is stored is irrelevant for the purpose of deeming the information to constitute a "document" for the purpose of this definition. A "document" includes summons, notice, order or other legal process and registers;

Education Permit means the authorization issued by the Registry of Companies to an Entity under the Education Regulation and the applicable Rules, Standards and Policies allowing it to conduct one or more Education Programs in DHCC;

Education Program means a program to educate or train persons in one or more areas, including a:

- (1) Post-Graduate Medical Education Program;
- (2) Post-Graduate Healthcare Education Program;
- (3) Continuing Medical Education Program
- (4) Continuing Healthcare Education Program;
- (5) Degree Granting Healthcare Program;
- (6) Non-Degree Granting Healthcare Program;
- (7) High School Education Program; and
- (8) Pre-School Education Program;

Education Regulation means the DHCC Education Regulation No. (5) of 2013, as in force from time to time;

Effective Date means the date upon which a Provisional Approval Letter or a License becomes effective;

Electronic Record means a record generated, communicated, received or stored by electronic, magnetic, optical or other means in an information system or for transmission from one information system to another;

Electronic Signature means any letters, characters, numbers or other symbols in digital form attached to or logically associated with an Electronic Record, and executed or adopted with the intention of authenticating or approving the Electronic Record;

Entity means an organization, institution, or corporation other than a natural person;

Equity Interest means an ownership interest, including stock or stock options, in an Entity that is a Sponsor of the research project;

Essential Documents means documents that, individually and collectively, permit evaluation of the conduct of the research and the quality of the data produced;

Executive Body means the Executive Body of the DHCA established under Article (12) of the Law and is presently known as Dubai Healthcare City Regulatory Authority (“**DHCR**”);

Facilities Committee means the committee set up under the purview of the Registry of Companies to carry out the day-to-day administrative functions of the Registry of Companies;

Fit and Proper Person is a determination made under the Governing Regulation or any other applicable Regulation with respect to a natural person who is to serve as a Controller, director, Associated Person or Manager with regard to an Entity, with such determination being made by consideration of such person’s probity, competence and soundness of judgment for fulfilling the responsibilities of the particular position, the diligence with which he is fulfilling or likely to fulfill those responsibilities and whether the interests of patients, vendors, investors, or the Agencies are, or are likely to be, in any way negatively impacted by his holding such position;

Fitness to Practice Panel means the Fitness to Practice Panel established by Part Eight of the Governing Regulation;

Governing Regulation means the DHCC Governing Regulation No. (1) of 2013, as in force from time to time;

Guidance means information developed by the DHCA or an Agency to assist the reader in understanding the Regulations, Rules, Policies or Standards for which such Agency has responsibility, but which is not binding;

Health Safety and Environment Regulations means those laws, regulations, rules or standards of general applicability to the health, safety and environment of buildings in DHCC, whether clinical in nature or not, enforced in DHCC from time to time;

Health Data Protection Regulation means the DHCC Health Data Protection Regulation No. (7) of 2013, as in force from time to time;

Healthcare Operators Regulation means the DHCC Healthcare Operators Regulation No. (4) of 2013, as in force from time to time;

Healthcare Professionals Regulation means the DHCC Healthcare Professionals Regulation No. (2) of 2013, as in force from time to time;

Healthcare Services means the healthcare and medical services provided by Licensed Healthcare Professionals, Licensed Complementary and Alternative Medicine Professionals and Licensed Healthcare Operators, and includes, but is not limited to, diagnosis, treatment, advice, service or goods provided in respect of the physical or mental health of a person;

High School Education Program means any high school education for children provided by qualified teachers and professionals, culminating in certification, certificate or diploma;

Home Jurisdiction means the jurisdiction outside of DHCC in which the Parent of a Branch has been incorporated, established or formed;

Human Biomedical Research means any systematic investigation, including research development, testing and evaluation that involves the use of either an investigational product in human subjects, the use of identifiable human tissue or Patient Health Information, with the objective of developing or contributing to generalizable knowledge;

Human Biomedical Research Application means the initial application for Human Biomedical Research that shall be submitted to the Academic and Research Council for in-principle approval;

Human Embryonic Stem Cell Research means any systematic investigation, including research development, testing and evaluation that involve derivation and the use of human embryonic stem cells;

Human Embryonic Stem Cell Research Application means the initial application for Human Embryonic Stem Cell Research that shall be submitted to the Academic and Research Council for in-principle approval;

Human Embryonic Stem Cell Research Oversight Committee means the Human Embryonic Stem Cell Research Oversight Committee established under section 27;

Human Subject means a living individual about whom an Investigator conducting an Approved Research Activity obtains either data through intervention and/or interaction with the individual or by obtaining that person's Patient Health Information;

Informed Consent means a process by which a Human Subject's, or where that person is a Vulnerable Subject, that person's Representative, voluntary confirmation of his willingness to participate in a particular Human Biomedical Research, after having been informed of all aspects of the study procedures that are relevant to such Human or Vulnerable Subject's decision to participate;

Interventional Study means Human Biomedical Research in which Human Subjects are assigned to receive specific diagnostic, therapeutic or other types of biomedical or behavioral intervention;

Investigational Product means any investigational drug, biologic or medical device being tested or used as a reference in Human Biomedical Research, including a product with a Marketing Authorization when used or assembled (formulated or packaged) in a way different from the Approved Use, or when used for an indication that is not an Approved Use, or when used to gain further information about an Approved Use;

Investigators means the Principal Investigator and Sub-investigators collectively;

Investigator's Brochure means a compilation of the clinical and pre-clinical data on an Investigational Product that is relevant to the study of the Investigational Product in Human Subjects;

Law means Dubai Healthcare City Law No. (9) of 2011, issued by the Ruler of Dubai, establishing Dubai Healthcare City Authority, and any amendments or variations to that Law;

License means a license issued by the Licensing Board with regard to healthcare professionals and Complementary and Alternative Medicine professionals or a license or permit issued by the Registry of Companies with regard to commercial companies, including Clinical Operating Permits, Non-Clinical Operating Permits, Research Permits and Education Permits;

Licensed Commercial Company means a company registered under the Company Regulation and licensed under the Commercial Services Licensing Regulation to provide Commercial Services within DHCC;

Licensed Complementary and Alternative Medicine Professional means a natural person engaged in the provision of Complementary and Alternative Medicine holding a License duly issued by the Licensing Board in accordance with the Complementary and Alternative Medicine Professionals Regulation and the applicable Rules, Standards and Policies;

Licensed Healthcare Operator means a hospital, clinic, laboratory, pharmacy or other Entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies;

Licensed Healthcare Professional means a natural person engaged in a healthcare profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies;

Licensee means a Licensed Healthcare Professional, Licensed Complementary and Alternative Medicine Professional, a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, a Licensed Commercial Company, or a Non-Clinical Operating Permit Holder;

Licensing Board means the Licensing Board as established by Part Six of the Governing Regulation;

Location means the site within DHCC, including the physical facility or facilities associated therewith, at which a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, or a Non-Clinical Operating Permit Holder conducts or proposes to conduct activities under its License;

Manager means the person who is appointed by a Licensee or Miscellaneous Permit Holder to be its principal representative in all dealings with external parties and authorities;

Mediator means the person appointed under this Regulation to carry out the mediation process in accordance with clause 128 hereunder;

Medical Liability Regulation means the DHCC Medical Liability Regulation, Regulation No. (5) of 2005, as in force from time to time;

Miscellaneous Permit means the authorization issued by the Registry of Companies to an Entity or a person allowing it to conduct one or more activities that is not a Healthcare Service, research activity, or education activity on a short-term basis;

Miscellaneous Permit Holder means a person or Entity holding a Miscellaneous Permit;

Monitoring means the act of overseeing the progress of Approved Research Activities, and of ensuring that it is conducted, recorded and reported in accordance with the approved Protocol, the Research Regulation and any applicable Rules, Standards and Policies;

Non-Degree Granting Healthcare Program means an Education Program that refers to the period of didactic and if appropriate clinical experience in a healthcare setting which does not culminate in certification, certificate, diploma or degree, and includes a residency training program and a house-officer training program;

Non-Clinical Operating Permit means the authorization issued by the Registry of Companies to a Licensed Commercial Company allowing it to conduct one or more activities that are not Healthcare Services, research activities, or education activities, and includes a public health permit;

Non-Clinical Operating Permit Holder means an Entity holding a Non-Clinical Operating Permit;

Parent means, with respect to a Branch, an Entity that has been legally formed outside DHCC, under the applicable law of the jurisdiction of formation, of which the Branch is a division, provided that a Branch is not a legal Entity separate from the Parent;

Patient Health Information means information about a patient, whether spoken, written, or in the form of an Electronic Record, that is created or received by any Licensee, that relates to the physical or mental health or condition of the patient, including the reports from any diagnostic procedures and information related to the payment for services;

Penalty means the penalty imposed on a Licensee in accordance with the applicable Regulations;

Planning Council means the Planning Council as established by Part Five of the Governing Regulation;

Policy means a defined course of action determined by the DHCA and adopted in accordance with the provisions of the Governing Regulation, on the position, strategy or standing on a subject that shall be followed by those identified within the policy;

Post-Graduate Healthcare Education Program means the period of didactic and clinical training in a healthcare specialty that follows the completion of a recognized undergraduate healthcare education program and which prepares the Trainee for the independent practice of a healthcare specialty, but does not include a Post-Graduate Medical Education Program;

Post-Graduate Medical Education Program means the period of didactic and clinical training in a medical specialty that follows the completion of a recognized undergraduate medical education program and which prepares the Trainee for the independent practice of a medical specialty;

Pre-School Education Program means any non-compulsory pre-school education for children provided by qualified teachers and professionals with the primary objective of promoting structured educational experiences based on learning through play and social interaction;

Practice and Procedure Oversight Committee means the Practice and Procedure Oversight Committee established under section 27;

Principal Investigator means an individual who is responsible and accountable for designing a Protocol, and conducting and Monitoring of an Approved Research Activity in accordance with the Protocol;

Professional Practice means with respect to any Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional, the provision of Healthcare Services and the performance of functions within the scope of his License, as provided in the Healthcare Professionals Regulation, the Complementary and Alternative Medicine Professionals Regulation and the applicable Regulations, Rules, Standards and Policies;

Proprietary Interest means property or other financial interest, including an interest in royalties, an interest in an Investigational Product, including, but not limited to, a patent, trademark, copyright, or licensing agreement;

Professionals Council means the Professionals Council as established by Part Five of the Governing Regulation;

Protocol means the document that describes the objective(s), design, methodology, statistical considerations and organization of the research activity;

Provisional Approval Letter means the approval issued to an Entity by the Registry of Companies to enable that Entity to:

- (1) commence the activities required to meet the requirements of the Commissioning; and

(2) obtain a License in accordance with the specific Regulations;

Provisional Approval Letter Holder means an Entity holding a Provisional Approval Letter;

Quality Council means the Quality Council as established by Part Five of the Governing Regulation;

Records means all papers, records, recorded tapes, photographs, statistical tabulations or other documentary materials or data, regardless of physical form or characteristics, including in written or electronic form;

Registry of Companies means the Registry of Companies established by Part Seven of the Governing Regulation;

Regulation means any regulation approved by the Chairperson under the Law, including any amendments to any such regulation;

Representative means the Human Subject's legal or personal representative who is authorized to act on behalf of a prospective Vulnerable Subject, with regard to the Human Subject's participation in Human Biomedical Research;

Research Accreditation and Code of Ethics means the Research Accreditation and Code of Ethics published by the Academic and Research Council from time to time;

Research Ethics Review Committee means the Research Ethics Review Committee, a Committee established under Part Three of this Research Regulation;

Research Permit means a permit issued by the Registry of Companies to an Entity authorizing it to conduct the Approved Research Activity;

Research Site means the Location(s) within DHCC at which an Approved Research Operator conducts its Approved Research Activities;

Risk means the probability of harm or injury, whether physical, psychological, social or economic, occurring as a result of participating in Approved Research Activities;

Research Regulation means the DHCC Research Regulation No. (6) of 2013, as in force from time to time;

Rules mean the rules approved by the Chairperson or DHCC Board of Directors as provided for under the Governing Regulation and any other Regulation, and include the rules as in force from time to time;

Serious Adverse Event means any unanticipated incident involving Risks or injury or death of Human Subjects that may present itself during the course of Approved Research Activities;

Significant Financial Interest means anything of a monetary value or an Equity Interest in an Entity held by an Investigator during the time he is carrying out the research and for 1 year following completion of such investigation as determined from time to time in the applicable Regulations, Rules, Standards and Policies;

Sponsor means pharmaceutical company, academic institution or any other Entity that takes responsibility for the initiation of research and arranges for the payment, if any, of the research;

Sub-investigator means an individual member of a research team, qualified by training and experience, designated and supervised by the Principal Investigator to perform critical research-related procedures and/or to make important research-related decisions;

Special Population includes Vulnerable Subjects and others with special needs and includes pregnant women and their *in utero* fetuses;

Standard means a specification that defines materials, methods, processes or practices and that is used to provide a basis for determining consistent and acceptable minimum levels of quality, performance, safety and reliability;

Trainee means a person who is participating in an Approved Post-Graduate Medical Education Program, an Approved Post-Graduate Healthcare Education Program or an Approved Non-Degree Granting Healthcare Program;

UAE means the United Arab Emirates;

Vulnerable Subject means vulnerable Human Subject with diminished competence and/or decision making capacity due to age, physical or medical conditions, or social economical status;

Zoning Regulations means those laws, Regulations, Rules or Standards of general applicability to zoning and the use of real estate enforced in DHCC from time to time.

15 Regulations include amendments

References in this Research Regulation or any other Regulations, to the Regulations, are to be read as references to any of such Regulations as in force from time to time.

16 Headings

The headings used in this Research Regulation are included for convenience of reference only and shall be ignored in the construction or interpretation of this Research Regulation.

17 Time periods

References in Regulations to time periods are to be construed in accordance with the Gregorian calendar. Whenever Regulations refer to a period of time, such period shall include every calendar day, except that:

- (1) when the last day of the period falls on a Friday or a Saturday, the period shall end instead on the next Sunday; and
- (2) when the last day of the period falls on a UAE or Dubai public holiday, the period shall end instead on the next day that is not a UAE or Dubai public holiday.

18 Gender

Pronouns indicating male gender are used to refer to persons of both genders.

19 Documents in languages other than English

A person who wishes to submit an original document, a photocopy or an electronic version of a document written in a language other than English shall also submit a notarized translation into English of such document prepared by a legal translation service acceptable to the officer, employee or agent providing the DHCA Services to whom the document is submitted.

20 Documents in writing

- (1) Unless otherwise specifically stated, references in the Regulations to any requirement for a document or notice to be submitted to the Registry of Companies,

the Licensing Board or any other Agency in writing shall be satisfied if such document or notice is submitted in the form of an Electronic Record.

- (2) Unless otherwise specifically stated, references in the Regulations to any requirement for a signature on any document or notice to be submitted to the Registry of Companies, the Licensing Board, or any other Agency is to be construed as being satisfied by an Electronic Signature that may be proved in a manner satisfactory to the Registry of Companies.

21 Meaning of Person

Unless the context otherwise requires, any reference in the Regulations to a “person” includes a reference to a natural person, and to a body corporate, limited liability company, association or partnership and to the legal or personal representatives, legal successors and lawful assigns of any such person.

22 Reference to sections

Unless otherwise specifically stated, references in a Regulation to a section and subsection mean the section and subsection of that Regulation.

Part Three Powers and Responsibilities

23 Powers and Responsibilities of Academic and Research Council

The Academic and Research Council shall have the following powers and responsibilities, including:

- (1) the overall planning for Approved Research Activities within DHCC;
- (2) supporting bio-medical research including pharmaceuticals, medical technology, biotechnology and healthcare services through partnerships and collaborations with world-class research entities;
- (3) oversight of the Research Ethics Review Committee, the Animal Care and Use Committee, the Human Embryonic Stem Cell Research Oversight Committee, and the Practice and Procedure Oversight Committee and other Committees;
- (4) the development of goals and approval of the Research Accreditation and Code of Ethics, Rules, Standards and Guidance for Approved Research Activities in DHCC;
- (5) grant in-principle approvals based on the Research Ethics Review Committee's review of Protocols submitted by Entities under this Research Regulation;
- (6) oversight of the provision of Approved Research Activities by Approved Research Operators within DHCC;
- (7) reviewing the need for Patient Health Information to be retained by an Investigator, Sponsor or Approved Research Operator for time periods exceeding those specified in the Health Data Protection Regulation;
- (8) reviewing and approval of reports or decisions submitted to the Academic and Research Council by the Research Ethics Review Committee; and
- (9) the power to obtain such information from Entities and Approved Research Operators, as it reasonably requires, in order to perform its functions, and to facilitate the performance of the functions of the Academic and Research Council under this Research Regulation and the other applicable Regulations, Rules, Standards and Policies.

24 Establishment and Powers of Research Ethics Review Committee

The Academic and Research Council shall establish the Research Ethics Review Committee to:

- (1) oversee the Committees established under section 27;
- (2) oversee and review the general processes of each Approved Research Operator's ethics committee;
- (3) coordinate and integrate the planning for and implementation of research activities;
- (4) review from a scientific and ethical perspective Protocols and consider if further information is required from the Approved Research Operator or if any modification of the Protocol is required;
- (5) make recommendations to the Academic and Research Council as to whether in-principle approvals should be granted in relation to Protocols submitted by Entities

under this Research Regulation, and the applicable Regulations, Rules, Standards and Policies;

- (6) monitor Approved Research Activities carried out by Approved Research Operators, including undertaking or arranging for the undertaking of periodic reviews of Approved Research Operators;
- (7) ensure ongoing regulatory compliance and adherence to the Protocol and Research Accreditation and Code of Ethics by the Investigator(s) associated with Approved Research Activities;
- (8) observe or have a third party observe the conduct of the Approved Research Operators' Approved Research Activities;
- (9) develop Rules, Standards and Policies, subject to the approval of the Academic and Research Council, that enhance the quality of Approved Research Activities and establishment of procedures for implementing and communicating these Rules, Standards and Policies.

25 Composition of Research Ethics Review Committee

The primary guiding principle for appointing members to the Research Ethics Review Committee is to ensure that the Research Ethics Review Committee has the appropriate expertise, skills, knowledge and perspectives in the regulation of research activities and/or the field of ethics.

26 Membership of Research Ethics Review Committee

The Research Ethics Review Committee shall consist of at least 5 members, who collectively have the qualifications and experience to regulate research activities and/or the field of ethics, including:

- (a) at least 1 member whose primary concerns shall be in scientific areas;
- (b) at least 1 member whose primary concerns shall be in non-scientific areas;
- (c) at least 1 member who shall be familiar with applicable laws, Regulations, Rules, Standards, Policies, and standards of ethical and professional conduct associated with Approved Research Activities; and
- (d) at least 1 member who shall be a resident of the UAE but who is not otherwise affiliated with the DHCA and who is not part of the immediate family of a person who is affiliated with the DHCA.

27 Establishment of Committees

The Academic and Research Council may establish Committees it considers necessary to assist the Academic and Research Council in performing its responsibilities and determined to be appropriate, including but not limited to the following Committees:

- (a) Animal Care and Use Committee for the purposes of reviewing from a scientific and ethical perspective, any Animal Research Application to undertake Animal Research within DHCC;
- (b) Human Embryonic Stem Cell Research Oversight Committee for the purposes of reviewing from a scientific and ethical perspective any Human Embryonic Stem Cell

Research Application to undertake Human Embryonic Stem Cell Research including that relating to *in vitro* human embryos or *in vitro* human gametes within DHCC; and

- (c) Practice and Procedure Oversight Committee for the purposes of reviewing from a scientific and ethical perspective any procedure, treatment or therapy that is being proposed to be carried out within DHCC by healthcare professionals or Complementary and Alternative Medicine professionals.

28 Purpose of Committees

The purpose of the Animal Care and Use Committee, and the Human Embryonic Stem Cell Research Oversight Committee is to provide ethical and scientific review of all Applications.

29 Committees may seek advice

In fulfilling their responsibilities under this Research Regulation, the Committees may seek advice from any source it considers appropriate.

30 Other provisions relating to Committees

- (1) Other provisions relating to the Committees identified in section 27 are set out in Schedule One of this Research Regulation.
- (2) In relation to new Committees to be established, the Academic and Research Council may adopt the provisions set out in Schedule One.

31 Powers and Responsibilities of other Committees

The Animal Care and Use Committee, the Human Embryonic Stem Cell Research Oversight Committee, the Practice and Procedure Oversight Committee and any other Committee established under section 27 shall have the powers and responsibilities as stated in the Regulations and Rules, Standards and Policies, subject to the approval of the Academic and Research Council.

32 Composition of other Committees

- (1) The primary guiding principle for appointing members to the Animal Care and Use Committee, Research Ethics Review Committee and the Human Embryonic Stem Cell Research Oversight Committee and any other Committee established under section 27 is to ensure that the Committee has the appropriate expertise, skills, knowledge and perspectives to conduct ethical and scientific review of any application to undertake research within DHCC.
- (2) The primary guiding principle for appointing members to the Practice and Procedure Oversight Committee is to ensure that the Committee has the appropriate expertise, skills, knowledge and perspectives to conduct ethical and scientific review of any procedure, treatment or therapy that is being proposed to be carried out within DHCC by healthcare professionals or Complementary and Alternative Medicine professionals.
- (3) The Academic and Research Council shall determine the appropriate composition of any Committee established under section 27.

- (4) Members of any Committee established under section 27 shall be appointed in accordance with the provisions of Schedule One of this Research Regulation.

Part Four

General Provisions relating to Provisional Approval Letters and Applications for Research Permits

33 Eligibility

- (1) Only an Entity which is registered or intending to be registered under the Company Regulation and the Commercial Services Licensing Regulation may submit an Application for a Provisional Approval Letter.
- (2) The Entity submitting an Application for a Provisional Approval Letter or a Research Permit under this Research Regulation shall be the eventual Approved Research Operator conducting the research activities for which the said Applications are filed.

34 Licensed Healthcare Operator may apply for Provisional Approval Letter

At any time during the term of a Licensed Healthcare Operator's License, the Licensed Healthcare Operator may apply for a Provisional Approval Letter under this Research Regulation.

35 Requirements

- (1) Only an Entity which is registered under the Company Regulation and the Commercial Services Licensing Regulation may become a Provisional Approval Letter Holder.
- (2) No person may obtain a Research Permit unless it is an Entity and has first obtained a Provisional Approval Letter, in accordance with this Research Regulation and the applicable Rules, Standards and Policies.
- (3) No person may obtain a Research Permit or a Provisional Approval Letter unless he has been granted the relevant in-principle approvals from the Clinical Affairs Department, Licensing Board and the Academic and Research Council.

36 Provisional Approval Letter Holder not entitled to carry out research activities

A Provisional Approval Letter Holder is not entitled to carry out any research activities within DHCC under the authority of the Provisional Approval Letter.

37 Requirement for Provisional Approval Letter Holders and Approved Research Operators to comply with Regulations

Both Provisional Approval Letter Holders and Approved Research Operators shall comply with all of the applicable requirements of this Research Regulation and any other applicable Regulations, Rules, Standards, and Policies.

38 Responsibilities of Provisional Approval Letter Holders

Each Provisional Approval Letter Holder shall ensure that when undertaking the design and construction of its facilities under its Provisional Approval Letter, that the Location at which it proposes to carry out research activities, upon issuance of a Research Permit, complies with all applicable provisions of the:

- (1) Building Regulations and Zoning Regulations;
- (2) Design and Construction Guidelines;
- (3) Health Safety and Environment Regulations; and
- (4) the applicable Rules, Standards and Policies.

39 Responsibilities of Approved Research Operators

Each Approved Research Operator shall ensure that all intended Research Sites at which it carries out research activities shall at all times comply with all applicable provisions of the:

- (1) Building Regulations and Zoning Regulations;
- (2) Design and Construction Guidelines; and
- (3) Health, Safety and Environment Regulations; and
- (4) Applicable Rules, Standards and Policies.

40 Exceptions from requirement to hold a Research Permit

- (1) A person or Entity who owns or leases land in DHCC or any building in DHCC in which a research activity is conducted or intended to be conducted, but does not himself conduct or manage such research activity on that land or in that building, shall not be required to obtain a Provisional Approval Letter or a Research Permit under this Research Regulation.
- (2) In such cases the person or Entity shall provide information to the Registry of Companies about:
 - (a) the research activities that the building is to be used for, and
 - (b) the manager or operator of the research activities.

41 Employed Licensed Healthcare Professionals' Professional Practice shall cover research activities provided by Approved Research Operator

An Approved Research Operator may only employ or engage a Licensed Healthcare Professional to engage in research activities in DHCC if the Licensed Healthcare Professional's Professional Practice covers the research activities provided by the Approved Research Operator.

42 Jurisdiction of Approved Research Operator

- (1) An Approved Research Operator is only licensed to provide within DHCC those research activities for which its Research Permit has been issued.
- (2) Except as specifically provided in this Research Regulation, any Approved Research Operator intending to provide services outside of DHCC shall be solely responsible for meeting any standards or other requirements of that other jurisdiction.

43 No assignment or transfer of Provisional Approval Letter or Research Permit

- (1) Neither a Provisional Approval Letter Holder nor an Approved Research Operator may transfer or assign its Provisional Approval Letter or Research Permit.

- (2) For the avoidance of doubt, where there is a change of Controller, this shall be considered to be an assignment or transfer and subject to subsection (1).

44 Compliance with requirements of Agencies

Each Approved Research Operator shall comply with all requirements that any of the Agencies may from time to time establish regarding data requirements, and shall ensure that each employee that it engages shall also comply with such requirements.

45 Exemption from certain requirements

- (1) The Registry of Companies, upon the recommendation of the relevant Agency, may provide a waiver (in such terms and conditions as it deems appropriate) to an Applicant, a Provisional Approval Letter Holder or an Approved Research Operator for the otherwise applicable requirements of the:
- (a) Building Regulations; or
 - (b) Design and Construction Guidelines.
- insofar as this is permitted under the applicable laws.
- (2) Such a waiver may only be granted if the Registry of Companies, together with the relevant Agency, both agree that:
- (a) doing so is in the public interest;
 - (b) requiring compliance with the particular requirements would create an undue hardship on the Applicant; and
 - (c) granting such waiver or waivers would not impair or endanger the health, safety or welfare of any person, including any research subject.

46 Fees

The Registry of Companies shall publish from time to time the applicable fees that are to accompany all Applications, Renewal Applications and other submissions to the Registry of Companies provided for under this Research Regulation.

Part Five Provisions relating to Provisional Approval Letters

47 Fee to be paid at time Application for a Provisional Approval Letter is submitted

The Applicant shall pay the applicable fee at the time the Application for a Provisional Approval Letter is submitted to the Registry of Companies.

48 Withdrawal of Application for Provisional Approval Letter

- (1) An Applicant may withdraw his Application at any time.
- (2) The Registry of Companies shall retain a record of the Applicant's withdrawal of the Application together with a copy of all the information provided by the Applicant or otherwise obtained during the course of consideration of the Application up until the time the Application is withdrawn.
- (3) Any fee submitted shall not be refunded.

49 Role of Applicant's Manager in Application process

The Applicant's Manager shall be the first point of contact with regard to any matters that arise during the Application process.

50 Form of Application

- (1) An Applicant shall submit an Application for a Provisional Approval Letter in the form and manner as may be required by the Registry of Companies.
- (2) An Application for a Provisional Approval Letter shall be considered only if it meets the following requirements:
 - (a) it is in English;
 - (b) it is typewritten or written in a legible manner;
 - (c) all data, information, and signatures required under this Research Regulation and the applicable Rules, Standards and Policies are supplied;
 - (d) the appropriate application form is utilized; and
 - (e) the applicable fee is submitted.

51 Information to be provided with Application for Provisional Approval Letter

The Applicant shall provide together with the completed application form:

- (1) documentation indicating that the Applicant is registered to carry on business or is intending to be registered in DHCC under the Company Regulation and the Commercial Services Licensing Regulation;
- (2) a description of the research activities for which the Applicant is seeking a Research Permit;
- (3) a copy of the Protocol, duly executed by the Principal Investigator;
- (4) written confirmation that the Approved Research Operator's ethics committee or an ethics committee of the Approved Research Operator's Parent or an Associated Person, has approved the Protocol;

- (5) information regarding any disciplinary action or adverse action taken in any jurisdiction against any Associated Person or Controller of the Applicant, including, if the Applicant is a Branch, of the Applicant's Parent;
- (6) Applications for Licenses to be granted to healthcare professionals comprising the key personnel of the Applicant, as may be stipulated by the Registry of Companies from time to time;
- (7) details of all Controllers, directors and Associated Persons relating to the Applicant;
- (8) details of the Manager who is appointed by the Applicant to be the principal representative in dealings with the Academic and Research Council;
- (9) the Location of the intended Research Site or Research Sites of the Approved Research Activity or Activities, including, unless otherwise agreed by the Registry of Companies, evidence of the Applicant's legal right to the use of each Location as of the Effective Date;
- (10) sufficient documentation, to the satisfaction of the Registry of Companies, that the Applicant is capable of satisfying all requirements established under this Research Regulation and the applicable Rules, Standards and Policies;
- (11) a written declaration that the Applicant shall promptly notify the Registry of Companies of any modifications or changes to the information or documentation contained in its Application that occur subsequent to the filing; and
- (12) any such other information or particulars, and verified in such manner, as the Registry of Companies or the relevant Agencies may require.

52 Declaration by Applicant

The Application shall be accompanied by:

- (a) a written declaration confirming the accuracy of the statements included in the Application and any accompanying documents;
- (b) an authorization for the Registry of Companies to verify the accuracy of any information provided and to conduct reference checks with any Entity or authority that the Applicant has had dealings with, and, subject to the Governing Regulation, to share such information and documentation with any party as the Registry of Companies considers necessary for purposes of such verification or checks.

53 Provision of incomplete Application for Provisional Approval Letter

- (1) It is the responsibility of the Entity making the Application to submit a completed application form and to ensure the accuracy of all information provided.
- (2) In the case of incomplete Applications, the Registry of Companies shall notify the Entity identifying the information that has not been provided and the timeframe within which the Application may be resubmitted.
- (3) The Registry of Companies shall specify a reasonable period of time within which the Application may be resubmitted with the required information.
- (4) The Entity shall not be required to pay an additional fee for resubmitting the Application within the specified timeframe.

- (5) If the Application is not submitted within the time specified, the Application shall be considered to be withdrawn and the Applicant will need to submit a new Application together with the applicable fee.

54 Requirement to provide further information in Application for Provisional Approval Letter

- (1) At any time after an Application is submitted to the Registry of Companies and before action on it is taken, the Registry of Companies and/or any relevant Agency may, by written notice to the Applicant and/or relevant party, require the provision of such additional information or documents as the Registry of Companies and/or any relevant Agency deems reasonable and necessary to review the Application, in such form and within such time period as required.
- (2) Such additional information may include:-
- (a) financial information regarding the Applicant and any Associated Person or Controller of the Applicant sufficient to assess the Applicant's financial capability to undertake the research activity or activities proposed; and
- (b) details of all Controllers, directors and Associated Persons relating to the Applicant.
- (3) Subsection (1) also applies to any person who is:
- (a) identified in the Application as a director, Controller or Manager of the Applicant;
- (b) identified in the Application as being intended to be a director, Controller or Manager of the Applicant; or
- (c) identified as the key personnel of the Applicant as may be stipulated by the Registry of Companies from time to time.

55 Failure to provide further information in Application for Provisional Approval Letter

- (1) If the Applicant fails to comply with the requirement to provide further information or resubmit the Application in accordance with sections 53(2) and 54, the Registry of Companies may consider the Application withdrawn on the basis of insufficient information.
- (2) If the Registry of Companies considers an Application withdrawn in accordance with subsection (1) on the basis of insufficient information, the Registry of Companies shall notify the Applicant and any fee paid by the Applicant shall not be refunded to the Applicant.

56 All information to be provided before Application for Provisional Approval Letter reviewed

- (1) An Application shall not be considered complete until all information required under this Research Regulation has been submitted to the Registry of Companies.
- (2) The Registry of Companies shall not review an Application until it has determined that the Application is complete based on the requirements set out in this Research Regulation and any applicable Rules, Standards and Policies.

57 Requirement to notify changes in Application for Provisional Approval Letter

- (1) At any time during the review of an Application and prior to the Registry of Companies issuing a Provisional Approval Letter, the Applicant shall promptly notify the Registry of Companies of any modification or change to the information or documentation contained in its Application.
- (2) Failure of an Applicant to notify the Registry of Companies of any such changes in accordance with subsection (1) shall result in the Application being considered incomplete and withdrawn in accordance with section 53.
- (3) If the notification of changes is received after the Registry of Companies has completed its review of the Application, the Applicant shall pay the applicable fee before the Registry of Companies undertakes a further review of the revised Application.

58 Information from other sources

At any time during the process of reviewing an Application, the Registry of Companies may inquire of the DHCA as to the information that the DHCA holds with regard to the capability of the Applicant to provide the research activity or activities proposed in the Application.

Part Six Review of Applications for Provisional Approval Letters

59 Evaluation of facilities by Registry of Companies

In preparation for a review of the Application for a Provisional Approval Letter, the Registry of Companies may arrange for an on-site evaluation of the Entity's facilities.

60 Consideration of Protocol by Research Ethics Review Committee

- (1) The Protocol and all relevant information shall be forwarded to the Research Ethics Review Committee for its review.
- (2) The Research Ethics Review Committee and/or the relevant Committee may:
 - (a) seek further information from the Applicant in relation to the Protocol;
 - (b) invite the Manager and/or the Principal Investigator to attend such meeting of the relevant Committee to provide further information to assist the Research Ethics Review Committee and/or the relevant Committee in its deliberations.

61 Grant of in-principle approval by Academic and Research Council

- (1) The Academic and Research Council may grant in-principle approval of the Protocol based on the Research Ethics Review Committee's review of the Protocol and all relevant information.
- (2) The decision of the Academic and Research Council on the grant of in-principle approval in relation to the Protocol shall be final.

62 Matters Registry of Companies takes into account

In considering an Application, the Registry of Companies may take into account any matters relating to:

- (1) the need to protect the public and the reputation of DHCC, Dubai and UAE;
- (2) any other factors identified in the applicable Regulations and Rules, Standards and Policies as appropriate to consider;
- (3) any person who is or will be employed by or associated with the Applicant for the purposes of any of the Applicant's research activities if a Research Permit is issued to the Applicant;
- (4) any person that is an Associated Person, director, Controller or proposed Manager of the Applicant;
- (5) the financial resources available to the Applicant to undertake and maintain the proposed research activity or activities;
- (6) in the case of an Applicant that is a Branch, the length of time the Branch's Parent has been conducting research activities prior to the Branch submitting its Application under the Research Regulation;
- (7) the likelihood that the Applicant shall be capable of complying with the requirements of this Research Regulation and the applicable Rules, Standards and Policies; and
- (8) the proposed name of the facility.

63 Action on Application for Provisional Approval Letter

Upon the completion of its review, the Registry of Companies may:

- (1) approve the Application;
- (2) approve the Application subject to conditions or restrictions as it considers necessary and proper to be included in the Provisional Approval Letter; or
- (3) deny the Application.

64 Approval of Application for Provisional Approval Letter by the Registry of Companies

The Registry of Companies shall not approve an Application unless it determines that:

- (1) the Applicant satisfies all relevant criteria contained in this Research Regulation, and the applicable Rules, Standards and Policies with regard to the type of research activities the Applicant proposes to undertake;
- (2) the Applicant shall ensure that all personnel who are intended to conduct the proposed type of research activities shall possess the qualifications and experience to conduct the research activities;
- (3) all Principal Investigators, Controllers, directors, Associated Persons and Managers identified in the Application are Fit and Proper Persons;
- (4) in-principle approval has been granted by the Clinical Affairs Department;
- (5) in-principle approval has been granted by the Licensing Board; and
- (6) in-principle approval has been granted by the Academic and Research Council.

65 Grounds for denying Application for Provisional Approval Letter

The Registry of Companies may deny an Application if it determines that:

- (1) any statements, information or documents submitted by the Applicant are false, misleading or deceptive, or are likely to mislead or deceive;
- (2) there has been a modification or change in the circumstances relating to the information or documentation contained in the Application subsequent to its filing and the Applicant has failed to notify the Registry of Companies of any such modification or change in a timely manner;
- (3) the Applicant has failed to satisfy any of the requirements in section 64; or
- (4) the Registry of Companies is not satisfied that the Applicant will comply with the provisions of this Research Regulation and the applicable Rules, Standards and Policies, if it were to hold a Research Permit.

66 Applicant to be notified of Registry of Companies' decision

- (1) The Registry of Companies shall notify the Applicant of its decision to:
 - (a) approve the Application and issue the Provisional Approval Letter;
 - (b) impose conditions or restrictions on the issue of such Provisional Approval Letter; or
 - (c) deny the Application for a Provisional Approval Letter.
- (2) The Registry of Companies shall also notify the Applicant of:

- (a) the details of the research activities covered by the Provisional Approval Letter and any conditions or restrictions imposed; and
- (b) the Effective Date.

67 No right of appeal of decision of Registry of Companies

The Applicant has no right to seek an appeal of the Registry of Companies' decision to deny an Application or to impose conditions or restrictions on the Provisional Approval Letter.

68 Restriction on submitting new Application for Provisional Approval Letter

If the Registry of Companies denies an Application, unless otherwise agreed by the Registry of Companies, the Applicant may not file a new Application for a Provisional Approval Letter to provide the same research activity or research activities as those proposed in the denied Application for a period of 6 months or such period as may be determined by the Registry of Companies following the Applicant's receipt of notice from the Registry of Companies under section 66.

69 Details contained in Provisional Approval Letter

A Provisional Approval Letter shall contain the following details:

- (1) the name of the Provisional Approval Letter Holder;
- (2) the name and Location of the intended Research Site;
- (3) the Effective Date of the Provisional Approval Letter;
- (4) the term of the Provisional Approval Letter;
- (5) the name of the Provisional Approval Letter Holder's Manager;
- (6) the research activity or activities proposed to be undertaken under a Research Permit; and
- (7) such other matters, including but not limited to any terms, conditions or restrictions included in the Provisional Approval Letter, as may be specified by the Registry of Companies.

70 Term of Provisional Approval Letter

Subject to the provisions of the applicable Rules, Standards and Policies or any terms, conditions or restrictions imposed by the Registry of Companies, a Provisional Approval Letter shall be valid for a period of 2 years or such further term as may be extended under section 79.

71 Abandonment of research activities

- (1) Unless otherwise agreed to by the Registry of Companies, a Provisional Approval Letter Holder shall be deemed to have abandoned its intent to implement one or more research activities encompassed by its Provisional Approval Letter if the Provisional Approval Letter Holder does not commence, within 6 months of receipt of the notice from the Registry of Companies under section 66, steps necessary for the eventual filing of an Application for an Research Permit.
- (2) The Registry of Companies shall make arrangements for the Applicant to be notified in writing of its decision regarding:
 - (a) the revised scope of the research activities covered by the Provisional Approval Letter due to abandonment of one or more research activities; or

- (b) the withdrawal of the Provisional Approval Letter due to abandonment of all research activities.

72 Restriction on submitting new Application for Provisional Approval Letter following abandonment

If the Applicant is deemed to have abandoned one or more research activities under section 71, the Applicant may not file a new Application for a Provisional Approval letter to provide the same research activity or activities for a period of 6 months following its receipt of notice from the Registry of Companies under section 71(2) unless agreed otherwise by the Registry of Companies.

Part Seven Obligations of Provisional Approval Letter Holders

73 Conditions imposed to ensure progress

Following issuance of its Provisional Approval Letter, each Provisional Approval Letter Holder shall:

- (1) make good faith efforts and continuing progress toward filing an Application for a Research Permit;
- (2) report to the Registry of Companies on its actions and continuing progress every 3 months or as requested by the Registry of Companies; and
- (3) comply with all terms, conditions and restrictions imposed on its Provisional Approval Letter.

74 Requirement to notify the Registry of Companies of modifications to an Application

The Provisional Approval Letter Holder shall promptly notify the Registry of Companies of any modification or change to the information or documentation contained in its Application for the Provisional Approval Letter.

75 Requirement to notify of changes in personnel

The Provisional Approval Letter Holder shall promptly notify the Registry of Companies of any changes as to the identity of all those persons who shall be the Principal Investigator, Associated Persons, Controllers and directors during the term of the Provisional Approval Letter.

76 Modification or changes to Provisional Approval Letter Holders which are Branches

When the Registry of Companies issues a Provisional Approval Letter to an Applicant that is a Branch, that Branch, shall notify the Registry of Companies in writing of any modification or change to the licensure, registration or equivalent authorization that it reported in its Application, together with the date of the occurrence of such modification or change, by no later than 20 days following any such modification or change.

77 Continuation of legal existence of Parent in Home Jurisdiction

During the term of the Provisional Approval Letter and prior to an Application for a Research Permit, the Provisional Approval Letter Holder shall provide the Registry of Companies on each anniversary of the Provisional Approval Letter's Effective Date, a certificate issued by the relevant authority in the Parent's Home Jurisdiction that proves the continuation of the legal existence of the Parent in the Home Jurisdiction and the validity of its licensure, registration or equivalent authorization with such authority.

78 Request for extension of term of Provisional Approval Letter

- (1) A Provisional Approval Letter Holder may request in writing for the Registry of Companies to extend the term of the Provisional Approval Letter.
- (2) The request shall specify the:
 - (a) period of time for the extension of the Provisional Approval Letter;

- (b) outstanding requirements to be completed; and
 - (c) details of any circumstances beyond the reasonable control of the Provisional Approval Letter Holder which have presented a substantial obstacle to the timely completion of the steps needed to make an Application.
- (3) Any such request shall be made no later than 60 days prior to the expiration of the Provisional Approval Letter, and submitted together with the applicable fee.

79 Extension of term of Provisional Approval Letter

- (1) Where the Provisional Approval Letter Holder makes such a request under section 78, and the Provisional Approval Letter Holder has made substantial progress during the term of its Provisional Approval Letter towards converting its Provisional Approval Letter to a Research Permit, the Registry of Companies may extend the time for such Provisional Approval Letter Holder to file its Application.
- (2) In considering the request under section 78, the Registry of Companies may take into account any advice provided to the Registry of Companies by the Facilities Committee regarding the progress of the Provisional Approval Letter Holder.

80 Period of extension

The Registry of Companies shall consider the request to extend the term of the Provisional Approval Letter no later than 30 days prior to the expiration of the Provisional Approval Letter and may extend the term for a further period of up to 2 years.

81 Notification of decision regarding request for extension of term

The Registry of Companies shall notify the Applicant in writing of its decision regarding the request for the extension of the term of the Provisional Approval Letter including:

- (1) whether the request is granted;
- (2) whether the request is denied and the reasons for denying the request; and
- (3) the expiry date of the Provisional Approval Letter.

82 No right of appeal of decision of Registry of Companies

The Applicant has no right to seek an appeal of the Registry of Companies' decision to deny the request for an extension of the term of the Provisional Approval Letter.

83 Failure to apply for Research Permit during term of Provisional Approval Letter

If a Provisional Approval Letter Holder fails to apply for a Research Permit prior to the expiration of its Provisional Approval Letter, such Provisional Approval Letter shall automatically terminate on the expiry date specified in the Provisional Approval Letter.

Part Eight Revocation and Suspension of Provisional Approval Letter

84 Grounds for suspension or revocation of Provisional Approval Letter

The Registry of Companies may suspend or revoke a Provisional Approval Letter on the grounds that the Provisional Approval Letter Holder has breached its obligations as set out in Part Seven of this Research Regulation or on the same grounds on which the Registry of Companies could have denied an Application for a Provisional Approval Letter under section 65.

85 Opportunity to rectify breach

Prior to suspending or revoking the Provisional Approval Letter, the Registry of Companies shall give the Provisional Approval Letter Holder an opportunity to rectify the breach within a period of time stipulated by the Registry of Companies.

86 Provisional Approval Letter Holder to be notified of suspension or revocation

The Registry of Companies shall notify the Applicant in writing of:

- (1) its decision to suspend or revoke the Provisional Approval Letter;
- (2) the reasons for its decision; and
- (3) in the case of suspension, any requirements that the Provisional Approval Letter Holder shall meet before the suspension will be lifted.

87 No right of appeal from decision of Registry of Companies

The Applicant has no right to seek an appeal of the Registry of Companies' decision to suspend or revoke the Provisional Approval Letter.

88 Lifting of suspension

- (1) Where the Provisional Approval Letter has been suspended subject to the meeting of certain requirements, the Provisional Approval Letter Holder may request the Registry of Companies to lift the suspension when those requirements have been met.
- (2) The Registry of Companies may request any information it considers necessary from the Provisional Approval Letter Holder to enable it to consider the request to lift the suspension.

Part Nine

Provisions relating to Applications for Research Permits

89 Requirements to convert Provisional Approval Letter to Research Permit

For a Provisional Approval Letter Holder to convert its Provisional Approval Letter to a Research Permit, it shall:

- (1) complete the Commissioning as determined by the Registry of Companies from time to time; and
- (2) have been granted the relevant in-principle approvals from the Clinical Affairs Department, the Licensing Board and the Academic and Research Council.

90 Provisional Approval Letter Holder responsible for submitting Application for Research Permit

The Provisional Approval Letter Holder is responsible for submitting the Application for a Research Permit to the Registry of Companies within the term of the Provisional Approval Letter together with the applicable fee.

91 Information to be provided with Application for Research Permit

- (1) The Application shall contain such information as the Registry of Companies may reasonably require, consistent with the provisions of this Research Regulation and the applicable Rules, Standards and Policies.
- (2) Each Provisional Approval Letter Holder making an Application for a Research Permit shall specify in its Application the research activity that it proposes to carry on, if different from the information contained in its Application for a Provisional Approval Letter.

92 Preparation for Commissioning

In preparation for Commissioning, the Provisional Approval Letter Holder shall develop policies and procedures for the provision of the research activity or activities included in its Provisional Approval Letter in accordance with the applicable Rules, Standards and Policies.

93 Commissioning

- (1) A Provisional Approval Letter Holder shall undergo the Commissioning to ensure that it complies with the applicable Rules, Standards and Policies, and any other standards that an Agency specifies are required to be met prior to issuing a Research Permit.
- (2) Following the submission of an Application for a Research Permit, the Registry of Companies shall undertake, or arrange for the undertaking of the Commissioning which shall include, but is not limited to:
 - (a) a review of the final versions of all of the Provisional Approval Letter Holder's written policies then required to be in place;
 - (b) a comprehensive on-site inspection and/or assessment of the intended Research Site at which the Provisional Approval Letter Holder proposes to conduct its research activities;

- (c) the review of information that supports the conclusion that the Provisional Approval Letter Holder shall be able to satisfy all provisions of this Research Regulation, and the applicable Rules, Standards and Policies; and
 - (d) the provision of documented evidence that the Provisional Approval Letter Holder has received all licenses and other approvals required under the applicable Building Regulations and Zoning Regulations
- (3) In undertaking the Commissioning, the Registry of Companies shall also determine if the Controllers, directors and Associated Persons of the Provisional Approval Letter Holder, as well as any Managers identified by the Provisional Approval Letter Holder, are all Fit and Proper Persons.
 - (4) On completion of the Commissioning, the Registry of Companies shall provide the Provisional Approval Letter Holder with a report on the preparedness of the Provisional Approval Letter Holder to provide research activities.

94 Requirement to provide further information towards Application for Research Permit

The Provisional Approval Letter Holder shall provide any such other information as the Registry of Companies may reasonably request within the timeframe specified by the Registry of Companies, in preparation for the Registry of Companies to review the Application for a Research Permit.

95 Review of Application for Research Permit by the Registry of Companies

- (1) The Registry of Companies shall consider the Application together with the report on the Commissioning and the in-principle approvals from the Clinical Affairs Department, Licensing Board and Academic and Research Council, if any.
- (2) In considering the information provided under subsection (1), the Registry of Companies shall take into account any applicable Regulations, Rules, Standards and Policies.

96 Action on Application for Research Permit

Upon review, the Registry of Companies may:

- (1) approve the Application;
- (2) approve the Application subject to conditions or restrictions as it deems necessary and proper to be included in the Research Permit; or
- (3) deny the Application.

97 Approval of Application for Research Permit

The Registry of Companies shall not approve an Application unless it determines that:

- (1) the Applicant satisfies all relevant criteria contained in this Regulation, and applicable Rules, Standards and Policies with regard to the type of research activities the Applicant proposes to undertake;
- (2) the Applicant has completed or is capable of completing all of the steps required by this Regulation and the applicable Rules, Standards and Policies to convert its Provisional Approval Letter to a Research Permit;

- (3) the Applicant has employed or engaged, or made arrangements to employ or engage Licensed Healthcare Professionals and others who possess the qualifications and experience to implement the research activities proposed in the Application;
- (4) all Principal Investigators, Controllers, directors, Associated Persons and Managers identified in the Application are Fit and Proper Persons;
- (5) no facts have been found that would constitute grounds for the Registry of Companies to deny the Application;
- (6) in-principle approval has been granted by the Clinical Affairs Department;
- (7) in-principle approval has been granted by the Licensing Board; and
- (8) in-principle approval has been granted by the Academic and Research Council in respect of the Protocol.

98 Grounds for denying Application for Research Permit

The Registry of Companies may deny an Application if it determines that:

- (1) any statements, information or documents submitted by the Applicant are false, misleading or deceptive, or are likely to mislead or deceive;
- (2) there has been a modification or change in the circumstances relating to the information or documentation contained in the Application subsequent to its filing and the Applicant has failed to notify the Academic and Research Council of any such modification or change in a timely manner;
- (3) the Applicant has failed to satisfy any of the requirements in section 97; or
- (4) the Registry of Companies is not satisfied that the Applicant will comply with the provisions of this Research Regulation, and the applicable Rules, Standards and Policies, if it were to hold a Research Permit.

99 Applicant to be notified of Registry of Companies' decision

The Registry of Companies shall notify the Applicant in writing of its decision to:

- (1) approve the Application and issue the Research Permit;
- (2) impose conditions or restrictions on the issue of such Research Permits; or
- (3) deny the Application.

100 No right of appeal of the Registry of Companies' decision

The Applicant has no right to seek an appeal of the Registry of Companies' decision to deny an Application or to impose conditions or restrictions on the Research Permit.

101 Right to be referred to as an Approved Research Operator

Where the Application is approved by Registry of Companies, the Applicant shall be entitled to:

- (1) refer to itself as an Approved Research Operator; and
- (2) conduct research activities within DHCC in accordance with its Research Permit.

102 Details contained on Research Permit

A Research Permit shall contain the following details:

- (1) the name of the Approved Research Operator;
- (2) the Effective Date of the Research Permit;
- (3) the name of the Approved Research Operator's Manager;
- (4) the Approved Research Activity or Activities the Approved Research Operator intends to conduct; and
- (5) such other matters, including any terms, conditions or restrictions included in the Research Permit, as may be specified by the Registry of Companies.

103 Display of Research Permit

An Approved Research Operator shall at all times, prominently post a copy of its Research Permit at each of its Research Sites, in such a manner that the Research Permit is visible to persons participating in the Approved Research Activities at such Research Site.

104 Details of Research Permit to be recorded on Register

At the time the Research Permit is issued, the details of the Approved Research Operator and the Research Permit, including any conditions or restrictions being included in the Research Permit, shall be added to the Academic and Research Council's Register in accordance with the Governing Regulation.

Part Ten

Obligations and Roles of Approved Research Operators, Investigators and Sponsoring Institutions

105 Compliance with Regulations

Each Approved Research Operator shall comply with all applicable requirements of this Research Regulations, and all other applicable Regulations, Rules, Standards and Policies.

106 Change of name, address and other details

- (1) An Approved Research Operator shall ensure that the information contained in the register is up to date and shall notify the Registry of Companies of any changes as soon as practicable after the date of change.
- (2) The Registry of Companies may require the Approved Research Operator to provide evidence to support any such change.

107 No addition or change of research activities

- (1) No Approved Research Operator may conduct a research activity not encompassed within its already issued Research Permit or substantially change an Approved Research Activity without first obtaining the Registry of Companies' approval.
- (2) Where an Approved Research Operator intends to change the research activities that have been approved within its Research Permit, the Approved Research Operator shall submit a new Application before it is able to provide such research activities.

108 Ethics committee

- (1) Each Approved Research Operator shall, as stipulated in the Regulations, Rules, Standards and Policies in force from time to time, establish an ethics committee to monitor and review the quality of the services provided by the Approved Research Operator.
- (2) Such ethics committee shall be responsible for the ethical review of all Protocols and its responsibilities shall include the following:
 - (a) review of each Protocol to determine compliance with the Research Accreditation and Code of Ethics, all relevant ethical principles and all applicable Regulations and approval of the same;
 - (b) undertake the continuing review of the Approved Research Activities to ensure the continued validity of ethics approval of such Approved Research Activities, ongoing regulatory compliance, and adherence to the Protocol;
 - (c) review of Serious Adverse Events;
 - (d) recommendation of corrective measures to prevent recurrence of such Serious Adverse Events;
 - (e) monitoring the implementation of such recommendations.

- (f) submission of reports on Serious Adverse Events including actions taken under subsections (d) and (e) to the Research Ethics Review Committee;
 - (g) providing feedback to, and maintaining dialogue about applicable standards with the Investigators.
- (3) Such ethics committees shall consist of relevant persons with the appropriate expertise.
 - (4) An Approved Research Operator is not required to establish an ethics committee if the Approved Research Operator's Parent or an Associated Person gives a written undertaking that its ethics committee shall undertake the role of an ethics committee set out in this section.
 - (5) An ethics committee of the Approved Research Operator's Parent or an Associated Person shall comply with all the responsibilities of an ethics committee set out in this section.

109 Obligations of Principal Investigators

- (1) Each Principal Investigator shall be a Licensed Healthcare Professional or a Licensed Complementary and Alternative Medicine Professional or in the case of a Principal Investigator who is not a Licensed Healthcare Professional or a Licensed Complementary and Alternative Medicine Professional, be engaged by a Licensed Commercial Company.
- (2) A Principal Investigator shall be qualified by education, training, and experience to assume responsibility for the proper conduct of the Approved Research Activity and shall provide evidence of such qualifications and/or other relevant documentation as requested from time to time by the Research Ethics Review Committee and any of the other Committees as considered appropriate.
- (3) Each Principal Investigator shall comply with all applicable requirements of this Research Regulation, and all applicable Regulations, Rules, Standards and Policies.

110 Training Requirements

All Principal Investigators, Sub-Investigators and other staff participating in the conduct of research shall:

- (1) prior to participating in an Approved Research Activity, complete a training program approved by the Academic and Research Council and an assessment of such training;
- (2) complete a refresher course approved by the Academic and Research Council at least once every 2 years.

111 Familiarity with Investigational Products

Each Principal Investigator shall be familiar with the appropriate use of Investigational Product(s), as described in the approved Protocol associated with the Human Biomedical Research, in the then current Investigator's Brochure and in any applicable device manual, product information or other relevant available information.

112 Absence of Significant Financial Interest

A Principal Investigator shall submit, for himself and each Sub-Investigator associated with the research, either a certification attesting to the absence of any Significant Financial Interest on the part of himself and any such Investigator or a disclosure statement of any financial Conflict of Interest on the part of any of them in accordance with section 113.

113 Presence of Financial Interest

Each Investigator who has a financial Conflict of Interest shall file a disclosure statement with the Research Ethics Review Committee that identifies:

- (1) any financial agreement entered into between the Sponsor of the research and the Investigator, whereby the value of the compensation to the Investigator for conducting the Research could be influenced by the outcome of the research;
- (2) any Proprietary Interest in the Investigational Product held by any Investigator involved in the research;
- (3) any significant payments of any other sort made from the Sponsor of the research such as a grant to fund ongoing research, compensation in the form of equipment, a retainer for ongoing consultation, honoraria, etc; and
- (4) any Equity Interest held by an Investigator associated with the Sponsor of the research.

114 Information to be provided to the Research Ethics Review Committee or relevant Committee

Each Principal Investigator shall submit the following reports to the Research Ethics Review Committee and/or the relevant Committee:

- (1) annual progress reports which include written summaries of the progress of the Approved Research Activities;
- (2) safety reports, promptly upon the occurrence of any Serious Adverse Event, which should include the following:
 - (a) a description of the incident;
 - (b) the extent of the impact on the Human Subject involved or any other Human Subjects;
 - (c) a review and analysis on whether research intervention, including termination or suspension of the Approved Research Activity, was required, and if so how such intervention was carried out;
 - (d) whether there was any non-compliance with the Protocol or any applicable Regulations, Rules, Standards and Policies;
 - (e) whether corrective measures were put into place to prevent recurrence of the incident.
- (3) a final report upon the completion of the Approved Research Activity, by no later than 90 days following such completion.

115 Obligations of Sponsors

Each Sponsor shall comply with all applicable requirements of this Research Regulations, other applicable Regulations, and all applicable Rules, Standards and Policies.

116 Allocation of responsibilities at the Research Site

Prior to initiation of any research, each Principal Investigator shall have defined, established and allocated all research-related responsibilities and functions and shared such information with all personnel at each Research Site who are involved with the research.

117 Responsibility for Investigational Product

Each Sponsor shall be responsible for supplying and handling each Investigational Product associated with Human Biomedical Research including but not limited to:

- (a) securing import approval and shipment of the Investigational Product only to Investigators participating in the Human Biomedical Research once the Human Biomedical Research is approved;
- (b) ensuring that written instructions are provided to the Principal Investigator regarding the handling and storage of the Investigational Product; and
- (c) taking steps to ensure that the Investigational Product is stable over the period of use.

118 Cooperation with regard to on-site assessment

- (1) The Approved Research Operator is required to comply with any reasonable requirements identified by the Clinical Affairs Department in the notice under subsection (2) related to an on-site assessment.
- (2) The Clinical Affairs Department may at any time during the term of a Research Permit, serve the Approved Research Operator a written notice to undertake an on-site assessment which includes:
 - (a) an on-site assessment of the Research Site that is subject to the Research Permit and the manner in which the Approved Research Operator is conducting the Approved Research Activity or Activities for which it has received its Research Permit; and
 - (b) a review of all of the Approved Research Operator's policies and procedures then in effect, to ensure that they remain in compliance with the requirements of this Research Regulation and all other applicable Regulations, Rules and Standards and Policies.

119 Provision of information

Each Approved Research Operator that is a Branch shall:

- (1) provide the Registry of Companies, on each anniversary of the issuance of the Branch's Research Permit, a certificate issued by the Home Jurisdiction of the Parent that proves the continuation of the legal existence in such Jurisdiction of the Parent and the validity of its licensure, registration or equivalent authorization with such authority; and
- (2) notify the Registry of Companies in writing of any modification or change to its Parent's licensure, registration or equivalent authorization that it reported in its Application, together with the date of the occurrence of such modification or change, by no later than 20 days following any such modification or change.

120 Notification of termination of research activities

- (1) An Approved Research Operator shall promptly notify the Registry of Companies if it decides not to proceed with the implementation of any of the Approved Research Programs for which its Research Permit has been issued.
- (2) Immediately upon the submission of a notification required by subsection (1), the Research Permit issued to such Approved Research Operator shall become null and void as it relates to any such Approved Research Activity and the Registry of Companies may issue a revised Research Permit.

121 Notification of changes to business

In addition to the information that an Approved Research Operator is otherwise required to provide under this Research Regulation or any other applicable Rules, Standards or Policies, each Approved Research Operator shall provide notice to the Registry of Companies of the occurrence of any of the following:

- (1) changes in the nature of any other business it carries on in conjunction with any of its Approved Research Activities;
- (2) any proposal of the Approved Research Operator to alter the nature or extent of any other business that it carries on;
- (3) changes to its Manager, Controllers, directors and Associated Persons; and
- (4) changes to the facility and medical equipments, if applicable, requiring design approvals and fit-out permits to be issued in accordance with the Design and Construction Guidelines.

Part Eleven: Actions by Research Ethics Review Committee and Clinical Affairs Department Following On-site Assessment

122 Non-compliance following on-site assessment

- (1) Subject to section 124, following an on-site assessment under section 118, the Clinical Affairs Department shall notify the Approved Research Operator if it finds non-compliance with the requirements of the:
 - (a) Approved Research Operator's Research Permit;
 - (b) any of the applicable requirements of this Research Regulation, or
 - (c) any other applicable Regulations, Rules, Standards and Policies.
- (2) Where an Approved Research Operator is found to be non-compliant under subsection (1), it shall:
 - (a) if required by the Clinical Affairs Department, file a plan of correction to rectify the breaches and implement this plan within such period of time as the Clinical Affairs Department may require; and
 - (b) in any case, comply with any requirements as directed by the Clinical Affairs Department to rectify the breaches within such period of time as the Clinical Affairs Department may require.
- (3) The Research Ethics Review Committee may at any time, direct the Clinical Affairs Department to take action under this section if, following the receipt of any report under section 114, it finds non-compliance with the requirements of the:
 - (a) Approved Research Operator's Research Permit; or
 - (b) any of the applicable requirements of this Research Regulation, or
 - (c) any other applicable Regulations, Rules, Standards and Policies.

123 Further on-site assessment

The Clinical Affairs Department shall undertake, or arrange to be undertaken, a further on-site assessment to monitor the rectification of the breaches.

124 Notification to CPU of failure to rectify breaches

If the Approved Research Operator fails to comply with section 122(2) or if the Clinical Affairs Department is not satisfied that the breaches have been rectified, the Clinical Affairs Department may notify CPU.

125 Notification to CPU of serious and imminent risk

- (1) If following an on-site assessment under section 118, the Research Ethics Review Committee or the Clinical Affairs Department identifies a serious and imminent risk to the health or safety of its employees, research subjects or the public, the Research Ethics Review Committee or Clinical Affairs Department shall notify CPU immediately.

- (2) The Research Ethics Review Committee or Clinical Affairs Department may include, in its notification to the CPU, a request for an immediate interim restriction or suspension to be imposed on the Approved Research Activities under the Research Permit, if they consider that there is reasonable cause to believe that it is necessary because:
- (a) action or inaction by such Approved Research Operator poses a serious and imminent risk to the health or safety of its employees, research subjects or the public;
 - (b) the on-site assessment undertaken by the Clinical Affairs Department under section 118 indicates a serious and imminent risk to the health or safety of its employees, research subjects or the public; or
 - (c) the Approved Research Operator no longer has Approved Professional Indemnity Insurance, if applicable, in effect.

Part Twelve: Imposition of Conditions, Revocation and Suspension of a Research Permit

126 CPU to act on information from Research Ethics Review Committee or Clinical Affairs Department

- (1) Where the CPU has received a notification from the Research Ethics Review Committee or Clinical Affairs Department pursuant to sections 124 or 125, CPU shall act in accordance with the provisions of this Part.
- (2) For purposes of this Part, any such notification shall be referred to as a complaint from the Research Ethics Review Committee or Clinical Affairs Department.

127 Initial assessment

- (1) After receipt of a complaint, the CPU shall carry out an initial assessment.
- (2) The CPU shall as soon as reasonably practicable send a copy of the complaint to the Approved Research Operator concerned and require him to submit his written explanation to the complaint within a stipulated time.
- (3) At any time, the CPU may refer a complaint for mediation in accordance with section 128.
- (4) At any time, the CPQ may take steps to obtain further information as it deems necessary pursuant to its powers as provided for in sections 136 to 143 of the Governing Regulation.
- (5) After its initial assessment, CPU may refer the complaint to a Fitness to Practice Panel for review.
- (6) Upon making its decision on its course of action, the CPU shall as soon as reasonably practicable, serve a written notification to the Approved Research Operator and the complainant, and in the case of the Approved Research Operator, provide it with a copy of the complaint.

128 Mediation

- (1) Where the CPU has referred the matter for mediation, the CPU shall notify the Approved Research Operator and the complainant.
- (2) Both the Approved Research Operator and the complainant must consent to the mediation before the mediation can proceed.
- (3) Upon obtaining such consent from the Approved Research Operator and the complainant, the CPU shall appoint a mediator to carry out the mediation.
- (4) If no such consent has been obtained from:
 - (a) the Approved Research Operator, the CPU shall refer the matter to the Fitness to Practice Panel;
 - (b) the complainant, the CPU may dismiss the complaint.
- (5) Upon the conclusion of mediation, the mediator shall submit a report to the CPU, including the terms of any amicable resolution of the matter reached.

- (6) In the event that the complainant and/or the Manager of the Approved Research Operator refused or failed without reasonable cause to attend the mediation, the mediator may recommend the following:
 - (a) refer the matter to Fitness to Practice Panel; or
 - (b) dismiss the complaint.
- (7) In the event that there is no amicable resolution of the matter, the CPU may, after consideration of the report submitted by the mediator, make the following orders:
 - (a) dismiss the complaint; or
 - (b) refer the matter to the Fitness to Practice Panel.

129 Interim restriction or suspension

- (1) Where the CPU has received a request from the Research Ethics Review Committee or Clinical Affairs Department pursuant to section 125(2) to impose an immediate interim restriction or suspension on the Approved Research Activities under the Research Permit, the CPU shall inform the chairperson of the Complaints Panel immediately.
- (2) The chairperson of the Complaints Panel shall review the complaint to determine whether an immediate interim restriction or suspension should be made.
- (3) The chairperson of the Complaints Panel may be assisted by a legal assessor in his review of the complaint.
- (4) The chairperson of the Complaints Panel shall provide the Approved Research Operator with a copy of the complaint and request it to provide its explanation as to whether an immediate interim restriction or suspension should be made, either in writing or at a hearing. If the Manager of the Approved Research Operator is called upon to attend a hearing, he shall attend the hearing alone, unless the chairperson of the Complaints Panel allows otherwise.
- (5) The chairperson of the Complaints Panel may impose an interim restriction or suspension on the Research Permit.
- (6) The chairperson of the Complaints Panel shall immediately serve a written notification of its decision under subsection (5) above to the Approved Research Operator, and such decision shall take effect from the date of receipt of such notification.
- (7) Such interim restriction or suspension shall remain in place until directed otherwise by the Fitness to Practice Panel following the completion of the review by the Fitness to Practice Panel.
- (8) For the avoidance of doubt, this Part of this Research Regulation shall continue to apply to an Approved Research Operator whose Research Permit is the subject of an interim restriction or suspension imposed by the chairperson of the Complaints Panel pursuant to subsection (5).

130 Referral to Fitness to Practice Panel

- (1) Where the CPU has made its decision to refer the complaint to the Fitness to Practice Panel, the chairperson of the Complaints Panel shall appoint a Fitness to Practice Panel in accordance with section 135 of the Governing Regulation.

- (2) The Fitness to Practice Panel shall review the complaint against the Approved Research Operator to determine whether an order to impose conditions on, suspend or revoke the Research Permit should be made.

131 Obtaining legal advice

The Fitness to Practice Panel may obtain legal advice from a legal assessor to assist in its review.

132 Preparation for Fitness to Practice Panel's review

- (1) The Fitness to Practice Panel may, at any time before its review commences, require:
 - (a) the Approved Research Operator to provide any additional information; or
 - (b) the Manager of the Approved Research Operator to meet with a member of the Fitness to Practice Panel to identify and clarify the nature of the issues that shall be considered or determined during the review.
- (2) The Fitness to Practice Panel shall provide the Approved Research Operator with Guidance concerning the conduct of the review prior to the commencement of the review.

133 Notification of Fitness to Practice Panel's hearing

When a Fitness to Practice hearing is to be held, the Fitness to Practice Panel shall:

- (1) within 3 days following its appointment, serve a notice on the Approved Research Operator that states:
 - (a) the nature of the hearing and of any allegations made against the Approved Research Operator or the issues that have been identified;
 - (b) the time and place of the hearing;
 - (c) that the Approved Research Operator has the right to make submissions at the hearing, through the Manager and/or counsel; and
 - (d) that the hearing shall be held in private unless required otherwise by the Fitness to Practice Panel.
- (2) fix a time and place for the hearing to be held, which time shall be no earlier than 21 days and no later than 45 days following notification to the Approved Research Operator under subsection (1) above.

134 Procedures for hearing

- (1) At the Fitness to Practice Panel hearing:
 - (a) the Fitness to Practice Panel shall hear and determine the matter before it;
 - (b) the Approved Research Operator is entitled to be present, by way of the Manager and/or legal counsel, to make submissions, to call witnesses and to undertake cross-examination; and
 - (c) the proceedings are to be closed to the public unless the Fitness to Practice Panel determines otherwise.
- (2) Subject to the other provisions of this section and any relevant Standards and Policies, the Fitness to Practice Panel:

- (a) may regulate its own procedure;
- (b) shall conduct the proceedings with as little formality and technicality as the requirements of this Research Regulation and the proper consideration of the matter reasonably permit;
- (c) is not bound by rules of evidence but may inform itself in any way that is reasonable; and
- (d) is bound by the rules of natural justice.

135 Decision of Fitness to Practice Panel

- (1) At the conclusion of the review, the Fitness to Practice Panel may:
 - (a) impose conditions or restrictions on an Approved Research Operator's Research Permit;
 - (b) suspend the Research Permit for a period stipulated by the Fitness to Practice Panel;
 - (c) revoke the Research Permit;
 - (d) remove or modify conditions or restrictions previously included in an Approved Research Operator's Research Permit;
 - (e) impose a Penalty in accordance with the schedule of prescribed fines issued by the Registry of Companies from time to time; or
 - (f) take no further action.
- (2) Further to subsection (1), the Fitness to Practice Panel may order the Approved Research Operator concerned to pay such sums as it thinks fit in respect of costs and expenses of and incidental to any proceedings before the Fitness to Practice Panel, and where applicable, the chairperson of the Complaints Panel. Such costs and expenses shall include:-
 - (a) the costs and expenses of any legal assessor appointed to assist the Fitness to Practice Panel in its review;
 - (b) such reasonable expenses as the Fitness to Practice Panel may pay to witnesses; and
 - (c) such reasonable expenses as are necessary for the conduct of proceedings before the Fitness to Practice Panel and the chairperson of the Complaints Panel.

136 Grounds for imposing conditions or restrictions, suspending or revoking a Research Permit

- (1) Grounds for the Fitness to Practice Panel imposing conditions or restrictions, suspending or revoking a Research Permit in full or in part include, but are not limited to, where the Approved Research Operator:
 - (a) has substantially contravened a provision of this Research Regulation, any other applicable Regulations, Rules, Standards and Policies, or the terms, conditions or restrictions included in its Research Permit;
 - (b) has failed to satisfy a material obligation to which it is subject to by virtue of this Research Regulation, or any other applicable Regulations, Rules, Standards or Policies;
 - (c) has repeatedly failed to correct deficiencies identified to it by the Research Ethics Review Committee or the Clinical Affairs Department, upon the

- Research Ethics Review Committee or the Clinical Affairs Department's periodic review, even if individually, any one such deficiency would not by itself constitute grounds for revocation of a Research Permit;
- (d) no longer holds a License to carry on business in DHCC under the Company Regulations;
 - (e) in the case of an Approved Research Operator that is a Branch, its Parent no longer has the right to carry on business in its Home Jurisdiction;
 - (f) fails to maintain Approved Professional Indemnity Insurance, if applicable;
 - (g) has furnished fraudulent, misleading, deceptive or inaccurate information to the Registry of Companies or the Academic and Research Council under or for the purposes of any provision of this Research Regulation, any other applicable Regulations, Rules, Standards and Policies;
 - (h) has not commenced one or more of the Approved Research Activities for which its Research Permit was granted within 90 days of such grant, or within such other period as may reasonably have been specified by the Registry of Companies;
 - (i) has not paid any applicable fee, including any Penalty, due and payable in respect of a Research Permit, or has not paid any other amounts due to the Registry of Companies;
 - (j) has either not commenced or for a period of 3 months, ceased to conduct any Approved Research Activity without written notice;
 - (k) is carrying on, purportedly under its Research Permit, a research activity or activities different from that for which its Research Permit was granted;
 - (l) has assigned the benefit and control of the Approved Research Activity or Activities of the Approved Research Operator to a third party.
- (2) The Fitness to Practice Panel may also impose conditions or restrictions on, suspend or revoke a Research Permit:
- (a) on the order of a court or tribunal having jurisdiction in DHCC; or
 - (b) on any other ground that the applicable Rules, Standards and Policies may specify as a proper and reasonable ground for the imposition of conditions or restrictions on, suspension or revocation of a Research Permit.

137 Approved Research Operator to be notified of Fitness to Practice Panel's decision

- (1) The Fitness to Practice Panel shall notify the Approved Research Operator in writing of its decision.
- (2) The Fitness to Practice Panel shall also provide the Approved Research Operator with:
 - (a) a written statement of reasons for its decision; and
 - (b) details of its right to seek an appeal of the decision.

138 Right of appeal of decision of Fitness to Practice Panel

- (1) The Approved Research Operator has the right to seek an appeal of the Fitness to Practice Panel's decision.
- (2) Any appeal shall be carried out in accordance with Part Thirteen of this Research Regulation.

139 Registry of Companies may suspend or revoke Research Permit in summary manner

- (1) The Registry of Companies may suspend or revoke a Research Permit of an Approved Research Operator in a summary manner where —
 - (a) the License(s) of Licensed Healthcare Professional(s) who are identified to be key personnel of the Approved Research Operator have been revoked or suspended; or
 - (b) the Approved Research Operator is not covered by the applicable insurance in accordance with section 174 while conducting Approved Research Activities.

- (2) Before suspending or revoking the Research Permit under subsection (1), the Registry of Companies shall —
 - (a) give to the Approved Research Operator notice in writing of its intention to do so; and
 - (b) in such notice, call upon the Approved Research Operator to show cause within such time as may be specified in the notice as to why its Research Permit should not be suspended or revoked.

- (3) If the Approved Research Operator —
 - (a) fails to show cause within the period of time given to him or such extended period of time as the Registry of Companies may allow; or
 - (b) fails to show sufficient cause, as to why the Research Permit should not be suspended or revoked,the Registry of Companies shall give notice in writing to the Approved Research Operator of the date from which the suspension or revocation of the Research Permit is to take effect and where applicable, the period of suspension.

- (4) Sections 146 and 147 of this Research Regulation shall apply in the same manner as if the Research Permit was suspended or revoked by the decision of the Fitness to Practice Panel as set out in Part Twelve of this Research Regulation.

Part Thirteen Appeal Process

140 Appeal against decision of Fitness to Practice Panel

Where a right of appeal against a decision of the Fitness to Practice Panel has been provided in this Research Regulation, the appeal process shall follow the provisions of this Part.

141 Fitness to Practice Panel's orders shall not take effect pending appeal

Unless otherwise ordered by the Fitness to Practice Panel, where the Approved Research Operator has filed an appeal against the Fitness to Practice Panel's orders, the orders shall not take effect until the conclusion of the appeal and the Appeals Board has made a decision under section 144.

142 Right to provide further information upon appeal

- (1) Where the Approved Research Operator files an appeal against the Fitness to Practice Panel's decision, the Approved Research Operator shall provide the Appeals Board with:
 - (a) a written notification of its intention to appeal the relevant decision;
 - (b) a written response to the statement of reasons set out in the notification under section 137; and
 - (c) such additional and supplemental information as it deems appropriate.
- (2) The information provided in subsection (1) above shall be provided to the Appeals Board within 30 days of receipt of the notification under section 137.

143 No right to be heard

- (1) The Approved Research Operator has no right to be heard by the Appeals Board, unless his attendance has been requested by the Appeals Board under subsection (2).
- (2) The Appeals Board may invite the Approved Research Operator to attend the meeting of the Appeals Board where the matter is to be considered.

144 Decision of Appeals Board

- (1) Following consideration of the matter together with the further information provided under section 142, the Appeals Board shall either:
 - (a) impose conditions or restrictions on a Approved Research Operator's Research Permit;
 - (b) suspend the Research Permit for a period of time stipulated by the Fitness to Practice Panel;
 - (c) revoke the Research Permit;
 - (d) remove or modify conditions or restrictions previously included on an Approved Research Operator's Research Permit;
 - (e) impose a Penalty in accordance with the schedule of prescribed fines issued by the Registry of Companies from time to time; or

- (f) take no further action.
- (2) Further to subsection (1), the Appeals Board may order the Approved Research Operator concerned to pay such sums as it thinks fit in respect of costs and expenses of and incidental to any proceedings before the Appeals Board. Such costs and expenses shall include:-
 - (a) the costs and expenses of any legal assessor appointed to assist the Appeals Board in its review;
 - (b) such reasonable expenses as the Appeals Board may pay to witnesses; and
 - (c) such reasonable expenses as are necessary for the conduct of proceedings before the Appeals Board.
- (3) The Appeals Board shall make its decision by a majority vote.

145 No right of appeal

The Applicant has no right to seek an appeal of the Appeals Board's decision.

Part Fourteen: Termination of Approved Research Activities

146 Actions following refusal to renew or revocation of Research Permit

- (1) Following a decision by the Fitness to Practice Panel or the Appeals Board to revoke the Approved Research Operator's Research Permit, or a decision of the chairperson of the Complaints Panel to impose an interim restriction or suspension on the Approved Research Operator's Research Permit, the Registry of Companies shall determine the duration of an orderly wind down period for the Approved Research Activity or Activities provided by the Approved Research Operator under the Research Permit.
- (2) In determining the duration of an orderly wind down period, the Approved Research Operator shall give due consideration to, among other relevant factors, the need for proper notice to Human Subjects in the case of Human Biomedical Research, especially those Human Subjects already participating in the research, and the time required to ensure that Human Subjects are properly discharged from the Human Biomedical Research or transferred to another Approved Research Operator undertaking the same Human Biomedical Research.
- (3) Where the Approved Research Operator has obtained a license to operate outside of DHCC in compliance with section 42(2), it shall notify the relevant authority of the revocation, refusal to renew, or the interim suspension or revocation of its Research Permit.
- (4) In the situation described in subsection (3), the Registry of Companies may also disclose the revocation, refusal to renew, or the interim suspension or revocation of the Approved Research Operator's Research Permit to the relevant authority.
- (5) The obligations in this section shall take effect upon the expiry of the 30 day period provided for the notification of an appeal to the Appeals Board.

147 Ceasing activities

Upon the completion of the orderly winding down of the Approved Research Operator's Approved Research Activity or Activities, the affected Approved Research Operator shall immediately cease providing all Approved Research Activities under its Research Permit and shall no longer be entitled to refer to itself as an Approved Research Operator.

Part Fifteen: Voluntary Termination of Approved Research Activities

148 Written notice to be provided

An Approved Research Operator may, at any time, provide written notice to the Registry of Companies that it intends to cease providing one or more Approved Research Activities under its Research Permit as of a date or dates specified in the notice.

149 Information to be provided

The Approved Research Operator shall include with the written notice under section 148, a plan for the orderly winding down of the Approved Research Activity or Activities that it proposes to cease providing including the date that the Operator expects to complete the winding down of the Approved Research Activity.

150 Advice from Registry of Companies, other Agencies and CPQ

The Registry of Companies may seek the advice of the other Agencies with regard to the voluntary termination of research activities on a permanent and temporary basis and in particular the adequacy of the plan submitted under section 149.

151 Sufficient time required to wind down Approved Research Activities

The date or dates specified in a notice provided under section 148 shall be sufficient to provide such time as is reasonable for the Approved Research Operator to provide for the orderly winding down of each Approved Research Activity identified in such notice. The Registry of Companies may consult with the Academic and Research Council and/or the Research Ethics Review Committee as to the sufficiency of such time required.

152 Registry of Companies may require extension of time

The Registry of Companies may require that any date specified in a notice under section 148 be extended if following a review of the information provided under section 149, it determines that more time is required in order to ensure that the affected Approved Research Activities are terminated in an orderly fashion.

153 CPQ may direct winding down

If the Registry of Companies considers a plan submitted under section 149 insufficient, or otherwise determines that the affected Approved Research Operator is not itself able to adequately arrange for the orderly closure of any of the affected research activities, it may direct CPQ or an organization appointed by CPQ to enter the Research Site at which the Approved Research Operator has been conducting such research activities solely to provide for an orderly winding down of all such research activities.

154 Registry of Companies may require continuation of Approved Research Activity

The Registry of Companies may, based on the opinion of the Research Ethics Review Committee that the termination of the Approved Research Activity shall adversely affect the Human Subjects participating in the Approved Research Activity, serve a written notice on

the Approved Research Operator requiring it to continue engaging in the Approved Research Activity for a reasonable period of time as specified by the Research Ethics Review Committee.

155 Termination of Research Permit

Upon the date specified in the notice under section 148 or any other date that may be stipulated by the Registry of Companies, the Research Permit shall be terminated and the Registry of Companies shall issue a revised Research Permit if necessary.

Part Sixteen: General Principles regarding the conduct of Human Biomedical Research involving Human Subjects within DHCC

156 General Requirements for Conducting Human Biomedical Research Involving Human Subjects

All Human Biomedical Research shall be conducted in accordance with the applicable requirements of this Research Regulation, and any other applicable Rules, Standards and Policies, as well as the ethical principles described in the Research Accreditation and Code of Ethics published by the Academic and Research Council from time to time.

157 Safety of Human Subject paramount

In accordance with section 165, in the case of the suspension or withdrawal of Human Biomedical Research, it is the responsibility of the Approved Research Operator and the Principal Investigator to ensure the safety of the Human Subjects.

158 Human Biomedical Research conducted in conjunction with other jurisdictions

It is acknowledged that from time to time, Human Biomedical Research being undertaken within DHCC shall be undertaken in conjunction with other jurisdictions and shall be in compliance with regulations from those other jurisdictions, including, but not limited to,

- (a) the relevant United States Code of Federal Regulations (CFR);
- (b) the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guideline on Good Clinical Practice (E6); and
- (c) the European Union and its requirements under the European Clinical Trial Directive (EUCT).

159 Requirement for approval of all Human Biomedical Research

All Human Biomedical Research shall be reviewed from a scientific and ethical perspective and approved by the Research Ethics Review Committee.

160 Clinical trials register

Any Human Biomedical Research involving a clinical trial, which has been approved to be undertaken within DHCC, shall be recorded on an internationally recognized clinical trials register as determined from time to time by the Research Ethics Review Committee, and as stated in the applicable Regulations, Rules, Standards and Policies.

161 Criteria for assessing Human Biomedical Research

The Research Ethics Review Committee when reviewing a Human Biomedical Research Application shall ensure that the Risks to the Subjects shall be minimized:

- (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose Human Subjects to Risk; and

- (b) whenever appropriate, by using procedures already being performed on the Human Subjects for diagnostic or treatment purposes.

162 Development of Human Biomedical Research Protocols

- (1) All Human Biomedical Research Protocols shall be well-designed according to sound scientific principles and, if applicable, be preceded by adequate laboratory and/or animal studies.
- (2) The Human Biomedical Research design should minimize Risk and maximize benefits to the Human Subjects and comply with the applicable Rules, Standards and Policies.
- (3) The use of placebo controls shall be scientifically based and ethically justifiable.

163 Requirement for Human Subjects to give informed consent

No Human Biomedical Research may be initiated without the Informed Consent of each participating Human Subject, except as otherwise provided in this Research Regulation. Informed Consent shall be obtained in the manner as provided for in the Research Accreditation and Code of Ethics published by the Academic and Research Council from time to time.

164 Situations under which Human Biomedical Research to be discontinued

- (1) An Approved Research Operator shall discontinue the Human Biomedical Research when the Risks to a Human Subject are found to be greater than anticipated, or when one treatment appears clearly to be less effective than another with which it is being compared.
- (2) Where subsection (1) applies, the Approved Research Operator shall follow the process set out in Part Fourteen.

165 Action following termination or suspension of Human Biomedical Research

If a Human Biomedical Research is discontinued, terminated prematurely or suspended for any reason, the Principal Investigator shall promptly inform all of the Human Subjects and ensure that appropriate therapy and follow up are provided for them.

166 Effective Treatment

Approved Research Operators are responsible for ensuring that Human Subjects shall not be denied the benefits of more effective treatment, once its value has been established.

167 Competency of Investigators

Human Biomedical Research shall be conducted at all times by competent Investigators, who:

- (1) are qualified by training and experience;
- (2) have been made aware of the requirements of this Research Regulation and any applicable Rules, Standards and Policies; and

- (3) are mindful of the ethical considerations relating to the Human Biomedical Research with Human Subjects.

168 Transparency

All Human Biomedical Research shall be conducted in a fair, honest, impartial and transparent manner, after full disclosure is made by those associated with the Human Biomedical Research of their interest in the research outcome and of any financial Conflict of Interest that may exist.

169 Use of Patient Health Information in Human Biomedical Research

A Human Subject's Patient Health Information shall only be disclosed in accordance with the Health Data Protection Regulation.

170 Recording of information

All information associated with Human Biomedical Research shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification and consistent with the provisions of the Health Data Protection Regulation.

171 Retention of information

All documentation, Essential Documents and other Records required by this Research Regulation and any applicable Rules, Standards and Policies to be developed and maintained by Approved Research Operators, Investigators or Sponsors shall be retained for the periods stipulated in the Health Data Protection Regulation.

172 Use of Investigational Products

Investigational Products used in Human Biomedical Research shall be used only in accordance with the approved Protocol for the investigation.

173 Data Safety Monitoring

- (1) All Interventional Studies shall include an adequate provision for data safety monitoring in its associated Protocol to ensure the continuing safety of participating and prospective Human Subjects.
- (2) The Research Ethics Review Committee may require the Approved Research Operator or Principal Investigator to set up a Data Safety Monitoring Board to assess the progress and safety of the research activities initiated by the Principal Investigator.

Part Seventeen

Approved Professional Indemnity Insurance

174 Requirement to have insurance

- (1) An Approved Research Operator may not conduct any research activities unless it is covered by the required Approved Professional Indemnity Insurance, public liability insurance and/or any other form of insurance, where applicable.
- (2) Such insurance under subsection (1) is to be obtained and maintained in such amounts and on such terms and conditions as the Central Governance Board may reasonably specify from time to time and/or as required under other applicable laws, Regulations, Rules, Standards or Policies in force from time to time in DHCC.

175 Approval by CPQ of insurers

- (1) Such insurance is to be obtained from carriers that have been approved by CPQ based on CPQ's assessment of their financial solvency and other characteristics that CPQ deems reasonable and relevant to assuring the ability of such carriers to meet their obligations under policies issued for Approved Research Operators in DHCC.
- (2) A list of such approved carriers shall be published by CPQ from time to time.

176 Approved Professional Indemnity Insurance required in addition to other insurance

The Approved Professional Indemnity Insurance, if applicable, shall be in addition to any other insurance that the Approved Research Operator is required to obtain and maintain under other applicable laws, Regulations, Rules, Standards or Policies in force from time to time in DHCC.

177 Restriction on granting Research Permit

The Registry of Companies:

- (1) shall not issue a Research Permit to a Provisional Approval Letter Holder unless it is satisfied that the Provisional Approval Letter Holder will, while conducting a research activity, has the required insurance cover under section 174; and
- (2) may revoke, suspend or refuse to renew the Research Permit of a Approved Research Operator if it is satisfied that the Approved Research Operator has the required insurance cover under section 174, while conducting an Approved Research Activity.

Schedule One: Provisions relating to Committees

1 Appointment of Members of Committee

The Academic and Research Council shall appoint the members of the Committee.

2 Appointment of chair of Committee

The Academic and Research Council shall appoint the chairperson of the Committee.

3 Term of appointment

- (1) Of the initial appointees to the Committee, the Academic and Research Council shall appoint:
 - (1) half the members to a term of 2 years each; and
 - (2) half the members to a term of 3 years each, including the chairperson.
- (2) In the case that there are an uneven number of members to be appointed, the majority of members shall be appointed for the term of 2 years.

4 Reappointment of members

A member is eligible to be reappointed to the Academic and Research Council unless he has held office for 6 consecutive years. In such an event, the member shall not be reappointed immediately unless the Executive Body consents in writing to his reappointment and holding office for more than 6 consecutive years, provided that such reappointment shall only be for one further term.

5 Resignation of members

A member of the Committee may resign from office by tendering a signed written notice to the Academic and Research Council.

6 Vacation of office

A member of the Committee ceases to be a member of the Committee if the Committee is de-established by amendment to this Research Regulation.

7 Removal from office

- (1) The Academic and Research Council may remove a member with just cause by giving written notice to the member. Such written notice shall include the date on which the removal takes effect, which shall not be an earlier date than the date on the notice which is received.
- (2) The notice shall also state the reasons for removal.
- (3) Just cause includes misconduct, inability to perform the functions required of the member, neglect of duty, and breach of any of the collective duties of the Agency or the individual duties of the member.

8 No compensation for loss of membership

A member of the Committee is not entitled to any compensation or benefit relating to his ceasing (for any reason) to hold office as a member of the Committee.

9 Appointment of secretary to Committee

- (1) The Academic and Research Council shall appoint a person who is not a member of the Committee to serve as secretary to the Committee. The secretary shall serve such term as the Academic and Research Council shall determine and may be removed by the Academic and Research Council at any time.
- (2) The secretary shall be appointed from the Research Ethics Review Committee.

10 Role of secretary

The secretary with the support of the Research Ethics Review Committee shall prepare and maintain adequate documentation of Committee activities, including, but not limited to:

- (1) the retention of copies of all Protocols submitted by Investigators and reviewed by the Committee, including information about any initial and continuing review;
- (2) the maintenance of a written record of all Committee meetings and of all actions taken by it, and any decisions and any recommendations made;
- (3) the retention of copies of all correspondence between the Committee and Investigators;
- (4) the maintenance of records of the Committee's continuing review or Approved Research Activities;
- (5) at the direction of the chairperson of the Committee, distributing the agenda for each meeting no less than 5 business days prior to such meeting and distributing the Applications and Protocols to be reviewed no less than 7 business days prior to such meeting;
- (6) maintaining responsibility for ensuring that the minutes of each meeting are distributed to the members of the Committee within 3 business days following each meeting;
- (7) maintaining a list of all Committee member details and qualifications;
- (8) maintaining a register of member interests as disclosed under clause 15;
- (9) ensuring availability of written procedures for the Committee; and
- (10) any such additional duties as the Academic and Research Council may from time to time prescribe.

11 Retention of information

All Committee's Records including but not limited to:

- (1) written procedures;
- (2) membership lists;
- (3) lists of occupations/affiliations of members;
- (4) submitted documents;
- (5) minutes of meetings; and
- (6) correspondence,

shall be retained for at least 5 years and in the case where the information relates to research, at least 5 years after completion of the research for the purposes of undertaking audits.

12 Meeting procedure

The Committee shall adopt standard operating procedures to govern its conduct consistent with the provisions of the Governing Regulation, Schedule One, clause 14, including:

- (1) in the case of the Research Ethics Review Committee, it shall meet at least once a month, or more regularly upon the call of the Academic and Research Council, at such times and places as the Academic and Research Council may designate;
- (2) in the case of the other Committees, it shall meet as required and as determined by the Academic and Research Council, at such times and places as the Academic and Research Council may designate;
- (3) all meetings shall occur with the physical presence of all participating members, provided, however, that meetings may take place via teleconference or such other means as determined by the Committee that allow all of the members to participate in the meeting at the same time;
- (4) a majority of the members of the Committee then in office shall constitute a quorum for the transaction of all business; however, a lay person member shall be present; and
- (5) only Committee members who participate in the review and discussion of a matter shall be entitled to vote on such matter.

13 Training of members

Each Committee member shall complete a training program approved by the Academic and Research Council before beginning his term, and shall be required to complete a refresher course every 2 years as long as he remains a Committee member.

14 Participation of other persons

- (1) The Committee may invite persons who are not members of the Committee to participate in Committee meetings when they have expertise in special areas to review Protocols.
- (2) No such invited participant shall be entitled to vote as a member of the Committee.

15 Disclosure of interests

- (1) A member of the Committee who is interested in a transaction shall, as soon as is reasonably practicable after the relevant facts have come to the member's knowledge, disclose the nature of the interest to the Committee.
- (2) Subject to clause 17 of this Schedule, a member of the Committee who makes a disclosure under this clause shall not:
 - (1) take part, after the disclosure, in any deliberation or decision of the Agency relating to the transaction; or
 - (2) be included in the quorum when a vote on the decision is to be taken; or
 - (3) sign any document in relation to the entry into a transaction or the initiation of the transaction.

16 Disclosure of interest shall be recorded

The disclosure shall be recorded in the minutes of the next meeting of the Agency and entered into the interest register maintained by the Secretary.

17 Member may be permitted to participate in deliberations

- (1) A member who makes a disclosure under this clause may take part in any deliberation (but not in any decision) of the Agency relating to the transaction concerned if a majority of the other members of the Agency permits the member to do so.
- (2) If the member is permitted to take part in the deliberation, the Agency minutes shall record:
 - (a) the permission and the majority's reason for giving it; and
 - (b) what the members says in any deliberation at the meeting relating to the transaction concerned.
- (3) Any relevant change to the member's circumstances affecting a matter disclosed is entered into the register of interests as soon as practicable after the change occurs.

18 Meaning of transaction

- (1) The provisions of the Governing Regulation, Schedule One, clauses 19, 20 and 21 apply to interpreting the meaning of a transaction.
- (2) In addition, only those Committee members who are independent of an Investigator and the Sponsor of the proposed Research may participate in the discussion and vote on such proposed research.