دبي الصحية
DUBAI HEALTH

جامعة محمد بن راشد
للطب والعلوم الصحية
Mohammed Bin Rashid University
of Medicine and Health Sciences

Ethical Review of Research at MBRU Policy

Contents

DIFFUSION
MyMBRU

N.B Document shall be reviewed every 3 years or on "as needed" basis.

1 Introduction

All research conducted at the MBRU must abide by the highest standards of scientific integrity, ethics, and Good Clinical Practice. In addition, due care must be applied to comply with the applicable local and federal regulations including but not limited to, UAE Federal Law No. (4) of 2016 on Medical Liability and the associated Executive Regulations and the concerned Cabinet Resolution No. (40) of 2019; as well as the rules, regulations and policies of Dubai Healthcare City Authority – Regulatory (DHCR).

MBRU values the full protection of the rights, health, safety, dignity, privacy and respect of human participants as well as the welfare of animals, protection of researchers and the reputation of the institution. This policy document provides information related to MBRU requirements for research involving human participants and animal subjects and outlines the roadmap for researchers to seek ethical approval prior to conducting their research. It includes all biomedical, behavioural or social sciences research involving human participants as well as research involving animal subjects. It provides a general guidance on the standards expected and the requirements for ethical approval of research at MBRU. This is not an exhaustive document and the ultimate responsibility to comply with the approval of ethical standards rests with the researcher carrying out the research project.

MBRU will have two committees that govern the ethics and safety of research on humans and human samples/tissue/data, as well the ethics of research on animals. The MBRU Institutional Review Board (MBRU-IRB) is already functional, while the MBRU Animal Research Ethics Committee (MBRU-AREC) will be established in the future.

1.1. The MBRU-IRB reviews, approves and monitors all research involving human participants and use of human samples/tissue/data. (This is also sometimes referred to as the Human Ethics Board/Committee or Ethical or Institutional Review Board.) The MBRU-IRB is authorized by DHCR to carry out ethical review of MBRU research proposals based on the approved research ethics policies and procedures. The MBRU-IRB follows strict criteria to assess the research projects in terms of their risk-benefit analysis, in order to determine whether or not a particular research project should be conducted. The purpose of the MBRU-IRB is to ensure that appropriate steps are taken to protect the rights and welfare of research participants/human subjects (including their tissue and data) participating in a research study.

1.2. The MBRU-AREC will be established to govern the ethics of animal research. This committee will follow strict and clear criteria for the protection of animals in research. Internationally accepted guidelines will be followed to assess the research projects and determine whether or not a particular research project using animals and animal samples/tissue should be conducted. The purpose of the MBRU-AREC is to determine whether the use of animals in research is avoidable and if valid/practical alternatives are available. If justified by the rationale presented, appropriate steps are to be taken to ensure that the animals in a research study are treated humanely.

2 Purpose

2.1 MBRU is committed to ensuring the highest standards of scientific and ethical conduct by all MBRU employees. MBRU regards the maintenance of high ethical and scientific standards in research as a fundamental responsibility and ensures that the ethics and integrity of research activities conducted under the auspices of MBRU are impeccable.

2.2 MBRU ensures that appropriate structures and processes are in place to govern ethics in research at MBRU.

2.3 This document provides a framework that includes mechanisms and standards for ethical review of research projects undertaken at MBRU. It includes policies, procedures, guidelines, as well as information on forms for researchers to prepare, submit and seek ethical approval for their research studies.

2.4 All MBRU academic and non-academic staff and researchers have the responsibility to act in accordance with all relevant UAE federal and local laws and must abide with the cultural norms within the UAE and the MBRU standards of professionalism.

2.5 MBRU expects adherence to the policies on research ethics by all MBRU faculty, staff and students of MBRU or working on behalf of MBRU.

2.6 MBRU requires that all research involving human participants and animal subjects to have obtained ethical approval from the appropriate ethics board prior to commencing with the research.

2.7 MBRU considers deliberate breaches of ethical standards very seriously and any such action will be referred for consideration to the pertinent MBRU bodies/committees related to misconduct in research.

3 Scope

3.1 This policy applies to all MBRU academic and non-academic staff, collaborators and students, undertaking human or animal research under the auspices of MBRU, or outside MBRU, where the research:

3.1.1 is conducted by or under the direction of MBRU academic and non-academic staff or students,

3.1.2 is conducted by an external organization, with sponsorship from the MBRU or with participation of its academic and non-academic staff or students, or using any property or facility of the university and

3.1.3 involves the use of MBRU's public or non-public information to identify or contact human research participants or prospective participants.

3.2 This policy does not apply to adjunct faculty unless the research is conducted at MBRU, or the research involves recruiting MBRU students as research participants. When the research is not conducted at MBRU, as agreed by the IRB members and recorded in the minutes of MBRU-IRB meeting of 07/2020, these adjunct faculty must seek ethical approval from the appropriate regulatory body depending on the research study site (DHCR, DHA, DoH, or MOHAP).

4 Definitions and Abbreviations

4.1 CITI - Collaborative Institutional Training Initiative

4.2 DHA – Dubai Health Authority

4.3 DHCC - Dubai Healthcare City

4.4 DHCR – The Regulatory arm of Dubai Healthcare City Authority

4.5 DoH – Abu Dhabi Department of Health

4.6 MBRU-AREC - MBRU-Animal Research Ethics Committee

4.7 MBRU - Mohammed Bin Rashid University of Medicine and Health Sciences

4.8 MBRU-IRB - MBRU-Institutional Review Board

4.9 MOHAP – UAE Ministry of Health and Prevention

4.10 PHRP – Protecting Human Research Participants

4.11 PI - Principal Investigator

4.12 SOPs - Standard Operating Procedures

4.13 UNCRC: United Nations Convention on the Rights of the Child

4.14 Academic Staff: Employee of MBRU who holds an academic rank (e.g., Professor, Associate Professor, Assistant Professor, Lecturer, Instructor, Part-Time / Adjunct and Visiting Faculty members)

4.15 Academic Unit: College or institute/center that reports to Academic Affairs

4.16 Coercion: Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

4.17 Deception: Deception occurs as the result of investigators providing false or incomplete information to participants for the purpose of misleading research participants.

4.18 Human Participants Research: Any research or clinical investigation that involves human subjects.

4.19 Minor: A person under the age of 18

4.20 Non-academic staff: Employee of MBRU whose primary assignment is non-academic or administrative in nature. Non-academic staff may be employed in an academic or non-academic unit.

4.21 Non-academic unit: Any unit indicated in the MBRU organization chart that does not report to Academic Affairs.

4.22 Personnel: A PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.

4.23 Undue influence: Undue influence often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, (s)he offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

5 Responsibilities

5.1 The MBRU-IRB is responsible for conducting review of research proposals from ethical and scientific perspectives. A research project must not start until it has obtained the needed ethical clearance from the MBRU-IRB for human research. Once the MBRU-AREC is established, similar clearance will be required for animal research. The two committees will also investigate any reported allegations of research misconduct or research performed at MBRU without ethical approval, if necessary.

5.2 Research Involving Human Participants/Tissue/Samples/Data:

5.2.1 All research procedures and protocols conducted at MBRU involving human samples or participants must undergo appropriate ethical scrutiny leading to the protection of the rights, dignity, safety and well-being of all those involved in the research project, ensuring confidentiality of information about human participants, cultural sensitivities in the UAE, and the reputation of MBRU.

5.2.2 This policy is designed to ensure that human participants are adequately protected during any research project conducted within or in connection with MBRU. Procedures must also be aligned and implemented with due care to follow all MBRU policies and applicable UAE laws (such as the UAE medical liability law No. (4) of 2016 and the DHCR Research Policy).

5.2.3 MBRU recognizes that in some cases, there may be potential conflicts between the rights of researchers, within the law, to carry out a research project and the rights of the participants. The overriding obligation of the researchers is to ensure that the participants' interests and rights in the study, whenever conflicts arise, come first.

5.2.4 The MBRU-IRB reviews all research proposals that involve human participants to ensure that the principles of the Belmont report, the Helsinki Declaration and Good Clinical Practice that revolve around respect for persons, non-maleficence, beneficence, and justice are met. Hence, the research project must ensure the voluntary participation of human participants (free from undue influence or coercion), clearly outline the informed consent process, and it should emphasize the fair and non-discriminatory recruitment of human participants (especially if recruitment entails vulnerable populations), and clearly outline how the risks associated with the research are reasonable and justifiable by the expected benefits. It must have a clear and adequate monitoring plan to ensure the safety of participants as well as indicate how additional protection will be provided, when vulnerable participants are included. In addition, the research proposal must adequately outline how matters of confidentiality are respected and how data storage and quality control are adequately maintained. Hence, all the steps involved in the research must comply in full with MBRU policies and procedures.

5.3 Research Involving Animals:

5.3.1 This policy is designed to ensure that the rights of animals are adequately protected during any research project conducted within or in connection with MBRU. In addition, it will ensure that all members of MBRU treat all research animals under their control with due care and consideration for their welfare, and to use animals in research and teachings in such a way as to cause them minimal harm, distress and suffering. Procedures will also be aligned and implemented with due care to comply with all MBRU policies and applicable UAE laws (i.e. Federal Law No. (16) of 2007 as amended by Federal Law No. (18) of 2016 , concerning animal protection).

5.3.2 When MBRU-AREC is established, all research projects that involve animals and animal tissues/organs will require approval from the MBRU-AREC prior to the start of the research project. The MBRU-AREC will develop its own regulations and procedures according to international standards for animal welfare, UAE laws and MBRU policies. Research on animals is approved only when it will contribute to the advancement of

knowledge and will lead to the improvement of the health and welfare of humans or a better understanding of the animals themselves.

5.3.3 During the design of the research project involving animals, the researchers should consider the three "R" principles which include: i) Reduction: to use the minimum number of animals; ii) Replacement: to use alternatives such as computer modelling or cell or tissue culture whenever possible and iii) Refinement: to strive for the highest possible standard of animal care and welfare and minimize animal suffering and stress during the research.

5.3.4 The avoidance or minimization of discomfort, distress, and pain for the animals is imperative and consistent with sound scientific practices and should be the main consideration when researchers are applying to obtain ethical approval for using animals in research or teaching. Procedures on animals that may cause pain or distress must be performed under appropriate sedation, analgesia or anaesthesia.

5.3.5 All animals will be cared for by dedicated and qualified staff and veterinarians in hygienic rooms and controlled environmental conditions and all MBRU faculty and staff working with animals will need to go through appropriate training in animal handling and care prior to conducting their research projects. The living conditions should be appropriate for maintaining health and comfort of different animal species.

5.4 It is the responsibility of the PI to ensure that all researchers involved in the research are aware of the university's ethics policies and procedures.

5.5 All MBRU academic and non-academic staff and researchers have the responsibility to act in accordance with all relevant UAE federal and local laws and must abide with the cultural norms within the UAE and the MBRU standards of professionalism.

5.6 The MBRU-IRB and MBRU-AREC as well as the Deanship of Research and Graduate Studies have the overall responsibility for all aspects of compliance with regulations and policies regarding the use of humans or animals in research studies.

5.7 Strategy and Institutional Excellence Department is responsible for organizing the process for updating policies and procedures at MBRU and monitoring and evaluating their proper implementation.

6 Procedure/Process

6.1 Procedure/Process of the MBRU-IRB (Research Involving Human Participants)

6.1.1 Structure of the MBRU-IRB

6.1.1.1 The MBRU-IRB is charged with the evaluation of all applications involving human participants and human samples/tissue/data in research at the MBRU and affiliated entities. The primary concern of the MBRU-IRB is to ensure that appropriate steps are taken to protect the rights and welfare of research participants. The MBRU-IRB reports to the Dean of Research and Graduate Studies, who in turn reports to the Provost.

6.1.1.2 The MBRU-IRB consists of at least seven members. The chair of the MBRU-IRB will be appointed by the MBRU Preident; the vice-chair will be nominated by the chair and approved by the Dean of Research and Graduate Studies. The chair should have the necessary experience to take on this responsibility effectively and efficiently. He/she should have served previously on an IRB and is expected to undertake the necessary training (specifically the training course offered by the Collaborative Institutional Training Initiative (CITI) program for Human Participants Research: https://www.citiprogram.org/) prior to assuming the role as chair. The other MBRU-IRB members are nominated by the Heads of Academic Units. MBRU-IRB members will serve for a renewable three-year term. Membership on the MBRU-IRB is considered service to the university and the community at large. Therefore, there will be no financial reimbursements (of any form) to the members of the MBRU-IRB. It is important that the members represent a wide range of expertise including different professionals, researchers, clinicians, counselors from within and outside MBRU, and a community representative. The committee should also include a researcher with extensive knowledge in the conduct of randomized controlled trials.

6.1.1.3 An administrative assistant will be assigned for the MBRU-IRB, who will not have any voting rights.

6.1.2 Responsibilities of the MBRU-IRB and the Review Process

6.1.2.1 The MBRU-IRB will have discretion on behalf of MBRU, based on the commitment to full ethical considerations, not to approve a research proposal or to require modifications/amendments as deemed appropriate. The responsibilities of the MBRU-IRB are as follows:

6.1.2.1.1 Develops or reviews the relevant policies, procedures, and guidelines (and forms) on research ethics at MBRU and ensures that there is awareness of the values and the responsibilities to maintain the highest standards of research ethics across the university, during the conduct of any research involving human participants/human tissue/data.

6.1.2.1.2 Seeks clarification from external bodies as deemed necessary on matters of ethical review policies and procedures.

6.1.2.1.3 Reviews all research proposals involving humans and human-derived materials/data and decides whether the submitted research proposal meets the ethical standards set by the university. The MBRU-IRB can either approve, reject the application, or ask for minor or major amendments to the research protocol. MBRU-IRB endeavors to adhere to the following timelines from accepted submissions of research proposals, to provide a feedback to PIs within a period of 4-8 weeks depending upon the date of receiving a complete application. However, these deadlines may be extended during the university's public holidays, winter and summer recesses.

6.1.2.1.4 Reviews and discusses all submitted research proposals, either electronically or at a board meeting (see below). The deadline for acceptance of proposals for discussion at meetings is ten (10) days before a scheduled meeting, provided that applications are complete. MBRU-IRB meetings are usually held on the last Tuesday of every month, unless otherwise specified.

6.1.2.1.5 Maintains the confidentiality of submitted applications, meeting deliberations, information of research participants and other matters.

6.1.2.1.6 Monitors adherence to MBRU policies and procedures.

6.1.2.1.7 Reports to the Dean of Research and Graduate Studies on their activities.

6.1.2.2 Members of the MBRU-IRB should attend all or most meetings of the MBRU-IRB and effectively contribute to the review of the applications.

6.1.2.3 For applications requiring full review, all MBRU-IRB members will review the applications,

however, a primary reviewer is assigned by the chair of the MBRU-IRB to review the application in detail and present it to MBRU-IRB members. Final decision on the application is made by the majority of the MBRU-IRB members during the assessment meeting. A quorum of more than half of the members is required for MBRU-IRB meetings to be held.

6.1.2.4 For applications requiring expedited review, the chair, the vice-chair or a designated reviewer on their behalf will review and approve the application, followed by endorsement by majority of the MBRU-IRB members, which can be done electronically.

6.1.2.5 For applications requiring exemption, the chair, the vice-chair or a designated reviewer on their behalf will review and approve the application, and there is no need for endorsement of exempted applications by MBRU-IRB members.

6.1.2.6 If the applicant is a member of the MBRU-IRB committee, he/she should withdraw from the meeting and shall not be involved in the decision-making process.

6.1.2.7 The applicant (PI) could be invited to the MBRU-IRB meetings if major clarifications on the application are needed. In all cases, discussion or decisions on any research project should be documented.

6.1.2.8 The final decision of the status of the research application will be notified to the PI and other relevant MBRU staff and administrators by the chair of MBRU-IRB or his/her designate.

6.1.3 Informed Consent

The most important principle for research involving humans is that of free and informed consent. All researchers conducting research on humans must obtain informed consent from participants in their research using the MBRU informed consent form (see section on Supporting Forms). While the form of consent may vary depending on the situation, the informed consent should:

6.1.3.1 require the participants to have the capacity to consent.

6.1.3.2 provide all the information regarding the research including those that may affect the participant's inclination to take part in the research project. This information should be provided to potential participants in a language that is clear and understandable. Information about the research should be provided to potential participants in writing and also ideally communicated orally. The use of deception or false information to induce physical or emotional distress is not justified and will not be tolerated.

6.1.3.3 make it clear that participation is voluntary and that participants may withdraw at any time. This includes the right of the participant to withdraw even if consent has previously

been provided. In this case, the participant's own data/recordings/material should be completely destroyed. However, there are limitations to the right of withdrawal. For example, it cannot be fully given after the research has been completed and published. Therefore, the rights and the time of withdrawal from research after consent should be made clear to the participants.

6.1.3.4 make it clear that not participating or withdrawing will not have any consequences in terms of the participant's subsequent treatment.

6.1.3.5 make it clear that participants are free to withdraw their consent at any time without prejudice and that withdrawal of participation from the research will not jeopardize any service they are eligible for whether at MRBU or any collaborating institutions.

6.1.3.6 request participation without undue pressure or enticement. Nevertheless, participants taking part in research may be rewarded appropriately such as reimbursement for transportation costs. Such reimbursements should not be used to entice participation in the research.

6.1.3.7 make it clear that participants have the right to ask as many questions as needed and that appropriate answers regarding their participation in the research will be provided as promptly as possible.

6.1.4 Research involving Children, Vulnerable Adults, Dependents, Pregnant Women, Prisoners and Others

6.1.4.1 Children, vulnerable adults, pregnant women, fetuses, neonates, students, employees, elderly, refugees, prisoners, disabled participants, or anyone who is economically, socially or educationally disadvantaged are all considered special populations and any research involving these groups would require additional protections and institution oversight. MBRU is committed to the protection of the rights of these vulnerable populations as participants in research studies and special care has to be taken as these participants may be more vulnerable to coercion and inappropriate influence such that their voluntary participation could be compromised.

6.1.4.2 In cases where the participant is legally incapable of providing consent or is a minor, the researchers must obtain approval from the participants' parent(s) or legal guardian(s), in addition to seeking the participants' agreement, explaining the research project and the

role of the participant, while ensuring the participants' best interests are served at all times.

6.1.4.3 Any research involving children should comply with Articles 3 and 12 of the United Nations Convention on the Rights of the Child (UNCRC) and UAE laws on protection of children, particularly Federal Law No. (3) of 2016 on Child Rights, informally known as Wadeema Law. UN Convention Article 3 stipulates that the best interest of the child must be the primary consideration in all actions concerning children, and UNCRC Article 12 stipulates that children who are capable of forming their own views should be granted the right to do so freely in all matters affecting them, appropriate with their age and maturity. Research involving children should also abide by relevant UAE laws on protection of the rights of children and ensure that no potential risks to the participants are associated with the research study. Following evaluation of the age, maturity, and psychological state of the child, assent from the child and parental/guardian permission (parallel to informed consent) should be obtained.

6.1.4.4 Any research involving a vulnerable adult (who is incapacitated or dependent due to cognitive, medical, economic, social or situational factors) must take the appropriate precautions to ensure that they have not been subjected to undue influence to participate by either the dependents, the research team or anyone else.

6.1.4.5 Any research involving pregnant women must abide by relevant UAE laws and ensure the safety and health of the mother and the fetus first and foremost. Therefore, as general guidelines, research on pregnant women is only acceptable if the research study holds direct benefits to both the mother and the fetus and/or has no risk or minimal risk to either. In addition, the research should result in research findings/data that cannot be obtained by other means. Moreover, consent should be obtained from both partners unless in special circumstances. For underage children who might be pregnant, both assent and parental/guardian permission need to be obtained for their participation in any research study. No monetary or other inducements may be offered to a pregnant woman to terminate her pregnancy for research purposes. Researchers involved in the research project are not allowed to make any decisions pertaining to the pregnancy or the viability of the fetus.

6.1.4.6 Any research involving prisoners must abide by the relevant UAE laws and it must ensure the safety and rights of prisoners. Therefore, as general guidelines, research on prisoners is only acceptable if the research project addresses the possible causes, effects, and processes of incarceration, and of criminal behavior, or focuses on prisons as institutional

structures or on prisoners as incarcerated persons provided that the research presents no more than minimal risk or inconvenience to the participants. In addition, if the research project investigates the conditions affecting prisoners (for example, vaccine trials or any other research that tends to be more prevalent among prisoners, such as on hepatitis, or research on social and psychological problems like alcoholism, drug addiction, and sexual assaults etc.), then appropriate experts should be adequately consulted prior to the study. Such research may also require additional approvals from other UAE agencies.

6.1.5 Participation of MBRU personnel and students in Research Activities

6.1.5.1 Psychosocial research

a. When investigators conduct their research at MBRU, it is imperative that they understand that their obligations to the field of study are only secondary to the university's concern for the rights and safety of all human subjects who are involved in research.
b. All researchers who are granted permission to conduct their research at MBRU should meet the following obligations:
    - Liability: Irrespective of how consent is obtained and whether or not participants are placed at risk, no exculpatory language may be included through which the participant is made to waive any of his/her legal rights, including any release of the researcher from liability or negligence.
    - Risk: Under no circumstance would the university permit to be conducted research that places human participants at risk. Researchers must be fully responsible for making known to the university and to each participant any and all of the attendant discomforts associated with a study. The investigator is also required to make clear why the discomfort is essential to the study and why the information cannot be obtained in any other way.
    - Privacy: Data obtained directly or indirectly about MBRU personnel and students are entirely confidential. Research reports are to be written in such form that anonymity is guaranteed. Individual permission to make public information about individual participants must be obtained from both the university and the participant.
    - Deception: There are occasions when a full disclosure of the research purpose and/or procedures will invalidate the study. Included in this type of research are studies that require deception. In cases of this kind, the responsibility is entirely upon the PI. The PI is required to make it clear why the deception is essential to the study and why the

information cannot be obtained in any other way. Procedures for debriefing deceived participants are required and, with students, the deceptive strategy should be turned into some instructional advantage. The overall effect of deception need not be negative and it is the responsibility of the researcher to provide adequate debriefing procedures. When deception is essential to the study, in which participants under the age of 18 are involved, parental or guardian consent must be obtained prior to making contacts in person or by telephone.

- Informed Consent: The following elements of informed consent are required of investigators who have received permission to conduct research at MBRU:
  - A fair explanation of the procedures to be followed and their purposes, including identification of any procedures that are experimental.
  - A description of any attendant discomforts and risks reasonably to be expected, if any.
  - A description of any benefits reasonably to be expected, either for subject or society.
  - An offer to answer any inquiries concerning the study.
  - An instruction that the individual is free to withdraw his or her consent and to discontinue participation in a project or activity at any time without prejudice to the subject.
  - An instruction that the individual is free to withhold his or her initial consent and discontinue participation in a project or activity at any time without prejudice to the subject.

6.1.5.2 Responsibilities of Research Participants:

a. Completely read the consent form and feel free to ask the PI any questions.
b. Know the dates of when the study will start and end.
c. Carefully weigh the possible benefits (if any) and risks of being in the study.
d. Talk to PI (the person in charge of the study) if they want to withdraw from the study.
e. Contact the PI and/or the IRB with any complaints or concerns related to the study.
f. Report to the PI immediately regarding any issues related to study drug/procedure/device.
g. Fulfil the responsibilities of participation as described in the consent form.
h. When applicable, confirm with the PI or co-investigator when the compensation has been received.
i. Have the right to ask for a copy of the results of the study.
j. Keep a copy of the consent form.

6.1.5.3 Rights of Research Participants

Research participants have the following rights:

a. To have enough time to decide whether or not to participate in the research study, and to make that decision without any pressure from the researchers who are conducting the research.
b. To refuse to be in the study at all or discontinue participating at any time without any prejudice.
c. To be provided with sufficient information regarding the study objectives, methodology, reasonably foreseeable risks and possible benefits of being in the study.
d. To be provided with sufficient information regarding any costs and/or compensation associated with being in the study
e. To be provided with sufficient information regarding confidentiality and how participants' personal information will be protected.
f. To be told whom to contact if a research participant has questions regarding the research, research-related injury, and rights of research participants.
g. If the study involves treatment or therapy:
h. To be told about other non-research treatment choices.
i. To be told where treatment is available should the participant have a research-related injury, and how the research-related injury treatment will be covered.
j. To receive a copy of the consent form.

6.1.5.4 Participation of MBRU students as research participants within their respective college or university:

a. When MBRU students are intended subjects of a research study, the researchers should carefully review and understand the concepts of coercion and undue influence.
b. Students should not be used as a population of convenience for faculty/staff research. In any proposed study that involves recruiting for research through classrooms, student listservs or other student groups, clear explanation or justification should be provided as to why those students are the most appropriate participants for the study.
c. Permission must be obtained from the respective Head of the Academic Unit or designate where research activities may take place.
d. For research through student programs or services, permission from the Head of the Academic Unit/designate should be requested through an appropriate administrator or

faculty adviser. Documentation of support or permission may be required in the IRB review process.

e. Researchers must ensure that the recruitment and informed consent processes minimize the possibility of coercion or undue influence:
    - For recruitment of students through verbal scripts, fliers, listservs, and/or web-based systems for student subject pools, a brief description should provide information about the study purpose, procedures and eligibility for individuals to take the next step towards the consent process.
    - Researchers must carefully consider the timing and the involvement of the instructor in any recruitment, consent process or study procedures that will take place in a classroom setting.
    - Many research activities can be similar to or overlap with normal coursework or class projects. It is the researcher's responsibility to ensure that students can truly understand what participation involves and can distinguish voluntary research activities from required course activities.

f. When faculty propose to conduct research with students in their own classrooms or students who they directly oversee, the potential for coercion or undue influence increases and additional protections are required. In many cases, the involvement of a co-investigator or neutral third party may be an effective way to address perceived coercion or undue influence.

g. If a study identifies a student at high psychological risk such as self-harm, the researcher will be responsible to refer the student to a member of a healthcare team while maintaining confidentiality and reducing social, economic and legal risks.

h. The PI is solely responsible to report incidences promptly to the MBRU-IRB.

i. Faculty and students involved in a MBRU-IRB approved project may report violations observed through an email to MBRU-IRB. Documentary evidence, if available, should be attached to support such reports.

j. In cases where non-compliance with approved protocol or violations in any form is observed, the MBRU-IRB reserves its right to reverse its previous approval and take punitive action as required.

k. Internal assessment of educational programs and assessments aiming at improvements of student experience at MBRU would not need IRB approval.

l. The MBRU-IRB considers the following factors in support of proposed enrollment of

participants with potential status relationships with the researcher(s):

- The research presents no greater than minimal risk to participants.
- The research represents a potential educational opportunity for participants.
- The recruitment/consent language contain clear statements to address and minimize coercion and undue influence.
- The recruitment and/or consent process is conducted by someone who does NOT have a status relationship with the potential participants.
- If the research is conducted within the classroom setting, the instructor will be blinded to the identity of participants - at least until grades are posted.

6.1.5.5 Participation of MBRU students as research participants outside their respective college or university:

a. MBRU students may not participate in any research activity external to the university without the prior approval of the university.
b. It is the responsibility of the student to direct any invitation to participate in external research to student services, who will then seek MBRU-IRB approval for the same.
c. Requests for participation of MBRU students in external research activities should be facilitated through an MBRU collaborator and approved by the MBRU-IRB.
d. The MBRU collaborator will be responsible for reporting violations observed in a study involving MBRU students and approved by MBRU-IRB. Faculty and students involved in a MBRU-IRB-approved project may report violations observed through an email to MBRU-IRB. Documentary evidence, if available, should be attached to support such reports.
e. The MBRU collaborator is solely responsible to report incidences promptly to MBRU-IRB.
f. In cases where non-compliance with approved protocol or violations in any form is observed, the MBRU-IRB reserves its right to reverse its previous approval and take punitive action as required
g. The MBRU-IRB may seek feedback of the Head/designate of the respective Academic Units should there be any direct concerns to the University.

6.1.5.6 Research activities external to the university that are approved by the MBRU-IRB are announced to students through student services.

6.1.6 Privacy

6.1.6.1 The privacy of all participants who have agreed to take part in the research project must be respected. Although they may have agreed to participate, they should not be expected

to disclose information about every aspect of their lives, such as personal and sensitive information. Moreover, it should be made clear to the participants that the decision as to what information they share solely depends on them and that they are under no obligation or pressure to discuss or disclose any issue that they perceive sensitive.

6.1.6.2 In cases where a researcher knows or has already developed a relationship with the potential participant(s) prior to the invitation to partake in the research, the researcher should obtain the explicit consent of the participant(s) if they accept to use their information that may have been shared with the researcher prior to their participation in the study.

6.1.6.3 All research participants must be invited at arms-length, through an intermediary (e.g., research assistant, research nurse, data collector etc.), with no direct contact with the PI. Potential participants will be informed that they may seek additional information should they be interested in learning more about the research (from the assigned member of the team) prior to and after consent. The assigned team member's contact information must be listed on the participant information sheet and informed consent form.

6.1.7 Confidentiality and Data Storage

6.1.7.1 All data related to research should be stored for a minimum of five years after the completion of the research project. However, the confidentiality of participant information/data in research projects that involve human participants is vital and must be protected. All personal information should, therefore, be encoded or made anonymous from the beginning of the data collection and codes kept separately. Moreover, when seeking consent from the potential participants, researchers should inform them of the measures that have been taken to ensure their privacy, data confidentiality, identity protection, and any limitations in these measures.

6.1.7.2 Although the researchers should honor the pledges of privacy and confidentiality, in certain cases (such as a court order or if the researchers have concerns over the safety or well-being of children participants) these guarantees may be overruled and the researchers may have an obligation to report their concerns to a third party or relevant authority. In all cases, every effort by all involved should be taken to ensure the protection of physical and psychological safety and well-being of all participants in research.

6.1.8 Safety and Well-being of the Participants

6.1.8.1 A risk assessment must be undertaken to assess and identify any potential adverse effects of the research, and measures to mitigate them should be taken at the earliest. Participants must never be exposed to unnecessary risk and the research should only be carried out if potential benefits outweigh possible risks. Any potential risk should be clearly explained to the potential participants at the beginning of the research and particularly during time of seeking consent.

6.1.8.2 It is the responsibility of the PI of the project to ensure that all research projects involving humans have obtained ethical approval by the MBRU-IRB and that the research is carried out in accordance with the MBRU research ethics policies and procedures, and in compliance with federal and local UAE laws on individual and public safety.

6.1.9 Responsibilities of the PI

6.1.9.1 All requests to use research involving human participants originating from inside or outside the MBRU community must be submitted by the PI of the project to the MBRU-IRB using the relevant application forms (see section 7 below).

6.1.9.2 As the MBRU-IRB relies on the information provided in the application form(s), it is expected that all information is complete, truthful and accurate. Failure to do so could be considered research misconduct.

6.1.9.3 It is important to understand that it is ultimately the responsibility of the PI and the research team to make sure that the project is carried out to the highest ethical and scientific standards.

6.1.9.4 Once the research project has been completed at the completion of data collection, the PI must notify the MBRU-IRB about the study completion by submitting an end-of-study report within one year of study completion.

6.1.10 Research Involving Other Institutions

6.1.10.1 Where MBRU academic and non-academic staff are engaged in joint research projects with other universities or institutions (within DHCC or outside), ethical approval would need to be sought from all joint institutions unless there is a clear agreement between all entities that MBRU-IRB ethical approval is the one accepted by other(s). Again, the PI must ensure that all ethical approvals have been obtained prior to the start of the research project.

6.1.11 Research Involving Genetic Material

6.1.11.1 All research projects involving study of genetic material will follow guidelines laid out by DHCR. In instances where particular analyses of material are not available within the UAE, it is permissible for material to be stored in an overseas facility. In this instance, a written signed agreement must exist between the UAE PI and the responsible overseas facility. MBRU-IRB will review any such agreements in consideration for approval.

6.1.12 Categories of Ethical Applications and Review

6.1.12.1 Exempted Applications

Before applying to the MBRU-IRB, PIs should consider whether their application is actually human medical research, as some work is not considered research. For what is considered research, please check the US Code of Federal Regulations for the Protection of Human Subjects (45CFR46). Please refer to the following website for guidance: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#.

Below are few examples where the research applications can be submitted for exemption from MBRU-IRB review:

- Research conducted in educational settings involving normal educational practices such as research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human participants can be identified (directly or through identifiers linked to the participants), or any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under the above paragraph of this section, if the participants are elected or appointed public officials or candidates for public office, or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving already collected data, documents, records, pathological specimens or

diagnostic specimens, provided that these different existent sources are publicly available/accessible or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

- Research and demonstration projects that are carried out by, or subject to, the approval of a department and aims to study, evaluate or otherwise examine the public benefit of service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures or possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or food is consumed that contains a food ingredient at or below the recommended level and found to be safe for use, food containing agricultural chemicals or environmental contaminants is at or below the levels found to be safe, by the national regulatory agencies of Food and Drug Administration, and/or for Environmental Protection, and/or for the Food Safety and Inspection for Agriculture Protection.
- Quality assurance projects where information about patients for purposes of improving patient care or delivery such as optimizing clinic schedules or determining appropriate therapeutic modalities from those available is being collected.
- Case studies/reports (e.g. fewer than 5) that by definition are not controlled experiments, or oral histories from patients that are intended for teaching but will not yield publishable reports.

Applicants seeking research exemption from the MBRU-IRB should receive their exempt approvals from the MBRU-IRB chair before proceeding with their research projects (see the exempt application form). The submission of an application for exemption does not mean that it has been approved. It should be noted that research projects which are eligible for exempt status are not exempt from the ethical principles that guide the responsible conduct of research involving human participants. Exempt research projects should and must adhere to the basic ethical principles clearly outlined and described by the Belmont Report that revolves around respect for persons, beneficence and justice. The researchers should ensure the voluntary participation of human participants, clearly outline the informed consent process and it should emphasize the fair and non-discriminatory recruitment of human participants.

All applications for exempt review must include the submission of Conflict-of-Interest forms filled out by each researcher involved in the project.

6.1.12.2 Expedited Applications

Examples of expedited applications include low-risk research where no personal health information is recorded and involves a minimally invasive procedure (such as a one-time blood collection by finger stick, urine samples, saliva, hair and nail clippings etc.). In addition, surveys or questionnaires could be considered through the exempted or expedited application process if they do not involve additional sample collection. Below are a few examples where the research applications can be submitted for expedited MBRU-IRB review:

- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture. For adults, normally not drawing blood exceeding 450 ml during an 8-week period and not more than twice a week. For children and those less than 50 kg, not more than 50 ml or 3 ml/kg, whichever is less, during an 8-week period and collection may not occur more frequently than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means, e.g., non-disfiguring hair and nail clipping, excreta and external secretion, placenta at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings etc.
- Collection of data through noninvasive means (i.e. not involving general anesthesia or sedation) routinely employed in clinical practice excluding radiographs and microwaves e.g. ECG, EEG, MRI, ultrasound, echocardiography, electrocardiography, electroencephalography, ultrasound, Doppler blood flow, thermography, body composition assessment, moderate exercise by healthy volunteers, muscular strength testing, weighing testing and sensory acuity.
- Research involving materials already collected (data documents, records and pathological or diagnostic specimens) or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital or image recordings made for research purposes.
- Research on individual or groups characteristics or behavior such as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior, test development where the investigator does not manipulate that subject's behavior and no stress to the subject may occur, or research using survey, interview, oral

history, or quality assurance methodologies (some research in this category can be exempt).

If the applicant has any doubt about whether the proposed research project falls under the exempt or expedited categories, it is advisable that they seek the advice of the MBRU-IRB prior to submission of the application and be guided accordingly (see the expedited/full application form).

All applications for expedited review must include the submission of Conflict-of-Interest forms filled out by each researcher involved in the project.

6.1.12.3 Full Applications

Any research that involves the collection of personal health information of the participants, invasive procedures, genetic testing, repeated visits by the participants, vulnerable population groups (children, pregnant women, elderly, prisoners etc.), culturally sensitive, or involves other institutions all require to go through the full application process. The full application form requires a detailed description of the project, outlining the voluntary participation of human participants and the informed consent process. It should emphasize the fair and non-discriminatory recruitment of human participants (especially if recruitment entails vulnerable populations). It should describe how the risks associated with the research are reasonable and justified by the expected benefits. In addition, the proposal should have a clear and adequate monitoring plan to ensure the safety of participants as well as indicate how additional protection will be safe guarded, when vulnerable population groups are included. It should also outline the data storage issues etc. (see the expedited/full application form). For proposals that have undergone a full ethical review in another institution, the MBRU-IRB requires the submission of copies of the application and approval letter along with the application material.

All applications for full review must include the submission of Conflict-of-Interest forms filled out by each researcher involved in the project.

6.1.13 Basis of Approval

The three main principles which guide the MBRU-IRB in making its decisions are based on the ethical principles of the Belmont Report document of April 1979 and revolves around respect for persons, beneficence and justice. The primary task of the MBRU-IRB is the ethical non-maleficence review of research proposals and submitted supporting documents, emphasizing the rights, safety and the well-being of the participants and researchers, as well as the informed consent and the suitability of the project from an ethical standpoint. For ethical approval by the MBRU-IRB, the committee should be satisfactorily reassured with the

description provided by the PI in the application material and accompanying documents, including:

6.1.13.1 the design and conduct of the study,

6.1.13.2 the selection and recruitment of the research participants,

6.1.13.3 the consent process,

6.1.13.4 the care and protection of research participants and others who may be affected,

6.1.13.5 the right of the participants to withdraw at any time and their voluntary participation,

6.1.13.6 the protection of participants' confidentiality and privacy,

6.1.13.7 the research data management plans and security,

6.1.13.8 the appropriateness of the facilities and the level of risk

6.1.13.9 the adherence to the university policies and procedures, social norms within the country, as well as the UAE laws

6.1.14 Monitoring and Compliance

6.1.14.1 All members of the research team have the personal responsibility for all matters related to the wellbeing of the human participants throughout the period approved by the MBRU-IRB. The PI has the ultimate responsibility to ensure that all involved in the research project understand and accept their responsibilities in the project.

6.1.14.2 MBRU-IRB has responsibility for oversight of approved research projects, where appropriate, to ensure adherence to MBRU's policies and standards and principles of the Belmont Report and Helsinki Declaration. This would include, but is not limited to, ad hoc inspection of consent forms, results, data storage and inspection of research premises. Oversight can involve all categories of approved research i.e., those that underwent full, expedited and exempt review.

6.1.15 General Conditions

MBRU-IRB expects researchers to be aware of, and adhere to, the following conditions and guidelines:

6.1.15.1 As of October 15, 2020, all new applications to the MBRU-IRB should be submitted electronically on the Cayuse system through which PIs would also have the ability to follow progress.

6.1.15.2 The PI and all researchers involved in research are required to submit evidence of certification of a course in research ethics. Accepted certification is available from CITI (https://www.citiprogram.org/index.cfm?pageID=22), PHRP (https://phrptraining.com/)

or a recognized regulatory body. Certification must be valid for two years and for the duration of the research project.

6.1.15.3 The PI has full responsibility for ensuring adherence to ethical principles during the conduct of the research, as well as for scientific quality, confidentiality, health and safety of participants and financial probity.

6.1.15.4 All approvals will be valid for one year from the date of approval. For a project whose duration is beyond a year, the PI should submit an annual report at the end of each year. Automatic reminders will be sent to the PI via Cayuse, beginning 42 days before the anniversary date of the project and every 10 days thereafter. The annual report should be submitted via Cayuse by the anniversary date. Reports submitted beyond this date may result in withdrawal of MBRU-IRB approval.

6.1.15.5 All approved research projects should start within 6 months of the approval letter. Inability to start within this time for any reason will require re-submission of application or justification of the reasons. It is the PI's responsibility to inform the MBRU-IRB of any cancelation of approved projects for any reason, clearly mentioning therein the reasons for cancellation.

6.1.15.6 Deviation or changes to the approved research protocol would require an amendment of the application, through an official application via email for research projects approved before 15 October 2020 and via Cayuse for projects approved after 15 October 2020.

6.1.15.7 Serious breaches to the protocol should be notified to the MBRU-IRB in writing as soon as possible and no later than 15 days after the breach.

6.1.15.8 The MBRU-IRB should be immediately informed in writing of any significant incidents in relation to the safety of the research participants during the study. For research projects approved before 15 October 2020, incidents should be reported via email, while for those approved after 15 October 2020, incidents should be reported via Cayuse.

6.1.15.9 Premature termination of the research requires written notification to the MBRU-IRB within 30 days of termination. However, a planned termination will require written notification within 60 days of end of study.

6.1.15.10 For monitoring purposes, members of the MBRU-IRB or their designee are authorized to visit the research site at any time.

6.1.15.11 Annual progress reports and an end-of-study report are to be submitted to the MBRU-IRB using appropriate forms for research projects approved before 15 October 2020. Reports on projects approved after 15 October 2020 should be submitted via the Cayuse

system within 30 days. Should an extension be required, the PI has to ensure that the report is submitted in a timely manner.

6.1.15.12 Failure by the PI to timely submit a progress or end-of-study report, and after two reminders, may result in punitive action being taken at the discretion of the MBRU-IRB, which may include refusal by the MBRU-IRB to accept applications by the PI for a designated period of time.

6.1.15.13 The MBRU-IRB reserves the right to rescind a prior approval based on concerns by members in the study design/protocol. Approval can then be re-granted, pending clarification by the PI.

6.2 Procedure/Process of the MBRU-AREC (Research Involving Animals)

6.2.1 Structure of the MBRU-AREC

6.2.1.1 The MBRU-AREC will be charged with the evaluation of all applications involving animals and animal samples/tissue in research or teaching at the MBRU and affiliated entities. The primary concern of the MBRU-AREC will be to ensure that appropriate steps are taken to protect the rights of animals in a study. The MBRU-AREC will report to the Dean of Research and Graduate Studies, which in turn reports to the Provost.

6.2.1.2 The MBRU-AREC will consist of at least five members. The chair of the MBRU-AREC will be appointed by the MBRU President. The chair should have the necessary experience to take on this responsibility effectively and efficiently. The other MBRU-AREC members are nominated by the Heads of Academic Units. The MBRU-AREC members will serve for a renewable three-year term and attention will be paid to maintaining continuity. Membership on the MBRU-AREC is considered service to the university and the community at large and is voluntary. Therefore, there will be no financial reimbursements (of any form) to the members of the MBRU-AREC. Members should have adequate expertise in animal research. It is important that the membership also include a veterinarian and a community representative. It is the responsibility of the MBRU-AREC chair to ensure that all members are fully prepared for their role on the committee. An administrative assistant will be assigned for the MBRU-AREC, who will have no voting rights. The MBRU-AREC may invite additional non-voting members on a temporary basis when the specialist knowledge of that person is needed.

6.2.2 Responsibilities of the MBRU-AREC and the Review Process. The MBRU-AREC will:

6.2.2.1 have discretion on behalf of MBRU, based on the commitment to full ethical considerations, not to approve a research proposal or to require modifications/amendments as deemed appropriate. The responsibilities of the MBRU-AREC are as follows:

6.2.2.2 develop or review the relevant policies, procedures, and guidelines (and forms) on research ethics at MBRU and ensure that there is awareness of the values and the responsibilities to maintain the highest standards of ethics across the university during the conduct of any research or teaching involving animals.

6.2.2.3 seek clarification from external bodies as deemed necessary on matters of ethical review policies and procedures.

6.2.2.4 review all proposals involving animals and animal tissue/material and decide whether the submitted proposal meets the ethical standards set by the university. All research or teaching studies involving animals, including animal observation- only projects (i.e. no physical contact with animals and no impact on the animals or their habitats), would need ethical approval by the MBRU-AREC. The committee can either approve, reject the application or ask for minor or major amendments to the research protocol. MBRU-AREC will endeavour to adhere to the following timelines from accepted submissions of research proposals, to provide an outcome to PIs within a period of 4-8 weeks depending upon the date of receiving a complete application. However, these deadlines may be extended during the university's winter and summer recesses.

- review and discuss all submitted research proposals, either electronically or at a board meeting (see below). The deadline for acceptance of proposals for discussion at meetings is ten (10) days before a scheduled meeting, provided that applications are complete. MBRU-AREC meetings will be usually held once every month, unless otherwise specified.

6.2.2.5 maintain records and the confidentiality of submitted applications, meeting deliberations and other matters.

6.2.2.6 monitor adherence to MBRU policies and procedures

6.2.2.7 report to the Dean of Research and Graduate Studies on their activities

6.2.2.8 Members of the MBRU-AREC should attend all or most meetings of the MBRU-AREC and effectively contribute to the review of the applications.

6.2.2.9 The chair of the MBRU-AREC is responsible for the education of MBRU staff and students as well as continuous training of the committee members (i.e. by encouraging attendance of conference and workshops, providing relevant literature etc.) on ethical matters related to animal use in research or teaching.

6.2.2.10 For all applications, a primary reviewer is assigned by the chair of the AREC to review the application in detail. However, all AREC members can review the applications and provide their feedback. Final decision on the application is made by the majority of the MBRU-AREC members, which can be done electronically or in a meeting. If this is done in a meeting, a quorum of more than half of the members is required for the meetings to be held. In either case, all ethical concerns of the members regarding a particular application would need to be satisfactorily addressed before the approval is granted.

6.2.2.11 For applications requiring expedited review, the chair, the vice-chair or a designated reviewer on their behalf will review and approve the application, followed by endorsement by majority of the MBRU-IRB members, which can be done electronically.

6.2.2.12 For applications requiring exemption, the chair, the vice-chair or a designated reviewer on their behalf will review and approve the application, and there is no need for endorsement of exempted applications by MBRU-IRB members.

6.2.2.13 For minor amendments to a previously approved protocol, the chair, or his/her designee will review and approve the application on behalf of the MBRU-AREC. However, these applications would also need to be presented to the full committee for endorsement in its next meeting.

6.2.2.14 The applicant (PI) could be invited to the MBRU-IRB meetings if major clarifications on the application are needed. In all cases, discussion or decisions on any research project should be documented.

6.2.2.15 If the applicant is a member of the MBRU-AREC committee, he/she should not be involved in the decision-making process.

6.2.2.16 The final decision of the status of the research application will be notified to the PI and other relevant MBRU staff and administrators by the chair of MBRU-AREC.

6.2.3 Confidentiality and Data Storage

6.2.3.1 It is important that the university stores all information and applications for ethical approval of use of animals in research or teaching securely for a period of not less than 10 years.

6.2.3.2 Access to this information will only be with the approval of the MBRU-AREC chair or MBRU President.

6.2.4 Monitoring and Compliance

6.2.4.1 All members of the research team have the personal responsibility for all matters related to the well-being of the animals throughout the approved period by the MBRU-AREC. The PI has the ultimate responsibility to ensure that all involved in the research project understand and accept their responsibilities for the care and use of animals in the project (see responsibilities of the PI below). Procedures for monitoring and assessing the wellbeing of the animals must be developed by the PI as part of the application form. Monitoring should be carried out by competent people who are knowledgeable about the normal behaviour and signs of pain and distress of the animals being used in the research project. The frequency of the monitoring should be sufficient to ensure that sick or injured animals are promptly detected, and appropriate action is taken. The person responsible for monitoring and emergencies should be specified on the application form. The PI should notify the MBRU-AREC immediately of any unexpected reaction or deaths during the experimental procedure.

6.2.4.2 It is the responsibility of the applicants to keep detailed records of the species, source and number of animals used, the approved procedures to which the animals were exposed, as well as the subsequent fate of the animals. Appropriate records of the monitoring must be kept and made available to all those involved in the care of the animals and for audit by the MBRU- AREC or authorized external reviewers. The MBRU-AREC decides on the frequency of inspection of the laboratory animals, their accommodations, or experimental records at any time to be sure that procedures and protocols are being properly carried out.

6.2.4.3 The health and safety of the MBRU staff and students is paramount in all research conducted at MBRU and therefore it is essential that appropriate risk assessments are done, and all steps are taken to mitigate against any risk or harm.

6.2.5 Complaints and non-compliance

6.2.5.1 All complaints and non-compliance are managed according to the MBRU policies and procedures on research ethics and research misconduct as well as relevant UAE laws on animal protection and care. Complaints may involve concerns about animal suffering and welfare, decisions made by the MBRU-AREC or about personnel involved in research or teaching using animals. Complaints about the personnel may be directed towards the researchers or to any member of the MBRU-AREC. Complaints are considered emergency

(i.e. where animal welfare is jeopardized or when animals are being subjected to protocols not approved by the MBRU-AREC) or non-emergency (i.e. complaints against personnel or decision by the MBRU-AREC). All complaints should be directed to the MBRU-AREC chair, who will initially review/investigate the matter and may refer it to the full committee or to the university leadership, as deemed appropriate. If the complaint relates to activities that have the potential to adversely affect animal wellbeing, it is considered an emergency and MBRU-AREC chair should ensure that these activities are ceased immediately. Any non-compliance with the MBRU-AREC regulations should also be reported to the chair. The MBRU-AREC will investigate suspected or alleged non-compliance and has the authority to suspend the use of animals by a researcher if it is found that animal welfare is jeopardized, or protocols are being conducted in breach of the approvals granted. Disciplinary action for non-compliance will be according to the MBU policies and procedures and relevant UAE laws.

6.2.5.2 The ultimate decision regarding the ethical acceptability of the research project lies with the MBRU-AREC and cannot be overridden. Applicants who disagree with the AREC decision would need to provide their reasons to the AREC chair and resubmit an application for re- evaluation. However, if the complaint is concerning the MBRU-AREC process of review of an application and it cannot be resolved by the applicant and the MBRU-AREC chair, then the complaint should be sent to the Office of Research and Graduate Studies in writing for appropriate action.

6.2.6 Standard Operating Procedures (SOPs)

6.2.6.1 All MBRU academic staff who want to use vertebrate animals (i.e., traditional laboratory animals) in research or teaching must submit an application form (see section 8) and seek ethical approval from the MBRU-AREC prior to the start of the study. The MBRU-AREC will only approve the use of animals in a research or teaching project when it is satisfied that each researcher and/or member of the team has the necessary expertise and competency to implement all parts of the proposed study. SOPs such as the ones provided below, can help in the preparation of the application for animal use in research or teaching. Examples of SOPs can be found on the following links:

https://www.umt.edu/research/LAR/sops/default.php

http://www.colorado.edu/innovate/iacuc/regulations-policies/standard-operating-procedures

https://www.mcgill.ca/research/researchers/compliance/animal/sop

6.2.7 Training

6.2.7.1 All personnel involved in the project and the handling of the animals would need prior knowledge and appropriate training of the use and handling of animals in research or teaching. Training consists of information on animal research laws and guidelines and methods for proper animal care, handling and experimental manipulations.

6.2.8 Animal Numbers

6.2.8.1 The number of animals used in any study should be kept to a minimum. In the application form, the PI should provide justification for the total number of animals used or produced (experimental group size and numbers of experimental groups) and not only the number of animals from which data will be collected. In the case of a breeding colony, he/she should list the number of breeding animals to be obtained, the total number of offsprings born, and the proportion of these actually used for experiments. If possible, the application should also include a consideration of the number of animals that can be expected to die due to failure of a procedure. Types of justifications for the number of animals needed in a particular study include statistical significance (i.e. the number of animals requested to provide sufficient statistical power and without using excessive numbers of animals), a specific quantity of tissue is needed to complete the study (i.e. justify why this quantity is needed), pilot study (i.e. if a small number of animals are needed for a pilot study to assess feasibility). However, for pilot studies, at the completion of the study, the PI must submit a separate and full protocol to the MBRU-AREC for review in which the total number of animals is adequately justified.

6.2.9 Pain and/or Discomfort of the Animals

6.2.9.1 An important component of ethics in animal research at MBRU is the prevention or alleviation of pain in animals used in the study. It is therefore our moral and legal obligation to prevent or minimize animal pain to the maximum extent possible, consistent with sound scientific practices. Prevention or minimization of pain in animals requires the ability to recognize or better predict the need for intervention with analgesic drugs. Analgesics are required for all procedures likely to cause significant pain in study animals, until specific

signs of pain are absent. Analgesics should generally be administered for at least 48 hours following a painful procedure such as a survival surgery. Information on the duration of administration of analgesics should be specified in the application form. Each animal used in the study should be evaluated at least once daily following a painful procedure, by the PI or his/her staff, for the presence or absence of specific signs of pain. Where there is doubt regarding the level of pain, stress or lasting harm to the animal, the PI should consult with MBRU-AREC chair. For additional information regarding the alleviation of pain and distress in research animals, the recommended analgesic agents, dosages, routes and frequencies refer to the "Investigator Manual", Department of Animal Resources and Institutional Animal Care and Use Committee, University of Southern California (https://iacuc.usc.edu/investigator-manual/).

6.2.10 Classifications of Animal Use

All animals from protozoa to mammals are living organisms that respond to stimuli and therefore, as with all experimental animals in research or teaching, the researchers should adhere to humane principles. This includes the use of appropriate anaesthetics and analgesics with invasive studies, or rapid humane euthanasia when death of the animal is necessary. The PI of the project should identify in which of the below categories the research or teaching study falls. However, the MBRU-AREC may request that certain procedures be classified differently than originally listed on the application form. Below is a list of categories that include all live vertebrate animals (i.e. rodents) used for research or teaching by faculty, staff or students of the MBRU, with possible examples of procedures representing each category.

6.2.10.1 Category A: Studies which cause no or little pain or distress to the animal.

- These include housing and brief restraint of animals for observation or physical examination, single blood sampling, single injections of non-toxic materials (intravenous, subcutaneous, intramuscular, intraperitoneal), or orally, short periods (a few hours) of food and water deprivation, behavioural observations, and standard approved methods of euthanasia that induce rapid unconsciousness such as anaesthetic overdose or decapitation preceded by sedation or light anaesthesia (without surgical interventions prior to death of the animal).

6.2.10.2 Category B: Studies that may involve minor pain or distress of short duration but where pain relieving drugs are given as part of the study.

- These include surgical procedures (such as cannulation or catheterization of blood vessels or

body cavities) and other studies on anesthetized animals where the animals either do not regain consciousness (surgery) or do regain consciousness (minor surgical procedures under anaesthesia, such as biopsies, laparoscopy) with minimal pain and distress, overnight or longer food or water deprivation, behavioural studies on awake animals that involve short-term restraint, studies using harmful stimuli from which escape is possible, and using tumour implants or hybridomas. In all cases, following any survival surgical procedures, the researchers should follow acceptable veterinary practices including postoperative analgesia, fluid therapy and nursing practices, as appropriate.

Comment: During and after category B studies, animals are not expected to show anorexia, dehydration, abnormal discharges, hyperactivity, increased recumbency or dormancy, increased vocalization, self-mutilation, aggressive-defensive behaviour or demonstrate social withdrawal and self-isolation.

6.2.10.3 Category C: Studies which may involve moderate pain or distress.

- These include major recovery surgical procedures performed under anaesthesia where there is possible distress in animals even though analgesics are given to eliminate pain, studies involving prolonged periods (several hours or more) of physical restraint or exposure of animals to noxious stimuli, prolonged deprivation of food or water, procedures which alter perceptual or motor functions such as the induction of paralysis or seizures, induction of behavioural stresses such as maternal deprivation, aggression, predatory-prey interactions, procedures which alter perceptual or motor functions which consequently affect locomotion and behavioural activity, and induction of infectious diseases or toxicities, immunization employing Freund's complete adjuvant administered subcutaneously or intramuscularly, induction of an anatomical or physiological deficit that will result in pain or distress, procedures that produce pain in which anaesthetics are not used such as toxicity testing with death as an end point, production of radiation sickness, and stress and shock research that would result in pain approaching the pain tolerance threshold. In all cases, following any survival surgical procedures, the researchers should follow acceptable veterinary practices including postoperative analgesia, fluid therapy and nursing practices as appropriate and when severe clinical symptoms begin to appear the animals are treated or euthanized.

Comment: During or after category C studies animals must not show signs of prolonged clinical distress such as behavioural abnormalities and aggressive-defensive behaviour or demonstrate social withdrawal and self-isolation, self-mutilation, lack of grooming, dehydration, hyperactivity, anaemia, circulatory collapse or decreased cardiac activity, abnormal and increased vocalization, prolonged anorexia, increased recumbency, dormancy, and increased signs of infectious processes (peritonitis, pneumonia, diarrhea, encephalitis etc). If these clinical abnormalities develop, the necessary treatments to alleviate the symptoms must be available and provided. If the symptoms cannot be alleviated, the animals must be euthanized with minimal delay using an acceptable method of euthanasia.

6.2.10.4 Category D: Studies that may involve moderate to severe pain or distress without the benefit of pain-relieving drugs or other appropriate therapy.

- These studies may not be limited to surgical practices and include application of noxious stimuli from which escape is impossible, exposure to noxious stimuli or agents whose effects are unknown, intradermal or foot pad injection using Freund's complete adjuvant, completely new experiments which have a high degree of invasiveness, behavioural studies about which the effects of the degree of distress are not known, induction of aggressive behaviour leading to self-mutilation or fighting, use of muscle relaxants or paralytic drugs without the use of anaesthetics, burn or trauma infliction on un-anesthetized animals, unusual euthanasia methods, and induction of infectious diseases or toxicities where death is an end point and animals are not treated or euthanized when severe clinical abnormalities develop.

Comment: Category D studies present an explicit responsibility on the faculty to explore alternative methods before proceeding with the study. Category D Studies are considered by some to be highly questionable or unacceptable, irrespective of the significance of the anticipated results. Before the MBRU-AREC can review and approve these projects, the justification statements and the veterinary involvement must be clearly presented.

6.2.11 Other MBRU Animal Ethics Issues

6.2.11.1 Adjuvants

When an adjuvant is necessary, those that cause less inflammation than complete Freund's adjuvant such as Ribi adjuvant or incomplete Freund's adjuvant or other adjuvants are desirable since the use of complete Freund's adjuvant may cause undesirable and painful side effects such as large inflammatory lesions or tissue necrosis and is not acceptable in some cases (i.e. intravenously or into lymph nodes) and depending on the route of administration.

6.2.11.2 Physical Restraint of Animals

Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for examination, collection of samples, drug administration, therapy or other experimental manipulation. The MBRU-AREC understands that animals will be restrained for brief periods of time (e.g. a few minutes) for many research applications. However, more prolonged periods of restraint must be listed on the application form for approval by the MBRU-AREC.

6.2.11.3 Food or Fluid Restriction

Although some experimental situations require food or fluid restriction, the degree and period of food or fluid restriction must be kept to a minimum. In all cases, some quantity of food and fluid must be provided for all animals at intervals sufficient to maintain development in young animals and long-term well-being of all animals. Overnight food and fluid restriction are approved by the MBRU-AREC as part of a standard veterinary care for animals undergoing surgical procedures. All other forms of food or fluid restriction must be listed on the application form and approved by the MBRU-AREC. As a general guideline, in the case of food restriction, the weight loss of the animal should not exceed

20 percent of its original body weight. For fluid restriction, frequent monitoring for signs of dehydration is needed.

6.2.11.4 Use of Radioactive or Biohazardous Materials in Animal Research

Research that involves radioactive or biohazardous materials would need to be assessed from the risk perspective as well as from the point of view of disposal of such animals. Personnel should assess the dangers associated with these materials to animals and select the appropriate safeguards. Other considerations should be the exposure intensity, duration and frequency, and susceptibility of the personnel involved in the study and animal handling. All animal research involving infectious agents, human tumour cells, recombinant DNA, hazardous chemicals, radiation, or the use of animals that present other unique hazards will

be reviewed and approved by the MBRU-AREC as well as other appropriate MBRU safety committees. Radioactive and biohazardous animal carcasses, waste, and bedding must be disposed according to the MBRU health and safety policies and procedures.

6.2.11.5 Tumour Growth

If tumour growth is induced in animals through spontaneous, transplantable, chemically induced, or genetic modification to increase incidences of a certain type of tumour etc., it is important that the PI states the condition under which the affected animals will be euthanized. Animals should be euthanized before their tumour burden becomes excessive and before the animals become debilitated. Assessment of pain, distress and discomfort should be based on evaluating changes in body weight, external physical appearance, observable clinical signs, changes in behaviour or changes in behavioural responses to external stimuli.

6.2.11.6 Blood collection

The maximum allowable volume of blood to be collected at any single bleed for all animal species must not exceed 10% of the circulating blood volume. When multiple blood collections are a part of the experimental design, this volume may be repeated after 3-4 weeks. The following formula should be used to calculate the volume of blood allowed for a single bleed.

Volume of blood allowed for a single bleed = Body weight (kg) x circulating blood volume (ml/kg) x 10%.

When the volume of blood collections is near the upper allowable limit or when there are other concerns, the MBRU-AREC or the veterinarian in charge may require additional laboratory monitoring including measurement of packed cell volume (PCV)/haematocrit and total protein. The frequency of monitoring required will be determined at the time of protocol review. At the time of each subsequent blood collection, the animal must be monitored for clinical signs of hypovolemic shock and anaemia.

6.2.11.7 Multiple Major Surgical Procedures

A multiple major surgical procedure is two or more major recovery surgical procedures performed on the same animal. This must be avoided or specifically justified for approval by the MBRU-AREC.

6.2.11.8 Induction of Seizures in Rodents

Seizures are sometimes induced by pharmacological or other means in rodents (drug withdrawal, picrotoxin, pilocarpine, and kainic acid treatments) to produce animal models for seizures in humans. These studies are considered to be a category C procedure. PIs should consider the use of repeated lower dose treatments (i.e. kainic acid) rather than a single high dose treatment, which can result in a more reliable model of the epileptic state with the use of fewer animals.

6.2.11.9 Transgenic animals

If transgenic animals will be used in the protocol, this must be clearly stated in the application form. If the transgenic animals will be produced by another laboratory or institution, the procedures used to produce the animals (superovulation, embryo collection, embryo transfer), and the source that will produce and supply the animals should be listed. Information regarding potential adverse effects and monitoring for adverse outcomes must be included for all protocols in which transgenic animals are to be used.

6.2.11.10 Lethal Dose (LD50) Testing in Animals

The LD_{50} test involves exposure of groups of animals in order to determine acute toxicity of a test drug or chemical where a single dose will kill 50 percent of the animals. The MBRU-AREC does not approve or allow the use of LD_{50} testing in animals. PIs who would like to study the toxicity of drugs or chemicals in animals will be required to use alternative methodologies or tests that that measure morbidity rather than mortality.

6.2.11.11 Humane Endpoints

Euthanasia of the animal should be done if there is an ulcerated tumour (regardless of size and weight), tumour burden exceeding 10% of body weight, the animal is unable to move or respond to gentle stimuli, has laboured breathing (particularly if accompanied by nasal discharge and/or cyanosis), has diarrhea or incontinence, is unable to eat and drink, has weight loss exceeding 20% of the body weight, or if animals are seen to be in distress, regardless of size of the tumour or the weight of the animal.

6.2.12 The Animal Facility

MBRU will ensure that the animal facility used by its faculty researchers follows accepted practices and scientific knowledge that include proper maintenance of animals, training of those responsible for routine care, as well as careful planning of experiments to ensure that

a minimum number of animals are used in line with the objectives of the experiment. In addition, the researchers should take all steps to minimize stress and pain to the animals and that all anaesthetic practices should conform to the normal veterinary standards. Animals should be killed in a humane manner at the conclusion of the experiment, when necessary. The animal facilities will prepare a guideline that will include all aspects of its operation including procurement of animals, the environment in which animals are kept (animal caging, ventilation, illumination, temperature and humidity), water and food, sanitation of cages, disposal of animal carcasses, housing of the animals and overcrowding, animal transfer and shipment, emergency care, occupational safety and health issues, access to the animal facilities, animal care provided by the researchers (PI and his/her staff), as well as per diem charges for the use of animals.

6.2.13 Research Involving Other Institutions

Where MBRU academic staff are engaged in joint research projects with other universities or institutions (within DHCC or outside), ethical approval is required from all joint institutions unless there is a clear agreement between the entities that ethical approval from the ethics committee of one institution is accepted by the other(s). Again, the PI must ensure that due consideration is given to the three "R" principles (reduction, replacement and refinement) in the design and delivery of the study and that all ethical approvals have been obtained prior to the start of the research project.

6.2.14 Responsibilities of the PI

6.2.14.1 The PI and all the members of his/her team who use animals in research or teaching are responsible to fulfil all ethical and legal requirements and are accountable by UAE laws and MBRU regulations and policies and procedures.

6.2.14.2 All requests to use animals in research or teaching originating from inside or outside the MBRU community must be submitted by the PI of the project to the MBRU-AREC using the appropriate application form (see section 8 below).

6.2.14.3 As the MBRU-AREC relies on the information provided in the application form(s), it is expected that all information is complete, truthful and accurate. Failure to do so could be considered research misconduct.

6.2.14.4 It is important to understand that regardless of the decision by the MBRU-AREC on a specific research project, it is ultimately the responsibility of the PI and the research team

themselves to make sure that the project is carried out to the highest ethical standards.

6.2.14.5 The PI should ensure that all the staff and/or students involved in the study are appropriately trained and have the competence and relevant licenses prior to the start of the study.

6.2.14.6 The PI should ensure that all records of the project are maintained for review, if needed.

6.2.14.7 The PI should minimize or avoid animal pain or distress according to sound scientific practices both during and after the project.

6.2.14.8 Once the research project has been completed, the PI should notify the MBRU-AREC about the study's completion and submit a final report to the MBRU-AREC.

6.2.15 Categories of Ethical Applications and Review

6.2.15.1 Expedited Applications

In the following cases, the application could fall under this category.

a. If the project is an observation-only study (i.e. with no physical contact with animals or no impact on the animals or their habitats), a full application form still needs to be filled for approval by the chair or his/her designee. Once approval is obtained, the project can be commenced. These applications are still provided to the full MBRU-AREC for ratification either electronically or at its next meeting. It is expected that most research projects at MBRU do not fall under this category.

b. If the research is using animal tissue only which will be supplied by another investigator (outside MBRU), then this should be clearly stated in the application form and the approval process could be expedited. It is expected, however, that the investigator responsible for ordering the animals must have an ethical approval from his/her own institution and agrees to the transfer of the samples. Again, in this case, a full application form would need to be filled.

c. In cases where minor amendment to the protocol is required, the process could be expedited, and a shorter application form is filled. After ethical approval of a study by the MBRU-AREC, any amendments to the protocol or the project will require submission of the minor amendment application form (see section 8). Amendments are classified as minor or major. Minor amendments are "not likely to cause harm to the animals, including pain and distress" and include change of the study title, change of the funding agency, addition or deletion of personnel, change of the animal strain (not species) and change of the facility where the research will be conducted. Major amendments require re-submission of the full application and include change of the animal species, any change to the procedure (i.e.

method of anaesthesia, blood collection etc.), addition of any new procedures, increase in animal numbers, transfer of the project to a new PI etc.. The chair of the MBRU-AREC decides whether the amendment can be considered minor. Approval for minor amendments can be made by the MBRU-AREC chair or his/her designee. However, major amendments require approval of majority of the MBRU- AREC members, following a full review process.

d. In some cases, the funding agency may require ethical approval from the university ethics committee for funding of research projects that use animals as participants. In such cases, the MBRU-AREC could review the application in an expedited manner and provide a temporary approval number, which would not be valid for ordering or maintaining animals. Following funding approval, the PI must then submit a full application form for approval by the MBRU-AREC.

6.2.15.2 Full Applications

All new research or teaching projects that involve the use of animals will require to go through the full application process. The full application form requires a detailed description of the project considering the 3Rs. It should also describe the risks to animals and the researchers involved in the study and justify all aspects of the use of animals in the study. Research merit needs to be established for all new projects before ethical approval from the MBRU-AREC can be given. This is normally done by a funding agency through a competitive funding process. Approval of projects is normally given for the period of the grant. However, the PI can request a longer ethical clearance through an amendment to the original approval, with appropriate justification.

6.2.15.3 Basis of Approval

The main principle which guides the MBRU-AREC in making its decisions is based on the 3Rs. The primary task of the MBRU-AREC is the ethical review of proposals and submitted supporting documents that use animals for research or teaching purposes. For ethical approval by the MBRU-AREC, the committee should be satisfactorily reassured with the description provided by the PI in the application material and accompanying documents, including:

a. the design and conduct of the study including the number of animals
b. the protocol used
c. the care and protection of animals and researchers that may be affected
d. health and safety issue and the level of risk
e. other university policies and procedures, social norms within the country, as well as the UAE laws.

f. For additional information on all ethical issues related to the use of laboratory animals in research and teaching refer to links provided in the references (section 9).

g. General Conditions

MBRU-AREC expects researchers to be aware of, and adhere to, the following conditions and guidelines:

- All new applications to the MBRU-AREC should be submitted electronically on the Cayuse system through which PIs would also have the ability to follow progress.
- The PI and all researchers involved in research are required to submit evidence of certification of a course in animal research ethics. Accepted certification is available from CITI (https://www.citiprogram.org/index.cfm?pageID=22), or a recognized regulatory body. Certification must be valid for two years and for the duration of the research project.
- The PI has full responsibility for ensuring adherence to ethical principles during the conduct of the research, as well as for scientific quality, health and safety of animals and financial probity.
- All approvals will be valid for one year from the date of approval. For a project whose duration is beyond a year, the PI should submit an annual report at the end of each year. Automatic reminders will be sent to the PI via Cayuse, beginning 42 days before the anniversary date of the project and every 10 days thereafter. The annual report should be submitted via Cayuse by the anniversary date. Reports submitted beyond this date may result in withdrawal of MBRU-AREC approval.
- All approved research projects should start within 6 months of the approval letter. Inability to start within this time for any reason will require re-submission of application or justification of the reasons. It is the PI's responsibility to inform the MBRU-AREC of any cancelation of approved projects for any reason, clearly mentioning therein the reasons for cancellation.
- Deviation or changes to the approved research protocol would require an amendment of the application via Cayuse.
- Serious breaches to the protocol should be notified to the MBRU-AREC in writing as soon as possible and no later than 15 days after the breach.
- The MBRU-AREC should be immediately informed in writing of any significant incidents in relation to the safety of the research participants during the study. Incidents should be reported via Cayuse IRB.
- Premature termination of the research requires written notification to the MBRU-AREC within 30 days of termination. However, a planned termination will require written

notification within 60 days of end of study.

- For monitoring purposes, members of the MBRU-AREC or their designee are authorized to visit the research site at any time.
- Annual progress reports and an end-of-study report are to be submitted to the MBRU-IRB via the Cayuse system within 30 days. Should an extension be required, the PI has to ensure that the report is submitted in a timely manner.
- Failure by the PI to timely submit a progress or end-of-study report, and after two reminders, may result in punitive action being taken at the discretion of the MBRU-IRB, which may include refusal by the MBRU-IRB to accept applications by the PI for a designated period of time.
- The MBRU-AREC reserves the right to rescind a prior approval based on concerns by members in the study design/protocol. Approval can then be granted, pending clarification by the PI.

7 Supporting Forms

7.1 Cayuse IRB System

8 Related Documentation

8.1 Research Policies and Procedures

8.2 Health and Safety Policies and Procedures

8.3 Faculty handbook

8.4 DHCR Research Policy (https://dhcr.gov.ae/en/AboutDHCR/regulatory-functions#/ClinicalResearch)

9 References

9.1 Commission for Academic Accreditation, Standards for Licensure and Accreditation. Ministry of Education, United Arab Emirates.

9.2 UN Convention on the Right of the Child (UNCRC) https://www.unicef.org.uk/what-we-do/un-convention-child-rights/

9.3 Federal Law 3 of 2016 on child rights

9.4 The Belmont Report, 1979

https://videocast.nih.gov/pdf/ohrp_appendix_belmont_report_vol_2.pdf

9.5 NIH IRB Guidebook, Office for Human Research Protection

https://ohsr.od.nih.gov/

9.6 US Code of Federal Regulations, Department of Health and Human Service; Public Welfare: Protection of Human Subjects (45CFR46) and Food and Drug Administration: Protection of Human Subjects (21CFR50) and Regulations for IRB (21CFR56)

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#

9.7 Queens' University Belfast Policies and Procedures on the Ethical Approval of Research

http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/

9.8 Institute of Laboratory Animal Resources. Guide for the Care and Use of Laboratory Animals, National Academy Press, 1996.

https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

9.9 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. NIH Guide for Grants and Contracts14 (8):23-24, 1985.

https://grants.nih.gov/grants/olaw/links.htm

9.10 Investigator Manual, Department of Animal Resources and Institutional Animal Care and Use Committee, University of Southern California

https://iacuc.usc.edu/investigator-manual/

9.11 USDA Animal Welfare Act, 1966.

https://www.nal.usda.gov/awic/animal-welfare-act

9.12 Public Health Service Policy on Humane Care and Use of Laboratory Animals (1996)

https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf

9.13 UAE Ministry of Health and Prevention Cabinet Resolution No. (40) of 2019 Concerning the Executive Regulations of Federal Decree Law No. (4) of 2016 on Medical Liability https://www.mohap.gov.ae/FlipBooks/PublicHealthPolicies/PHP-LAW-EN-79/mobile/index.html

9.14 UAE Ministry of Climate Change and Environment https://www.moccae.gov.ae/en/media-center/news/12/12/2018/ministry-of-climate-change-and-environment-issues-executive-regulations-for-federal-law-on-animal-welfare.aspx#page=1

9.15 Federal Law No. 16 of 2007 on Animal Welfare

9.16 Ministerial decision No. 384 of 2008 on the Executive Bylaw of the Federal Law No. 16 of 2007 concerning Animal Welfare

10 Policy History

MODIFICATION AND REVISION HISTORY			
REV	**Description of Change**	**Reviewer**	**Review Date**
1	New – Approved by Academic Council	RGS	Apr 2017
2	New template, updates in MBRU-IRB sections – Approved by Academic Council	MBRU-IRB Members	Sep 2021
2.1	Amended terms/names as per new Organizational Structure	SIE	Nov 2022