Ethical Policy of Human Research at RAKMHSU

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What is the difference between exempted, expedited and full review researches

Exempted, expedited, and full review are three categories of research review processes to evaluate and approve research involving human subjects.

1. **Exempted Review:**

Exempted research is typically low-risk and involves minimal involvement or impact on human subjects.

Examples of exempted research may include surveys, interviews, or observations of public behavior where no identifiable information is collected, or when data are obtained from existing sources (e.g., medical records) with no direct subject interaction.

2. **Expedited Review:**

Expedited review is for research that poses minimal risk to participants but may involve more than minimal interaction or identifiable information.

Examples of research that may qualify for expedited review include certain clinical studies, behavioral interventions, or studies involving the collection of sensitive data with appropriate safeguards, e.g. Biological specimens.

3. **Full Review:**

Full review is the most comprehensive and rigorous type of review.

It is required for research that involves greater than minimal risk to participants or vulnerable populations, or when the research raises complex ethical concerns.

Examples of research that typically undergo full review include clinical trials, studies involving vulnerable populations (e.g., children, pregnant, elderly or prisoners), and research with potential risks to physical or psychological well-being.

Note:

Review of literature, systematic review of published data need only the submission of the title page for sake of documentation with no need of institutional ethical clearance.

Contents

1. ABBREVIATIONS

1.1 RAKMHSU- RAK Medical and Health Sciences University

1.2 HEC- RAKMHSU-Human Ethics Committee

1.3 PI- Principal Investigator

1.4 UAE MOHAP- United Arab Emirates Ministry of Health and Prevention

2. INTRODUCTION

The highest standards of scientific integrity, ethical conduct, and medical responsibility should be adhered to in all research carried out at the RAKMHSU. These requirements are outlined in Federal Law No. 4 of 2016 governing medical responsibility. The Human Ethics Committee- RAKMHSU values the complete preservation of individuals' rights, health, safety, dignity, and privacy, as well as the respect for human subjects' and researchers' safety. This policy paper details the steps for researchers to take in order to obtain ethical approval before performing their

research and includes information regarding RAKMHSU requirements for research involving human and animal subjects. It covers all studies involving human participants who take part in behavioral, social, or biomedical disciplines as well as all studies involving animals. It offers a broad overview of the criteria required and needed for RAKMHSU research to receive ethical approval. The researcher conducting the research endeavor bears the primary responsibility for adhering to the approved ethical standards because this is not an exhaustive document. Everyone conducting research under the direction of RAKMHSU is subject to this policy, including faculty academics, employees, researchers, students, and partners. The Principal Investigator (PI) is accountable for making sure that all researchers taking part in the study are aware of the university's ethics policies and practices. The Human Ethics Committee (HEC) has been created by the RAKMHSU to oversee the safety, morbidity, and morality (if applicable) of research involving human subjects, human samples, human tissue, and human data.

All research applications involving human subjects and human samples/tissue/data at RAKMHSU are subject to assessment, approval, and oversight by the HEC-RAKMHSU. In order to decide whether or not a particular research project should be carried out, this committee will adhere to strict standards to evaluate the research proposals in terms of their risk-benefit analysis. To ensure that the proper measures are taken to protect the rights and welfare of people/tissue/data participating in a research project is the goal of HEC-RAKMHSU.

3. PURPOSE

A framework for the ethical review of research initiatives carried out at RAKMHSU is provided in this document, together with procedures and guidelines. It contains the necessary paperwork for researchers to plan, submit, and request ethics approval for their research investigations. It also includes policies, procedures, and guidelines.

4. SCOPE

These guidelines apply to all RAKMHSU academics, academicians, researchers, staff members, and students as well as to any research projects conducted at RAKMHSU facilities that use humanl subjects, where the research:

- is conducted by or under the direction of RAKMHSU faculty members, staff, or students,
- is conducted by an external organization, with sponsorship from the RAKMHSU or with participation of its faculty researchers, staff, or students, or using any property or facility of the university and
- involves the use of RAKMHSU's public or nonpublic information to identify or contact human research subjects or prospective subjects.

5. POLICY STATEMENT

5.1 All RAKMHSU Researchers will be held to the highest standards of scientific and moral behavior, as determined by RAKMHSU. RAKMHSU will make sure that the ethics and integrity of research operations carried out under its auspices are flawless since it views upholding high ethical standards in research as a key obligation.

5.2 RAKMHSU will make sure that the proper procedures and frameworks are in place to oversee research ethics at RAKMHSU.

5.3 All Researchers at RAKMHSU are expected to conduct themselves in line with all applicable UAE laws, as well as with UAE cultural customs and the University's standards of professionalism.

5.4 All RAKMHSU Researchers who are affiliated with RAKMHSU or who are working on its behalf are expected to comply to its policies on research ethics.

5.5 Any research involving human subjects must first receive ethical permission from the HEC-RAKMHSU before work can begin.

5.6 RAKMHSU will take intentional transgressions of ethical standards very seriously, and any such action may be forwarded to the relevant RAKMHSU bodies or committees for consideration with regard to research misconduct.

5.7 RAKMHSU has created the Human Ethics Committee (HEC-RAKMHSU) for reviewing research involving human subjects, samples, and data. In certain cases, both the Human Ethics Committee and Animal Ethics Committee of RAKMHSU may look into any complaints of unethical research practices or research conducted at RAKMHSU. HEC-RAKMHSU is supposed to evaluate the study's risks and rewards, necessity, applicability, methodology, and, most importantly, the protection of the

human participants. The researcher's expertise in the consent procedure, confidentiality, funding, and conflict of interest will help to ensure that the study is conducted in a professional manner. The compensation process for individuals who might experience negative effects or injury while participating in research is also evaluated by the HEC-RAKMHSU. The HEC members will conduct interim evaluations after approval to make sure the protocol is followed exactly.

5.8 Research Involving Human Subjects/Tissue/Samples/Data:

5.8.1 RAKMHSU is committed to ensuring the ethical conduct of all research activities involving human participants. This involves a comprehensive review process that safeguards the rights, well-being, and confidentiality of participants. Cultural sensitivities in the UAE and the University's reputation are also important considerations in this process.

5.8.2 This policy underscores the importance of upholding the rights and safety of human participants throughout research endeavors associated with RAKMHSU. Adherence to RAKMHSU policies and relevant UAE laws, such as the UAE medical liability law No 4, 2016, is paramount.

5.8.3 RAKMHSU acknowledges that there might be instances where the researcher's lawful research pursuits could potentially clash with the rights of participants. In such cases, researchers are ethically bound to prioritize the well-being and rights of participants, even when it involves navigating conflicting interests.

5.8.4 The HEC-RAKMHSU is tasked with evaluating research proposals involving human participants to ensure alignment with the principles articulated in the Belmont report and the Helsinki Declaration. These principles encompass treating individuals with respect, avoiding harm, promoting benefit, and ensuring fairness. Consequently, research must secure voluntary participation, informed consent, and equitable recruitment, especially for vulnerable populations. The proposal should also demonstrate that potential risks are reasonable and justifiable in relation to expected benefits. Adequate safety measures and additional safeguards for vulnerable populations must be outlined. Furthermore, the proposal should detail measures to maintain confidentiality, ensure data storage, and

uphold research quality. Every research stage must fully adhere to RAKMHSU's established protocols and guidelines.

6. RESPONSIBILITIES

6.1 The HEC-RAKMHSU is responsible for reviewing all applications involving human subjects, as well as human samples, tissues, and data utilized in research within RAKMHSU and its affiliated entities. Its primary mission is to ensure the protection of the rights and well-being of individuals participating as research subjects. Reporting directly to the Vice President- Research and Postgraduate Studies, RAKMHSU, the HEC-RAKMHSU oversees these ethical considerations.

6.2 The Chairman, HEC-RAKMHSU must possess prior experience relevant to this role, coupled with adequate training, particularly the course provided by the Collaborative Institutional Training Initiative (CITI) program for Human Subjects Research: https://www.citiprogram.org/ prior to assuming the Chairman's responsibilities.

6.3 The HEC-RAKMHSU bear the primary accountability for ensuring full adherence to regulations and guidelines concerning the involvement of humans in research investigations.

6.4 In terms of policy enhancement and implementation oversight, the Vice President-Research and Postgraduate Studies, RAKMHSU holds the responsibility. This role includes orchestrating the policy revision process, as well as overseeing the continuous monitoring and assessment of their effective implementation.

6.5 The HEC-RAKMHSU holds discretionary authority on behalf of RAKMHSU to withhold approval for a research proposal or to request appropriate modifications when ethical considerations warrant such actions. The committee's duties encompass:

- Developing or reviewing pertinent policies, procedures, and guidelines (along with forms) on research ethics at RAKMHSU, and fostering awareness of values and responsibilities for upholding the highest research ethics standards across the university in studies involving human subjects or data.
- Seeking clarifications from external bodies, if required, concerning ethical review policies and procedures.

- Evaluating all research proposals involving human subjects and human-related materials/data to determine if they adhere to the university's ethical standards. The HEC-RAKMHSU can approve, reject, or request minor/major revisions to the research protocols. The committee aims to meet specific review timelines: 4-6 weeks for full reviews, 2-3 weeks for expedited reviews, and 1-2 weeks for exempt reviews, provided submissions are complete and don't necessitate modifications. Extensions may apply during University breaks.
- Reviewing and discussing submitted research proposals, either electronically or during board meetings. Proposals must be accepted for discussion at least 10 days before a scheduled meeting, contingent upon application completeness.
- Safeguarding the confidentiality of applications, meeting discussions, participant information, and other confidential matters.
- Ensuring adherence to RAKMHSU policies and procedures.
- Reporting their activities to the Vice President- Research and Postgraduate Studies, RAKMHSU.

6.6 Members of the HEC-RAKMHSU are expected to actively attend most or all meetings and contribute effectively to application reviews.

7. PROCEDURE/PROCESS

7.1 Categories of Ethical Applications and Review

7.1.1 Exempted Applications

Before submitting applications to the HEC-RAKMHSU, PI is advised to evaluate whether their proposed work qualifies as human medical research, as some activities may not fall under the definition of research. For what constitutes research, you can refer to the US Code of Federal Regulations for the Protection of Human Subjects (45CFR46). Additional guidance can be found on the following website: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#

Here are a few examples of scenarios where research applications can be considered for exemption from HEC-RAKMHSU review:

- **Research in Educational Settings:** Research involving normal educational practices, such as evaluating instructional strategies or comparing instructional techniques, curricula, or classroom management methods.
- **Educational Tests, Surveys, Interviews, and Observations:** Research utilizing educational tests, surveys, interviews, or observations of public behavior, unless the collected information can directly identify subjects or could put them at risk.
- **Research Involving Elected/Public Officials:** Research involving educational tests, surveys, interviews, or observations of public behavior, if the subjects are elected or appointed public officials or candidates, and confidentiality is mandated by federal statute.
- **Analysis of Existing Data or Specimens:** Research involving already collected data, records, specimens, etc., if they are publicly available or recorded in a manner that prevents subject identification.
- **Research and Demonstration Projects:** Projects assessing the public benefit of service programs, procedural changes, or payment methods, conducted under department approval.
- **Taste and Food Quality Evaluation:** Studies evaluating taste, food quality, and consumer acceptance of safe foods, adhering to national regulatory agencies' standards.
- **Quality Assurance Projects:** Collecting patient information to enhance patient care, like optimizing clinic schedules or determining appropriate therapeutic modalities.
- **Case Studies/Reports:** Case studies or reports involving a small number of subjects (e.g., fewer than five) that don't constitute controlled experiments.

  Applicants pursuing research exemption from the HEC-RAKMHSU must obtain approval from the HEC-RAKMHSU chair before proceeding with their projects (using the exempt application form). It's important to note that applying for exemption doesn't guarantee approval. Furthermore, research projects eligible for exempt status are not exempt from the ethical principles guiding responsible research involving human participants. Exempt research projects must adhere to ethical principles outlined in the Belmont Report, which emphasize respect for

persons, beneficence, and justice. Researchers should ensure voluntary participation, clearly outline the informed consent process, and prioritize fair and non-discriminatory participant recruitment.

7.1.2 Expedited Applications

Expedited applications are typically appropriate for research projects that involve low risk and do not require recording personal health information. These might include minimally invasive procedures like one-time blood collection through methods such as finger stick, urine samples, saliva, hair and nail clippings, etc. Additionally, surveys or questionnaires without additional sample collection might also be considered for expedited review. Here are a few examples of research scenarios that can be submitted for expedited review to the HEC-RAKMHSU:

- **Blood Sample Collection:** Collection of blood samples through methods like finger stick, heel stick, ear stick, or venipuncture. For adults, blood drawing should not exceed 450 ml within an 8-week period, and not more than twice a week. For children and individuals less than 50 kg, not more than 50 ml or 3 ml/kg (whichever is less) within an 8-week period, with no more than 2 times per week.
- **Noninvasive Biological Specimens:** Prospective collection of biological specimens for research through noninvasive means like hair and nail clippings, excreta, placenta, amniotic fluid, buccal scraping, skin swab, etc.
- **Noninvasive Data Collection:** Collection of data through noninvasive means commonly used in clinical practice (excluding x-rays and microwaves), such as ECG, EEG, MRI, ultrasound, echocardiography, electroencephalography, Doppler blood flow, thermography, body composition assessment, etc.
- **Use of Existing Materials:** Research using materials already collected (data documents, records, specimens) or collecting data for non-research purposes (e.g., medical treatment or diagnosis).
- **Recordings for Research:** Collection of data from voice, video, digital, or image recordings made for research purposes.
- **Research on Characteristics or Behavior:** Research on individual or group characteristics or behaviors like perception, cognition, motivation, identity, language, communication, cultural beliefs, social behavior, test development

without behavior manipulation or stress to subjects, surveys, interviews, oral history, or quality assurance methodologies (some research in this category may be exempt).

- If an applicant is uncertain whether their proposed research project fits under the exempt or expedited categories, it's recommended that they seek guidance from the HEC-RAKMHSU before submitting the application. All applications for expedited review must include Conflict of Interest forms completed by each researcher involved in the project. These forms are an important part of the review process.

7.1.3 Full Applications

Any research involving certain specific factors requires the full application process for ethical review. These factors include:

- Collection of personal health information of participants????.....not retrospective
- Invasive procedures
- Genetic testing
- Repeated participant visits
- Involvement of vulnerable populations (children, pregnant women, elderly, prisoners, etc.)
- Culturally sensitive research
- Collaboration with other institutions

The full application form necessitates a comprehensive project description, highlighting:

- Voluntary participation of human participants
- Informed consent process
- Fair and non-discriminatory participant recruitment (especially for vulnerable populations)
- Justification of reasonable risks against expected benefits
- Clear monitoring plan for participant safety
- Additional safeguards for vulnerable populations
- Data storage protocols

For proposals previously reviewed ethically by another institution, the HEC-RAKMHSU requires submission of application and approval documentation along with the new application materials.

All Full review applications must include Conflict of Interest forms, completed by each researcher involved in the project. These forms are crucial components of the review process to assess any potential conflicts that might impact the research's ethical integrity.

7.2 Review Process (Research involving human subjects)

7.2.1 For applications necessitating full review, all HEC members assess the applications, but the chair appoints a primary reviewer to meticulously review and present the application. Final decisions are reached by majority vote during assessment meetings, requiring a quorum of over half the members.

7.2.2 Expedited review applications are reviewed and approved by the Chairman, HEC-RAKMHSU or a designated reviewer on their behalf, followed by endorsement from the majority of HEC members, often through electronic means.

7.2.3 Applications qualifying for exemption are reviewed and approved by the Chairman, HEC-RAKMHSU or a designated reviewer, with no requirement for HEC members' endorsement.

7.2.4 If a HEC-RAKMHSU committee member applies for ethical approval of their research project, they must recuse themselves from the meeting and decision-making process.

7.2.5 The PI of the research project may be invited to HEC-RAKMHSU meetings if significant clarifications on the application are needed. In all instances, discussions and decisions about research projects should be documented.

7.2.6 The Chairman, HEC-RAKMHSU will communicate the final decision regarding the research application's status to the PI and other pertinent RAKMHSU personnel and administrators.

7.3 Basis of Approval

The decision-making process of the HEC-RAKMHSU is guided by the ethical principles outlined in the Belmont Report from April 1979. These principles encompass respect for persons, beneficence, and justice. The primary

responsibility of the HEC-RAKMHSU is to conduct an ethical review of research proposals and accompanying documents with a focus on ensuring the well-being, rights, and safety of both participants and researchers. Additionally, it evaluates the appropriateness of the project's ethical aspects, including informed consent.

To grant ethical approval, the HEC-RAKMHSU examines the details provided by the PI in the application materials and related documents. These encompass:

- The study's design and execution
- Participant selection and recruitment methods
- Consent procedures, participant care, and protection
- Participant autonomy and voluntary participation
- Measures to safeguard confidentiality and privacy
- Data management plans and security
- Facility adequacy and risk level assessment
- Alignment with university policies, social norms, and UAE laws

By scrutinizing these components, the HEC-RAKMHSU ensures that the research adheres to ethical principles and standards, promoting the welfare of all parties involved while complying with relevant regulations.

7.4 Monitoring and Compliance

All members of the research team bear individual accountability for the well-being and care of human subjects throughout the duration approved by the HEC-RAKMHSU. The Principal Investigator (PI) holds the ultimate responsibility to ensure that all team members comprehend and embrace their roles within the research project.

The HEC-RAKMHSU assumes the duty of supervising endorsed research endeavors, when necessary, to ensure alignment with RAKMHSU's protocols, standards, and the fundamental tenets of the Belmont Report and Helsinki Declaration. This oversight may encompass various activities, such as sporadic assessments of consent forms, findings, data storage procedures, and site visits for inspection. This supervisory role encompasses all classes of sanctioned research, including those subjected to full, expedited, and exempt review.

7.5 Informed Consent

7.5.1 The fundamental principle guiding research involving human participants is that of obtaining free and informed consent. Researchers engaging in human research are required to secure informed consent from their participants using the RAKMHSU informed consent form. Informed consent, while adaptable to the specific context, generally entails that participants:

- Possess the capacity to provide consent.
- Receive comprehensive information about the research that could impact their decision to partake as research subjects. This information should be conveyed in a clear and understandable manner, both in written form and, ideally, verbally. The use of deception or false information to induce distress, whether emotional or physical, is not justifiable and will not be tolerated.
- Are aware that participation is voluntary and that they retain the right to withdraw at any time, even if they had previously granted consent. In such cases, any of the participant's personal data, recordings, or materials should be entirely eradicated. However, it's important to note that there are limitations to the withdrawal right, for instance, it cannot be fully exercised after the research has concluded and been published. Therefore, participants should be fully informed about the specifics of their withdrawal rights and the associated timelines.
- Understand that choosing not to participate or withdrawing from the research will not result in any adverse consequences concerning their subsequent treatment.
- Recognize their freedom to withdraw consent without any negative repercussions, ensuring that their eligibility for any services, whether provided by RAKMHSU or collaborating institutions, remains unaffected.
- Are invited to participate without undue pressure or enticing offers. While participants may be appropriately rewarded, such as receiving reimbursement for transportation expenses, such compensation should not be utilized to induce participation.

- Are aware that they are entitled to seek clarifications and receive accurate responses concerning their research participation, with promptness being a priority.

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

7.6.1 Special populations, including children, vulnerable adults, pregnant women, fetuses, neonates, prisoners, students, employees, the elderly, refugees, disabled individuals, and those economically, socially, or educationally disadvantaged, require additional safeguards and institutional oversight when involved in research. HEC-RAKMHSU is dedicated to safeguarding the rights of these vulnerable groups as research participants, recognizing that their unique circumstances may make them more susceptible to coercion and inappropriate influence that could compromise their voluntary participation and informed consent.

7.6.2 When dealing with participants who are legally incapable of providing consent, such as minors, researchers must obtain assent (approval) from the participants' parents or legal guardians. Alongside this, researchers should seek the participants' agreement, explaining the research's purpose and their role, while prioritizing the participants' best interests.

7.6.3 Research involving children should adhere to the United Nations Convention on the Rights of the Child, particularly Articles 3 and 12, as well as relevant UAE laws protecting children, including Federal Law No. 3 of 2016, known as the Wadeema Law. Article 3 emphasizes the child's best interests as the primary consideration, while Article 12 grants children capable of forming their views the right to do so in matters affecting them. UAE laws on child protection should also be followed, and any potential risks to child participants must be minimized. Depending on the child's age, maturity, and psychological state, both assent from the child and parental permission (akin to informed consent) are necessary.

7.6.4 Research involving vulnerable adults (those incapacitated or dependent due to cognitive, medical, economic, social, or situational factors) must take precautions

to ensure they haven't been unduly influenced to participate, whether by dependents, the research team, or others.

7.6.5 Research involving pregnant women must adhere to relevant UAE laws while prioritizing the safety and health of both the mother and the fetus. Generally, research on pregnant women is acceptable if it directly benefits both mother and fetus, or poses minimal risk to either. Additionally, the research must yield unique findings not attainable through other means. Consent from both partners is usually required, with exceptions. For pregnant underage children, both assent and parental permission are necessary. Monetary or other incentives must not be offered to induce pregnancy termination for research purposes. Researchers cannot make decisions concerning the pregnancy or fetus viability.

7.6.6 Research involving prisoners should follow relevant UAE laws, ensuring their safety and rights. Generally, research on prisoners is acceptable if it pertains to the causes, effects, or processes of incarceration or criminal behavior, and if it poses minimal risk or inconvenience to participants. Research investigating prison conditions or prisoners' experiences may require consultation with experts and additional approvals from UAE agencies. If the study focuses on issues prevalent among prisoners, such as vaccine trials, hepatitis, or social and psychological problems, appropriate experts should be consulted, and additional approvals might be necessary.

7.7 Privacy

7.7.1.1 Respecting the privacy of all research participants is crucial. Even though they have consented to participate, participants should not be pressured to divulge personal or sensitive information about all aspects of their lives. It's vital to communicate to participants that the decision to share information rests entirely with them, and they are not obligated or coerced to discuss any sensitive matters they are uncomfortable with.

7.7.1.2 If a researcher possesses prior knowledge or a pre-existing relationship with potential participants before inviting them to partake in the research, the researcher must obtain explicit consent from the participants if their previously shared information is to be used in the study.

7.7.1.3 For ethical considerations, all research participants should be approached indirectly, typically through an intermediary like a research assistant, research nurse, data collector, etc. The principal investigator should not have direct contact with potential participants. Participants should be informed that they can seek additional information from the designated team member if they are interested in learning more about the research, both before and after providing their consent.

7.8 Confidentiality and Data Storage

7.8.1 Storing research-related data is mandated for at least five years post the research project's completion. Nevertheless, upholding the confidentiality of participant information and data is paramount, especially in research involving human participants. All personal details should be encrypted or anonymized right from the onset of data collection, with corresponding codes stored separately. Additionally, during the consent process, researchers should apprise potential participants of the measures undertaken to guarantee privacy, data confidentiality, identity protection, as well as any limitations inherent to these measures.

7.8.2 While researchers are bound to uphold promises of privacy and confidentiality, there are circumstances in which these assurances may be superseded. For instance, if researchers harbor concerns about the safety or well-being of child participants, they might be obligated to report these concerns to a relevant authority or third party. In all instances, everyone involved must exert maximum effort to ensure the physical and psychological safety and well-being of all research participants.

7.9 Safety and Well-being of the Participants

7.9.1 Before commencing research, a comprehensive risk assessment should be conducted to identify possible adverse effects, and prompt measures to mitigate these risks must be implemented. Under no circumstances should participants be subjected to unnecessary risks, and research should proceed only if the potential benefits clearly outweigh the potential risks. Any potential risks should be transparently communicated to potential participants at the outset of the research, particularly during the process of seeking their informed consent.

7.9.2 The PI of a research project bears the responsibility for ensuring that any research involving human participants has received ethical approval from the HEC-RAKMHSU. Furthermore, they are accountable for conducting the research in alignment with RAKMHSU's research, ethics policies and procedures, while also adhering to UAE laws pertaining to individual and public safety.

7.10 Responsibilities of the Principal Investigator

7.10.1 Requests for utilizing research involving human subjects, originating from either within or outside the RAKMHSU community, must be formally submitted by the PI of the project to the HEC-RAKMHSU.

7.10.2 Since the HEC-RAKMHSU relies on the information presented in the application form(s), it is imperative that all details provided are comprehensive, accurate, and truthful. Any failure to adhere to these standards could be construed as research misconduct.

7.10.3 It's crucial to recognize that, regardless of the HEC-RAKMHSU's decision on a specific research project, the primary responsibility for ensuring the project's adherence to the highest ethical standards lies with the PI and the research team. Upon concluding the research project, the PI should promptly inform the HEC-RAKMHSU about the study's completion. Within one year of study conclusion, an end-of-study declaration and a final summary report should be submitted to the HEC-RAKMHSU.

7.11 Research Involving Other Institutions

When RAKMHSU Researchers collaborate on research projects with other Universities or Institutions, whether within the UAE or outside the UAE, ethical approval must be obtained from all collaborating institutions unless a well-defined agreement exists among these entities that allows the ethical approval granted by one institution's Human Ethics Committee (HEC) to suffice for the others. It is essential to emphasize that the principal investigator bears the responsibility of ensuring that all necessary ethical approvals have been secured before initiating the research project.

7.12 Research Involving Genetic Material

All research projects focused on the study of genetic material are obligated to adhere to the directives outlined by the concerned department of the UAE Government. In scenarios where, specific analyses of genetic material are unavailable within the United Arab Emirates (UAE), it is acceptable for the material to be stored in a facility located abroad. However, a formal written agreement, bearing signatures, should be established between the PI in the UAE and the designated overseas facility. The HEC-RAKMHSU will thoroughly assess and evaluate such agreements to determine their suitability for approval.

7.12 General Conditions

7.12.1 Following the study approval from HEC-RAKMHSU, PI must go through the rule and regulations of the UAE Ministry of Health and Prevention and as per their directives on study categorization- Hospital, Community research etc., he/she should submit the proposal along with appropriate documents for approval from the relevant authority (For example, RAK-REC).

7.12.2 Once approval is granted by the HEC-RAKMHSU, Researchers are expected to uphold the following conditions and guidelines:

- **Research Ethics Certification:** The Principal Investigator (PI) and all research team members must provide evidence of completion of a research ethics certification course. Certification from recognized bodies like CITI https://www.citiprogram.org/index.cfm?pageID=22 or NIH https://phrp.nihtraining.com/users/login.php, or from a recognized regulatory authority, is acceptable. This certification must remain valid for two years and throughout the research project's duration.
- **PI's Responsibilities:** The PI holds full responsibility for adhering to ethical principles throughout the research's execution. This encompasses scientific rigor, participant confidentiality, safety, and financial integrity.
- **Timely Initiation of Research:** Approved research projects should commence within six months of receiving the approval letter. If this timeline cannot be met for any reason, the application may need to be resubmitted, or a justification must be provided.

- **Changes to Approved Protocol:** Any deviations or alterations to the approved research protocol necessitate an amendment to the original application.
- **Reporting Breaches:** Any serious breaches of the approved protocol should be communicated in writing to the HREC within 15 days of their occurrence.
- **Safety Incidents:** Significant incidents related to the safety of research participants during the study should be promptly reported in writing to the HREC.
- **Premature Termination:** In cases of premature research termination, written notification must be submitted to the HREC within 30 days of termination. If the termination is planned, written notice is required within 60 days of the study's conclusion.
- **Site Monitoring:** For monitoring purposes, HREC members or their representatives have the authority to visit the research site at any time.
- **Progress and End-of-Study Reports:** Annual progress reports and a comprehensive end-of-study report must be submitted to the HREC using the designated forms.
- **Rescinding Approval:** The HEC-RAKMHSU retains the right to withdraw a prior approval based on concerns expressed by committee members regarding the study design or protocol. However, approval can be reinstated pending clarification from the PI.

  Researchers are expected to familiarize themselves with and adhere to these guidelines once their research project has been granted approval by the HEC-RAKMHSU.

8. Key Performance Indicators (KPIs)

The requested metrics provide insight into the processes and efficiency of the ethical review committees:

8.1 Proportion of Applications Approved: This metric evaluates the success rate of applications submitted to the HEC-RAKMHSU on an annual basis.

8.2 Types of Applications Reviewed: This metric involves categorizing applications into three groups: exempted, expedited, and fully reviewed. It assesses the number and proportion of each category for HEC-RAKMHSU in every academic year.

8.3 Average Review Time: This metric indicates the average duration taken by the HEC-RAKMHSU to review an application. It offers an understanding of the efficiency of the review process on an annual basis.

Collectively, these metrics provide valuable insights into the volume, effectiveness, and speed of the ethical review processes conducted by HEC-RAKMHSU.

9. References

- The Belmont Report, 1979. https://videocast.nih.gov/pdf/ohrp_appendix_belmont_report_vol_2.pdf
- NIH IRB Guidebook, Office for Human Research Protection https://ohsr.od.nih.gov/
- 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)
- Queens' University Belfast Policies and Procedures on the Ethical Approval of Research http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/
- Investigator Manual, Department of Animal Resources and Institutional Animal Care and Use Committee, University of Southern California
- https://iacuc.usc.edu/investigator-manual/

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