



## Ethical Approval Application Form



### Notes:

1. This application form should be filled **electronically** by the **chief investigator (staff/PGR student)** seeking ethical approval for an individual research project.
2. Please, read carefully the research ethics handbook which is available from the Research Ethics Committee (REC) before completing this form.
3. Please, note that it is **the researcher's responsibility** to ensure the completion of this form **accurately** and send it, together with all related documents, to the REC in electronic and hard copies.
4. Research must **not** begin nor data can be collected/analysed before ethical approval is obtained from the Committee.
5. Please, define any terms or acronyms that might not be familiar to lay reviewers of the application.

### PART A: Core study information

#### A1. Administrative details

**A1-a. Full title of the research:** Feasibility a combining rehabilitation program at field exercises and tele-exercises to enhance daily life activities to rural women in Iraq

**A1-b. Applicant's name:** Assistant Prof. Dr. Munib Abdullah Fatthe

**A1-c. Application Type:** (Tick as appropriate).

- ☐ For academic qualification: please specify. ☐ M.Sc. ☐ Ph.D.  
☒ For academic promotion.  
☐ Community service.  
☐ Other, please specify.

**A1-d. Duration of study.**

Proposed start date: **01/06/2024**

Proposed end date: **15/10/2024**

Approximate duration: Four months

**A1-e. Location of study:** (Tick as appropriate).

- ☐ College of Physical Education and Sport Sciences /University of Mosul.  
☒ Other.

*If location other than college of College of Physical Education and Sport Sciences /University of Mosul will be used, please provide details of the approval to gain access to that location as an appendix.*



<b>A1-f. Chief investigator (CI) Dr. Munib Abdullah Fathe and Principal Investigator (PI) Dr. Stevan Jajju Karash</b>	
Name (first name, surname)	Munib Fathe
Qualifications	PhD
Position	Assistant Professor
Email	m.a.fathi@uomosul.edu.iq
Telephone	009647701680770
Educational establishment/affiliation: Department/College/University	Sport Sciences, College of Physical Education and Sport Sciences, University of Mosul, Mosul, Iraq
<b>A1-g. Principal investigator (PI)</b>	
<i>If this study will be conducted by PGR student, please give the details of academic supervisor(s). if the applicant is a staff member, please go directly to section A2.</i>	
Academic supervisor 1	
Name (first name, surname)	
Qualifications	
Email	
Telephone	
Educational establishment/affiliation: Department/College/University	
<b>Academic supervisor 2 (if any).</b>	
Name (first name, surname)	Munib Fathe
Qualifications	PhD
Email	m.a.fathi@uomosul.edu.iq
Telephone	009647701680770
Educational establishment/affiliation: Department/College/University	Sport Sciences, College of Physical Education and Sport Sciences, University of Mosul, Mosul, Iraq
<b>A2. Overview of the research</b>	
<i>To provide all the information required by REC, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers. Please read the guidance notes for advice on this section</i>	
<b>A2-a. Summary of the study. Please provide a brief summary of the research (maximum 500 words) using language easily understood by lay reviewers.</b>	
Abstract	



*Objective: To design implement a combined rehabilitation program (CRP) that integrates home-based therapeutic exercises with popular games, aiming to enhance the physical well-being and quality of life of rural women.*

*Setting: The women's forum of the Church of the Sisters of the Virgin Mary in the Hamdaniya district, northeast of the province of Nineveh in Iraq*

*Participants: Sixty-six women, averaging (46) years old, engaged in agricultural work for (18-23) years, experiencing Musculoskeletal pain in the upper and lower extremities, neck, and lower back in severe level according to the Numeric Rating Scale (NRS-11).*

*Design: Quasi-Experimental, One-Group Pretest-Post test Design. The women joint voluntarily, and applied remote exercises with author's supervising via WhatsApp videos. In conjunction with twice sessions of popular games weekly for 12-week at the monastery's field to regain muscular strength balance that measured by handheld MicroFET2. The sessions lasted 45-60 minutes, including 15-20 minutes of rest.*

*This study will introduce a novel, combined rehabilitation program (CRP) that effectively integrates remote home-based therapeutic exercises with culturally appropriate popular games in a rural Iraqi context*

**A2-b. What is the principal research question/objective? Please, summarise briefly the objectives of the research ((Maximum 150 words).**

objective of this study was to enhance the quality of life and daily routines of the rural women involved in this study by strengthening the muscles of the upper and lower extremities and trunk, addressing joint pain by returning the balance between muscle strength associated with the physical demands burden of daily life activities by incorporating simple and safe clinical exercises with simple popular games that suit their conditions.

**A2-c. What is the main aim(s) of the research?**

*enhance the physical well-being and quality of life of rural women.*

**A2-d. What is the scientific justification for the research (Project Benefits)?**

This study introduces a novel, combined rehabilitation program (CRP) that effectively integrates remote home-based therapeutic exercises with culturally appropriate popular games in a rural Iraqi context.

The program will give a good result in significant pain reduction and increased muscle strength, as well as improved social engagement among participants.

It demonstrates the feasibility and effectiveness of using low-cost, community-integrated interventions supervised remotely via mobile technology in resource-limited settings.

**A2-e. Proposed research methods and design.**

This study will employ a quasi-experimental design with pre and post-test without control.

Participants will recruit during meetings held at the women's forum of the Church of the Sisters of the Virgin Mary in the Hamdaniya district, northeast of the province of Nineveh in Iraq, during the summer months.

A lecture will involve conducted to raise awareness about the importance of exercise for maintaining body composition and its functional health. Following the lecture, an open discussion will hold to address the participants' experiences with physical injuries. So, it will



investigate many of the women suffered from movement functional issues, particularly muscle and joint pain which causes them difficulty in carry out their daily activities.

However, given the social and family participants' circumstances, which made daily attendance for the therapeutic program hard to achieve, the authors keep in their mind developing a combining rehabilitation program (CRP) combining remote and in-field exercise and incorporate simple and safe exercises with simple popular games that suit their conditions thereby maximizing effectiveness through a combination of psychological simulation and physical impact while ensuring safety, and evaluate its efficacy as a field exercises and tele-exercises program. For a tele-exercise's component, therapeutic exercise units were designed for participants to perform at home under the supervision and guidance of one of the authors, with continuous follow-up. Twice-sessions were held weekly at the sports field of the monastery's affiliated. The program spanned 12 weeks, with each session lasting between 45 and 60 minutes, including rest intervals of 15 to 20 minutes. The remote sessions were facilitated through pre-recorded instructional videos shared via a WhatsApp channel.

**A2-f. What are the main ethical issues with the research and how will these be addressed?**

Some social and family participants' circumstances, which made daily attendance for the therapeutic program hard to achieve, the authors keep in their mind developing a combining rehabilitation program (CRP) combining remote and in-field exercise and incorporate simple and safe exercises with simple popular games that suit their conditions thereby maximizing effectiveness through a combination of psychological simulation and physical impact while ensuring safety, and evaluate its efficacy as a field exercises and tele-exercises program

**A3. Conflicts of interest**

**A3-a.** Will the researcher receive any benefits or incentives for taking part in this research over and above normal salary?

☐ Yes ☒ No

If yes, indicate how much and on what basis this has been decided.

**A3-b.** Is there scope for any other conflict of interest? If so, please describe this potential conflict of interest, and outline what measures will be taken to address any ethical issues that might arise from the research.

There is no conflict of interest.

**A4. Funding and sponsorship**

**A4-a.** What is the source of funding of this study?

☒ Self-funded.

☐ Other, please specify;

**A4-b.** Who is the sponsor of this study?

☒ Ministry of Higher Education and Scientific research.

☐ Ministry of Health.



<input type="checkbox"/> Other, please specify.
<b>A4-c. What is the commercial status of this study?</b> <input type="checkbox"/> Commercial. <input checked="" type="checkbox"/> Non-commercial.
<b>A5. Sources of Data.</b> Please, tick the appropriate category(ies) from the list below and fill the relevant part. <input checked="" type="checkbox"/> Study involves human only. Please, fill part B. <input type="checkbox"/> Study involves animals only. Please, fill part C <input type="checkbox"/> Study involves hazards and biohazards. Please, fill part D. <input type="checkbox"/> Combination of above. Please fill the relevant parts.

## Part B: Study involves human

### B1. Select from the list below to describe your research: (You may select more than one)

- ☒ Research on or with human participants.
- ☐ Research working with data of human participants (retrospective study).
- ☒ New data collected by qualitative methods.
- ☒ New data collected by quantitative methods.
- ☒ New data collected from observing individuals or populations.
- ☒ Routinely collected data or secondary data.
- ☐ Research working with aggregated or population data (focus group).
- ☐ Research using already published data or data in the public domain (systematic review).
- ☐ Research working with human tissue samples.

### B2. Research participants details

#### B2-a. Inclusion Criteria: Please list the principal inclusion criteria (list the most important, max 100 words).

The study will include women aged 40–65 years. Their diagnose with chronic musculoskeletal pain. They residing in rural villages near Mosul, Iraq. Also, they capable of following exercise instructions, and they will give informed consent to participate.

#### B2-b. Exclusion Criteria: Please list the principal exclusion criteria (list the most important, max 100 words).

The study will exclude the women who have recent surgery or acute injury in the past 3 months, severe cardiovascular or respiratory disease, cognitive impairment affecting communication or understanding, current participation in another clinical study and pregnancy or breastfeeding

#### B2-c. Will the participants be from any of the following groups? (Tick as appropriate).

- ☐ Children under 16. Specify age group: \_\_\_\_\_.
- ☐ Adults with learning disabilities.



- ☐ Adults with other forms of mental incapacity or mental illness.
- ☐ Adults in emergency situations.
- ☐ Those who could be considered to have a particularly dependent relationship with the investigator, e.g. members of staff, students.
- ☒ No participants from any of the above groups.
- Please justify the inclusion of the above groups, explaining why the research cannot be conducted on non-vulnerable groups.*

**B2-d. Approximate number:** *Please, give the estimated number of the participants.*

**60-75 Participants**

**B2-e. How was the sample size decided upon?** *It is important to ensure that enough participants are recruited to be able to answer the aims of the research. If a formal calculation was used, please replicate it here to justify and reproduce the calculation.*

The participants consisted of local female residents, totalling (500). The authors will select between (60-75) women to present the really sample of study who will consent for participating voluntarily. This number of participants will enough to attending the aims of study statistically and to control on study procedures.

**B2-f. The age range of participants:**  
(40-33) Year

**B3. Risk Assessment**

*In this section, the researcher should identify, as far as possible, all potential risks (small and large) to participants (e.g. physical, psychological, etc.) that may be associated with the proposed research. In addition, any risk management measure that will be put in place to minimize these risks should be identified.*

**B3-a.** What are the potential benefits and/ or risks for research participants in both the short and medium-term?

Participants may experience mild physical discomfort or muscle soreness during or after initial exercise sessions, which is a common response to unaccustomed physical activity. To mitigate this risk, the exercise program will begin with safe, low-intensity activities, with gradual progression tailored to each participant's tolerance and condition. Recovery strategies—including guided stretching, relaxation exercises, and the use of hot water baths—will be implemented after each session to support physical recovery and reduce discomfort. Participants will also receive education about expected sensations and pain to alleviate anxiety and promote continued participation. Any participant who experiences persistent or unusual pain will be withdrawn from the program and referred for medical assessment to ensure safety.



In the short and medium term, participants may benefit from improved physical function, reduced pain, and enhanced psychological well-being, as the program is designed to promote safe physical activity and recovery.

**B3-b.** Does the research involve any risks to the researchers themselves, or people not directly involved in the research?

☐ Yes ☒ No

*If yes, please describe:*

**B3-c.** Will the study involve any intervention, such as extra steps or treatment of any type?

☐ Yes ☒ No

*If "Yes", please give details:*

**B3-d.** Is it possible that the duration of the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity?

☐ Yes ☒ No

*If "Yes", please answer question B3-g.*

**B3-e.** Is it possible that the study will induce greater than minimal psychological stress/pain/discomfort?

☐ Yes ☒ No

*If "Yes", please answer question B3-g.*

**B3-f.** Is it possible that the study will expose participants to greater than minimal physical or medical risk?

*Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.*

☐ Yes ☒ No

*If "Yes", please answer question B3-g.*

**B3-g.** Please state the precautions taken to minimize any physical or psychological risk such as stress/pain/discomfort.

To reduce physical risk, all exercises will be selected for safety and suitability based on participants' health status and functional ability. The program will begin with low-intensity activities and progress gradually, allowing participants to adapt safely. Recovery techniques, including stretching, relaxation exercises, and hot water baths, will be integrated after each session to alleviate muscle soreness and fatigue.

To address psychological risks such as stress or anxiety, participants will be thoroughly informed about the procedures and expected physical sensations to reduce fear or



uncertainty. Ongoing support and education will be provided to encourage confidence and emotional comfort. Any participant reporting persistent discomfort, stress, or unusual pain will be promptly assessed and, if necessary, referred for medical or psychological support and excluded from further participation to ensure their well-being

#### **B4. Recruitment and selection of participants**

**B4-a.** Where will participants be recruited from?

The women's forum of the Church of the Sisters of the Virgin Mary in the Hamdaniya district, northeast of the province of Nineveh in Iraq

**B4-b.** What materials will be used to recruit participants and how will they be used? *Please, provide details of any posters, leaflets, participant information sheets, consent forms, advertisements, emails and letters that will be used.*

Participants were recruited during meetings held at the women's forum of the Church of the Sisters of the Virgin Mary in the Hamdaniya district, northeast of the province of Nineveh in Iraq, during the summer months. By lecture conducted to raise awareness about the importance of exercise for maintaining body composition and its functional health. Following the lecture, an open discussion which will held to address the participants' experiences with physical injuries, and it will reveal to women suffered from movement functional issues, particularly muscle and joint pain, and which are causes them difficulty in carry out their daily activities. This will guid the researchers to undertake the present study and share its findings with the participants, who voluntarily expressed their willingness to participate.

**B4-c.** How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?

Participants were recruited during meetings held at the women's forum of the Church of the Sisters of the Virgin Mary in the Hamdaniya district, northeast of the province of Nineveh in Iraq, during the summer months. This link is refereed to activities of this church: <https://www.acimena.com/amp/news/2668/mltk-akhoat-mrym-albtol-yftth-mhrganh-alsabaa-baanoan-alknys-alsryanyw-aamk-otarykh-okdas>. The participants consisted of local female residents, totalling (500). The authors will arrive to participants by assistance of the administration of the Cultural and Social Center of the Syriac Catholic Sisters of the Virgin Mary and the spiritual leader, Father Momika, for their valuable support.

**B4-d.** Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients?

☒ Yes

☐ No

#### **B5. Informed consent**

*Copies of any written consent form, written participant information sheet (PIS) and all other explanatory material should accompany this application.*

Question	Yes	No	N/A
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<b>B5-a.</b> Will you inform participants that their participation is voluntary?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-b.</b> Will you inform participants that they may withdraw from the research at any time and for any reason?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-c.</b> Will you inform participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-d.</b> Will the data be anonymous?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-e.</b> Will you provide an information sheet that will include the contact details of the researcher/team?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-f.</b> Will you obtain written consent for participation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-g.</b> Will you debrief participants at the end of their participation (i.e., give them an explanation of the study and its aims and hypotheses)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-h.</b> Will you provide participants with written debriefing (i.e., a sheet that they can keep that shows your contact details and explanations of the study)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-i.</b> Will you inform participants of the results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-j.</b> If using a questionnaire, will you give participants the option of omitting questions that they do not want to answer?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>B5-k.</b> If an experiment, will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-l.</b> If the research is observational, will you ask participants for their consent to being observed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B5-m.</b> Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals? <i>If participants are to be recruited from any of potentially vulnerable groups, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>B6. Confidentiality</b> <i>In this section, personal data means any data relating to a participant who could potentially be identified.</i>			
<b>B6-a.</b> Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate).			
<input checked="" type="checkbox"/> Access to research data by those outside the direct healthcare team. <input checked="" type="checkbox"/> Electronic transfer by magnetic or optical media, email or computer networks. <input checked="" type="checkbox"/> Sharing of personal data with other organisations. <input type="checkbox"/> Publication of data that might allow identification of individuals. <input type="checkbox"/> Publication of data that might allow identification of individuals.			



- ☒ Use of audio/visual recording devices (This should be mentioned in the PIS).
- ☐ Storage of personal data on any of the following:
- ☐ Manual files including X-rays.
  - ☐ Physical Education and Sport Sciences college computers.
  - ☒ Home or other personal computers.
  - ☒ Flash memory or other portable storage devices.
  - ☒ Cloud computing services.
- ☒ Using photography, video-recording, or audio recording of participants during the study. If so, please provide details and justifications for the recording, and storage strategies.

**B6-b. How will you ensure the confidentiality of personal data?** *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation procedures, secure storage and coding of data. You should include details on **how** and **where** the data will be stored. Information must be provided on the full data lifecycle, from collection to archive.*

No personally identifiable data will be collected in this study. All data will be anonymized and coded at the time of collection to protect participant identity. The data will be securely stored on password-protected institutional devices and backed up on encrypted storage systems with access limited to the research team. Any data sharing will only occur upon formal request and will involve only anonymized datasets. Data will be retained securely for the required duration according to institutional and ethical guidelines, after which it will be archived or destroyed in accordance with data protection policies.

**B6-c. Who will have access to participants' personal data during the study?**  
All authors who participate in this study.

**B6-d. Will any personal information including names, contact details, email addresses of participants etc. be accessed for purposes of recruitment? If yes, outline how and by whom this information will be accessed.**

*Researchers must ensure that personal information is not accessed without the consent of the individual.*

No, the personal information is not available in this study and it is not used in methods.

**B6-e. How long will personal data be stored or accessed after the study has ended?** *Please explain why this length of time has been chosen.*

- ☐ Less than 3 months.
- ☐ 3 – 6 months.
- ☐ 6 – 12 months.
- ☒ 12 months – 3 years.
- ☐ Over 3 years.



**Maybe for another research future work.**

**B6-f. How the data will be destroyed?**

By delete it from any memory store.

**B6-g. How do you intend to share the research data?** (Tick as appropriate).

- ☐ Sharing data with other organisations.
- ☐ Publication of direct quotations from respondents.
- ☐ Publication of data that might allow identification of individuals to be identified.
- ☒ Submitting to a journal to support a publication.
- ☐ Depositing in a self-archiving system or an institutional repository.
- ☐ Dissemination via a project or institutional website.
- ☐ Informal peer-to-peer exchange.
- ☐ Depositing in a specialist data centre or archive.
- ☐ Other, please state: \_\_\_\_\_.
- ☒ No plans to report or disseminate the data.

**B6-h. How do you intend to report and disseminate the results of the study?** (Tick as appropriate).

- ☐ Conference presentation.
- ☐ Peer reviewed journals.
- ☐ Publication as an Thesis in the Institutional repository.
- ☐ Publication on website.
- ☐ Other publication or report, please state: \_\_\_\_\_.
- ☐ Submission to regulatory authorities.
- ☒ No plans to report or disseminate the results.

### PART C: Study involves animals

**C1. Overall justification.** Explain how the potential impacts on the wellbeing of animals in this project are justified by the potential benefits of the proposed work.

**Not compatible with the type of study**

#### C2. Replacement.

Replacement refers to methods that avoid or replace the use of animals. Examples of replacement include the use of Animal cell lines, tissues and cells; Human volunteers, tissues and cells; Mathematical or computer models.

**C2-a.** Explain why it is necessary to use animals for the proposed work. *The unjustified use of animals is not ethical. State reasons why animals are necessary for the.*

**Not compatible with the type of study**



**C2-b.** Provide evidence for the consideration of alternatives to animal use. *Applicants are required to consider the principle of replacement where possible. List possible alternatives to animal use and state why these are unsuitable. For example, evidence from the literature may indicate that scientifically valid outcomes can only be achieved using your chosen animal model.*

**C2-c.** Provide information about the species, number, gender and age range of animal used.

Species	Number	Gender	Age

**C2-d.** Provide justification for the choice of animals (species, number, gender and age).

### C3. Reduction.

Reduction refers to methods that minimise the number of animals required to achieve the aims of the work. **Please, provide statistical or other justification for the number of animals requested. Break down the total number by procedures, treatments, repeats, groups, etc.**

*Note: Applicants must demonstrate that the minimum number of animals required to attain scientifically meaningful or statistically significant results will be used. Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals that are used. Note that the use of too few animals may invalidate results and result in wastage of animals.*

### C4. Refinement

*Refinement refers to methods that minimise pain and suffering and improve animal welfare for those animals that are used. Describe, as relevant, how protocols/procedures, housing have been refined in order to minimise the impact on animals. In addition, describe strategies that will be implemented to support and safeguard animal welfare, and how these will be reviewed during the lifetime of the activities.*

### C5. Health and/or safety risks

Indicate which of the following health and/or safety risks to other animals, people or the community are involved with this project.

- ☐ Anaesthetic gases.
- ☐ Carcinogens.
- ☐ Teratogens.
- ☐ Chemically hazardous material or cytotoxic substances (not including anaesthetic gases).
- ☐ Biologically hazardous materials (microorganisms, human tissue, fluids etc).
- ☐ Radiation hazard.
- ☐ Other - Provide brief details:
- ☒ Not Applicable.

### C6. Monitoring



<p><b>C6-a.</b> Explain how the wellbeing of animals will be monitored and assessed throughout the project. Monitoring should be specific to the type of procedure and the species/type of animal.</p> <p><b>Not compatible with the type of study</b></p>
<p><b>C6-b.</b> Outline the frequency of monitoring and assessment, and provide details of who will be doing the monitoring.</p>
<p><b>C6-c.</b> Outline intervention criteria, and the actions to be taken if those criteria are reached.</p>
<p><b>C6-d.</b> Outline the humane endpoints, i.e. the intervention criteria used to determine that an animal should be humanely killed, prior to the planned end of the experiment.</p>
<p><b>C7. Fate of the Animals.</b> <i>Please, clearly outline what will happen to the animals at the end of the project. The planned endpoints of the work must occur as early as possible, so as to avoid and minimise pain or distress to the animals.</i></p>
<p><b>C7-a.</b> If animals will be killed at the end of the experiment, please provide details of killing of animals (method, drug, route, and place of killing).</p>
<p><b>C7-b.</b> If animals will not be killed, please describe their fate.</p>
<p><b>C8. Housing of animals.</b> <i>Please, provide further details of housing, including, as relevant, details of outdoor housing, any special housing requirements, details of enrichment etc. Where housing is not applicable, please explain why. Failure to provide appropriate housing has clear impacts on the wellbeing of animals and potentially on research quality.</i></p>
<p><b>C8-a.</b> Outdoor housing.</p>
<p><b>C8-b.</b> Group housing of animals.</p>
<p><b>C8-c.</b> Special housing requirements.</p>
<p><b>C8-d.</b> Justification for individual housing.</p>
<p><b>C9. Repetition or Re-use</b></p>
<p><b>C9-a.</b> Does this project include the repetition of work conducted previously?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes. <i>If yes, briefly describe the previous work done in this area, and why it needs to be repeated?</i></p>
<p><b>C9-b.</b> Does this project involve the re-use of any animals that have been used in another project?</p>



- ☐ No
- ☐ Yes. If yes, briefly describe the type of previous work, the period between previous and current work, the cumulative burden and provide justification for re-use.

#### PART D: Study involves radiation, hazards and biohazards

*This section is related to laboratory study that involves dealing with radiation, hazardous, biohazardous and toxic materials/substances.*

**D1. What type of hazards/ biohazards will be used in this study?**

- ☐ Microorganisms (e.g. Bacteria, Virus, Fungus, Parasitic Agents).
- ☐ Human Blood, Blood Components, Fluids, Unfixed Organs, Tissues and Cells (*including established cell lines*).
- ☐ Non-human Primate Derived Materials (*including established cell lines*)
- ☐ Nucleic Acids (RNA, DNA, synthetic or recombinant nucleic acids).
- ☐ Plants.
- ☐ Biological Toxin.
- ☐ Toxic reagent.
- ☐ Other. Please specify.....

**D2. What is the pathogenicity, toxicity or agent characteristics?**

**D3. What is the risk group (RG) (for details, see section 2 in REC handbook)? Please, enclose product information data sheet (if applicable).**

- ☐ RG1                      ☐ RG2                      ☐ RG3

**D4. What is the biosafety level (BSL) required? (for details, see section 2 in REC handbook).**

- ☐ BSL-1                      ☐ BSL-2                      ☐ BSL-3

**D5. Where the biohazardous material will be handled (work location)?**

**D6. Indicate which personal protection equipments and processes will be used while handling agents to reduce the risk (e.g. wear safety glasses, gloves, lab coat, full face shield etc.).**



**D7.** Where do you intend to store the biohazardous material/substance when not in use?  
*Must be located in a secure area with limited to access.*

**D8.** Decontamination: Describe how biohazardous material and waste will be decontaminated?

- ☐ Autoclave.
- ☐ Pick-up for incineration.
- ☐ Ethanol or isopropanol 70%.
- ☐ Disinfectant. Please specify.....
- ☐ Bleach.

**D9.** What type of waste produced will be produced?

- ☐ Solid waste
- ☐ Liquid waste
- ☐ Sharps waste
- ☐ Pathological waste
- ☐ Infected animal waste
- ☐ Other

**D10.** Indicate how the material will be disposed off?

**D11.** Describe the researcher's previous experience using the biohazardous agents described in this form or using similar procedures. If the applicant does not have relevant experience, explain how the required expertise will be provided/acquired.



## PART E: Submission checklist

Please complete the ethical application form and provide it with copy of supporting documents (electronic and hard copies) when applicable.

	Document	YES	NO	N/A
1	Ethical approval application form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Participant information sheet	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Participant consent form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Research proposal (maximum 4 pages)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Peer review evidence from the scientific Committee	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Questionnaire/Survey	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9	Interview/Focus Group Questions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Evidence of approval to gain access to off-site location	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11	Product data sheet	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12	Advertising material (posters, flex, emails etc)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14	Electronic copy of application form and all related documents	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15	Export certificate from FDA or Ministry of Health in Iraq for any Pharmaceutical or biomedical product	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



## PART F: Declaration

In making this application, I certify that I have read and understand the University's Policy on Research Ethics Committee (REC), and I will comply with the ethical principles of these documents. I will report to the REC if there is any amendment, new information on the project and any research-related incidents, such as physical or emotional harm to the participants during the research process or breaches of confidentiality. I will also submit a final completion report on the request of the REC. I undertake not to proceed with data collection/analysis before I receive the letter of approval of this application, and understand that failure to do so will lead to disciplinary action.

**Munib Abdullah Fathe**

Name of Chief Investigator

Signature

May/03/2024

Date

I/We hereby endorse this application with my approval and confirm that the investigator is appropriately qualified in the research area involved to conduct the proposed research project, and I am capable of undertaking this research study in a safe and ethical manner.

Name of Supervisor (for RPG students only)

Signature

Date

