

# Scientific Research Unit Operational Manual

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## **Introduction**

The research unit at Mohammed Al Mana College for Health Sciences supervises the research activities at the college and makes contribution to the achievement of the college's strategic goals. The research unit is found to identify key areas of research based on health care needs of the society and encourage academic staff and students to contribute on those priority areas of research. The research unit will act to maintain ethical standards of practice in research to protect both participants and the researcher.

### **Purpose**

To ensure that interdisciplinary research of Pharmacy, Medical Laboratory Technology, Nursing, Linguistics and Social Sciences studies at Mohammed Al Mana College for Health Sciences are established in an appropriate and consistent manner.

### **Mission Statement**

The MACHS Research Unit is committed to promoting scientific researches in health sciences by faculty and students and to disseminate the results for the benefit of the community, the nation and the world at large.

## **Vision Statement**

The MACHS Research Unit is a leading academic organization dedicated to enhancing, and facilitating high standards of scientific research in all areas of health sciences to serve college, the community, and the Kingdom of Saudi Arabia.

## **Objectives**

- Establish and collaborate research activities in the health sciences
- Encourage students to carry out scientific researches within the institution and in collaboration with other institutions nationally and internationally
- Establish and develop research relationships, with similar research unit locally, nationally, and internationally
- Ensure excellence in scientific researches carried out by staff and students by closely monitoring the standard of ongoing researches.
- Facilitate research collaboration among the students and faculties of the institution's respective departments
- Sustain a research center that follows the institutional strategic research plan.
- Adopt the incorporation of research experience in undergraduate programs, leading to research-based learning in the academic disciplines across the institution.

## **Values**

### **Relevance- The unit shall:**

- Consider the implications and effectiveness of research results
- provide the tools and resources to carry out researches as approved by the college council

### **Cooperation and teamwork-The unit shall:**

- Promote collaborative and interdisciplinary researches
- Encourage creativity and the free flow of ideas
- Adhere to mutual respect, encouragement and support
- Share information within the college about new ideas and research findings
- Recognize major achievements of researchers through announcements, social media, etc.

### **Excellence-The unit shall:**

- Measure its performance against the criteria outlined in the college by-laws
- Evaluate its work through peer review processes
- Use performance indicators for benchmarking
- Expect high levels of competence

**High ethical standards and scholarly integrity-The unit shall:**

- Necessitate observance of national and international policies governing the conduct of research
- Educate and inform the researchers, both faculty and students about research ethical issues
- Be committed to academic integrity, accuracy and consistency in research conduct
- Engage in discussions about research ethical issues



**MACHS Institutional Review Board (IRB)**

- **Head of Board of Trustees**
- **Vice Dean for Academic Affairs**

**Scientific Research Unit (SRU)**

- Head of the Scientific Research Unit
- Representative of the Nursing Department
- Representative of the Prep Year
- Representative of the MLT Department
- Representative of the Pharmacy Department
- Unit's Administrator

**Journal Club**

Dr. Sana Al Mahmoud  
Dr. Ayaz Ahmed  
Dr. Jenan Al Matouq  
Mr. Mohammad Daud Ali  
Mrs. Rasha Hamza  
Mr. Ejaz Akbar  
Mrs. Amnah Alsultan

**Human Research Ethics  
Committee (HRE)**

- Chair (RU)
- Two representatives of the RU
- Two or more with relevant research experience

<b>Policy area:</b> Institutional Review Board IRB	<b>Subject:</b> Institutional Review Board Policy
<b>Title of Policy:</b> Institutional Review Board	<b>Number:</b> 01
<b>Effective Date:</b>	<b>Developed By:</b> Dr. Sana Al Mahmoud Dr. Abbas Al Mutair Dr. Jenan Al Matouq Dr. Indo Benna Dr. Ayaz Ahmed Dr. Wasim Ahmad Mrs. Amnah Al Sultan
<b>Revised Date:</b>	<b>Revised By:</b> Quality and Academic Accreditation Centre
<b>Approved Date:</b>	<b>Approved by:</b> Dr. Sana Al Mahmoud Acting Dean

## **Institutional Review Board Policy**

### **1. Rational for the policy:**

- A. To ensure the protection of rights and welfare of human research subjects at Mohammed Al Mana College for Health Sciences by providing the best possible service and protection to our participants, our researchers.
- B. To Ensure that the risk to subjects are minimized.

### **2. Policy statement:**

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- A. The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices MACHS.
- B. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by Laws of KSA, and other appropriate authorities. Research, whether funded or not, conducted by faculty or students, must be reviewed and approved by the IRB.
- C. Any research will not begin if it has been disapproved by the IRB.
- D. The IRB reports directly to the Head of Trustees, the highest administrative authority at MACHS.

### **3. Procedures**

- If the research does not involve human subjects, IRB review is not required. If the research does involve human subjects, IRB review is required.
- If IRB review is required for the project, the principal investigator shall prepare the submission to the IRB.
- The submission involve completing the MACHS IRB form including the following:
  1. Cover sheet
  2. Structured abstract of the proposed study (should not exceed 200 words)

3. Research proposal (should not exceed 1000 words) detailing the title of the study, brief introduction, methodology, study design, sample size, inclusion and exclusion criteria of the subjects and ethical considerations.
  4. Work plan and responsibilities of investigators (if more than one).
  5. Comprehensive literature review.
  6. Informed consent (if required)
  7. Attach MACHS CV along with the form.
  8. All investigators shall complete the On-line NIH Course "Protecting Human Research Participants" and attach the certificates with the IRB form.
  9. Any other documents that will be given to the research subjects (e.g. questionnaires/surveys, interview protocol)
- Failure to follow these requirements can result in delay of review and approval by IRB.
  - External investigator shall not be the principal investigator on any project. The principal investigator shall be only from MACHS, any external investigator can be listed as second investigator.
  - Undergraduate student investigators shall not be listed as principal investigator on any project. The principal investigator of the students' project shall be the principal investigator.

- If the research project being submitted has been previously reviewed by a local or international IRB other than the MACHS IRB, a **copy of the approval or disapproval letter from that IRB.**
- The IRB form shall be signed by the principal investigator and the Head of the Academic department where he belongs.
- The full packet of IRB form shall be submitted by the principal investigator to the Scientific Research Unit Secretaries.
- The **SCU committee** shall review and have the authority to approve, require modifications to, table or disapprove all research activities.
- If the project was approved, it will then be sent to the college council and Head of Board of Trustee for final approval.
- The research activities can be started only if a letter of approval signed by the Head of Board of Trustees or MACHS Dean is secured to the principal investigator.

<b>Policy area:</b> Scientific Research at MACHS	<b>Subject:</b> Scientific Research Unit Policy
<b>Title of Policy:</b> Scientific Research	<b>Number:</b> 02
<b>Effective Date:</b>	<b>Developed by:</b> Dr. Sana Al Mahmoud Dr. Abbas Al Mutair Dr. Jenan Al Matouq Dr. Indo Benna Dr. Ayaz Ahmed Dr. Wasim Ahmad Mrs. Amnah Al Sultan
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<b>Approved Date:</b>	<b>Approved By:</b> Dr. Sana Al Mahmmoud Acting Dean

## Scientific Research Unit Policy

### 1. Rational for the Policy:

To ensure that guidelines for interdisciplinary research in the field of pharmacology, Medical Laboratory Technology, Nursing, Social Sciences and Languages at Mohammed Al Mana College for Health Sciences are established in an appropriate and consistent manner with the nature and mission of the institution.

## **2. Policy Statement:**

- Priority shall be given to scientific research that go in conformity with the College's message, strategy and objectives, and serve regional and local national developments objects.
- To protect the rights of the College and researchers relating to scientific research and their findings in a way that doesn't conflict with patent rights or copyrights applicable in **Kingdom.(should be Kingdom of Saudi Arabia)**
- To publicize the correct criteria used to apply for research in the institute.
- To support scientific research projects according to the College's objectives.
- To provide supervision to scientific seminars and conferences on scientific research.
- To protect the college rights to be the owner of any patent as long as it is acquired as a result of a contract with the inventor to dedicate his efforts to get that invention. However, inventor's name shall be mentioned in the patent, and the College shall be entitled to all rights originating from the literary and financial patents.

## **3. Procedure:**

### **A. Scientific researches submission procedures**

1. Each faculty shall carry out a maximum of two studies each year, one per semester, and publish them in a well ranked journal (see appendix) journal with high impact factor.
2. Researcher shall submit printed copy of the research proposal to head of the department to which he/she belongs (see appendix- research application flow chart) .In case there is more than one researcher conducting the research together from different departments; the said proposal shall be submitted by the head of the department of the principal investigator.
3. The proposal should be approved by the department then forwarded to the Scientific Research Unit SRU.
4. The SRU shall examine the research proposal and give notices which include the following:
  - a. Evaluation made by the unit for the research proposal.
  - b. To what extent the researched benefited from services available within the College.
5. The SRU reserves the right to approve or disapprove any proposal.
6. In case the research proposal is accepted, the research unit shall submit the proposal to the dean, accompanied with the SRU opinion.
7. The dean shall refer the proposal to the head of IRB to take the final decision.



8. The council shall consider the research proposal in order to take the appropriate decision and outline the type and size of support need. The dean shall report directly to the Head of Board of Trustees.
9. The researcher shall submit a report at the end of each stage to the research unit stating the process of his/her research. The said report shall contain a description what has been achieved and charges incurred. SRU shall have the right to evaluate the seriousness of the research and assess the scientific findings of each interim report. In the light of the aforesaid, the said committee shall decide whether the researcher is to complete his research or not.
10. The researcher shall submit 3 printed copies of the completed research to the SRU.
11. A final report shall be submitted by the SRU to the dean stating the opinion of the SRU in order that the latter direct the same to the committee.
12. In case the research was published in a well ranked journal, the SRU may consider it as a positive progress.
13. The support given to the researcher may be suspended/recovered by the SRU in the following cases:
  - a. The assurance of the research unit that the researcher didn't meet the necessary requirements according to the specified plan.

- b. Providing evidences with respect to spending the subsidy amount on things other than planned.

**B. Participation in scientific researches conferences, Symposia and Seminars inside or outside the Kingdom:**

1. The faculty may participate in up to two national and two international scientific highly reputed conferences per year.
2. A copy of the research shall be submitted to the head of the department to which he/she belongs. The said research shall be submitted by the researcher of the department to the College **Scientific Research Unit and research unit** after obtaining approval of the head of the department to take part in such conference Symposia and Seminars.
3. The SRU shall study that request in terms of the importance of the research and the topic subject matter and send the recommendations to the Dean.

4. The Dean shall refer the research to the College Council to identify the type and

<b>Policy area:</b> Research Ethics
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<b>Subject:</b> Research Ethics Policy
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size of needed support then to report the necessary recommendation to the Head of Board of Trustee for final approval.

### **Research Ethics on Living Creatures Policy**

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<b>Title of Policy:</b> Research Ethics	<b>Number:</b> 03
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<b>Revised Date:</b>	<b>Revised by:</b> Quality and Academic Accreditation Centre
<b>Approved Date:</b>	<b>Approved By:</b> Dr. Sana Al Mahmmoud Acting Dean

### 1. Rational for the Policy:

The MACHS Research Unit has compiled research ethics policies and procedures, which aim to help staff and student researchers, think through the ethical aspects of their research thoroughly to enhance its quality. All research conducted by MACHS faculty and students should be performed in accordance with the research ethics framework.

### 2. Policy Statement:

The investigators have the responsibilities to:

1. To protect the welfare and interests of the participating subjects.
2. To design the study so as to minimize risks to subjects.
3. To protect the interests and welfare of the research subjects.
4. To take into account the following ethical consideration: respect of human being, research merit, and justice and beneficence.

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5. To communicate to the prospective subject all the information necessary for adequate informed consent
6. To give the prospective subject full opportunity and encouragement to ask questions
7. To seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has had sufficient opportunity to consider whether to participate or not.
8. To obtain from each prospective subject a signed form as evidence of informed consent; and renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.

### **3. Procedure:**

#### **A. Protection of participants and their rights**

1. All participants have the right not to participate in any investigation and this right must be respected. There should be no coercion of research subjects to participate in the research.
2. Each participant must have the right to withdraw easily from the project whenever and for whatever reason without explanation or penalty. That is, participants should be free to leave the experimental room at any point if they wish to do so.

3. All participants and research assistants have the right to expect protection from physical, psychological, social and economic harm at all times during the investigation.
4. Participants and researcher's assistants must be fully informed in advance of and protected against any hazardous, stressful or uncomfortable contexts and procedures.
5. Researchers should avoid harm not only to the research subjects, but also to their wider family and community.
6. Should any hostile reaction event occur, the researcher must report this immediately in writing to the Scientific Research Unit. The report should describe fully the reaction event, the action taken and the date, time and place of the event.

#### **B. Informed Consent**

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding:

- A. Each individual is invited to participate as a subject in research, and the aims and methods of the research; -the expected duration of the subject's participation; the benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;

- B. Any foreseeable risks or discomfort to the subject, associated with participation in the research.
- C. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested.
- D. The therapy will be provided free of charge for specified types of research-related injury

**C. Data privacy and storage**

1. All participants have the right to expect that the information supplied by them will be treated as confidential.
2. All participants have the right to expect that their identity will be protected.
3. Researchers must ensure protecting the confidentiality and anonymity of participants.
4. All data materials will be stored in an appropriate way, in a locked locker for the period of three years in the SRU and then will be discarded through a shredder.

**D. Research with Animals**

1. All procedures carried out on nonhuman animals are to be reviewed by the Scientific Research Unit to ensure that the procedures are appropriate and humane.

2. Consideration for the humane treatment and well-being of the laboratory animal should be incorporated into the design and conduct of all procedures involving such animals.
3. Researchers have the responsibility to ensure that procedures to be performed on the animals are reasonable for that species.
4. Researchers have the responsibility to use the appropriate anesthetics and analgesics for potentially painful procedures.
5. Researchers have the responsibility to setting the earliest possible time for completing the experiment. That is, if the necessary information can be gathered before the animal experiences any ill effects from the experiment.
6. Using proper handling techniques for animals.
7. Laboratory animals are to be provided with humane care and healthful conditions during their stay in any facilities of the institution.
8. To minimize the number of nonhuman animals used, multiple research uses of individual animals should be considered. Such uses must be compatible with the goals of the research, sound scientific practice, and the welfare of the animal.



<b>Policy area:</b> Journal Club	<b>Subject:</b> Journal Club Policy
<b>Title of Policy:</b> Journal Club	<b>Number:</b> 05
<b>Effective Date:</b>	<b>Developed by:</b> Dr. Sana Al Mahmoud Dr. Indo Benna Dr. Abbas Al Mutair Dr. Jenan Al Matouq Dr. Ayaz Ahmad Mrs. Amnah Al Sultan
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## Journal Club Policy

### 1. Rational for the Policy

The Journal Club of Mohammad Al-Mana College of Health Sciences (MACHS) aims to facilitate discussions and evaluations of new researches in order to keep the faculty and students updated with new knowledge.

### 2. Policy Statement

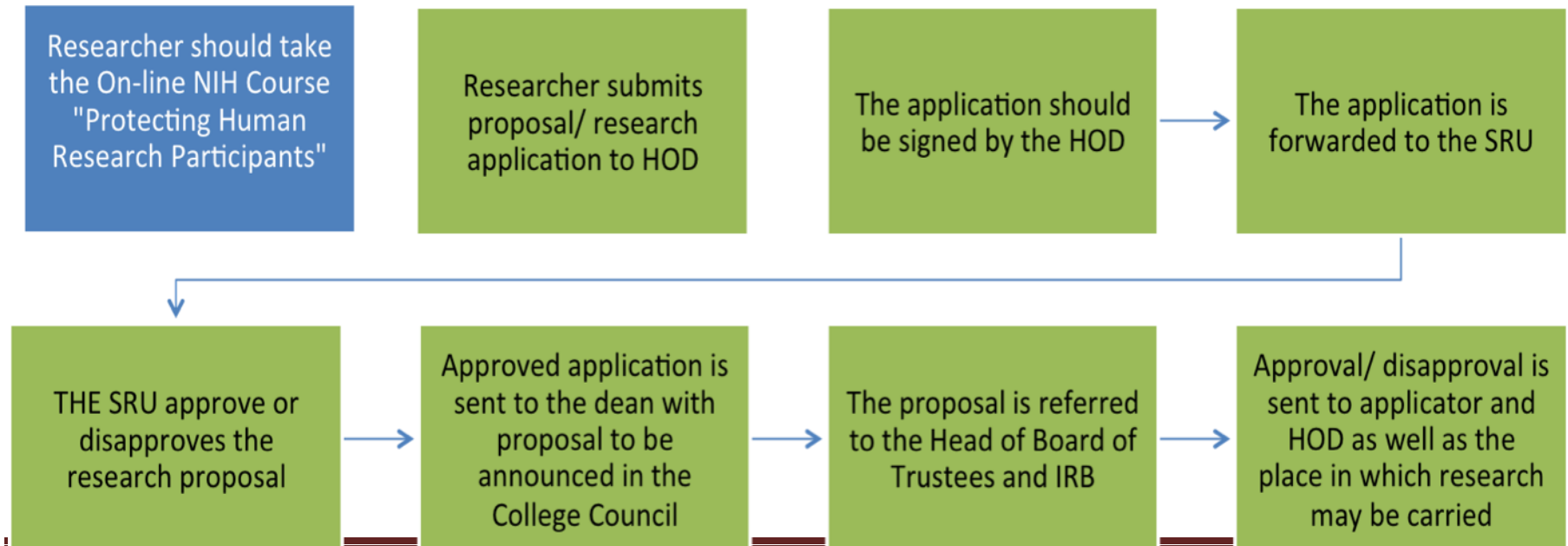
The Scientific Research Unit has the responsibility to develop and design journal club activities to empower both students and faculties' knowledge in research methodology and critique.

### **3. Procedure**

1. The research Unit will send invitation to faculty and students to indicate their interests.
2. Invitation will be sent once a semester (beginning of the semester).
3. Articles to be reviewed should be from a well recognized journal and published within the last five years.
4. A presenter should not present his/her own work.
5. The Research Unit coordinates with the faculty or students on the date for the presentation.
6. Articles to be presented should have a short overview of the background of the reviewed paper, a critical review of the key findings, and a brief summary of the significance of the article.
7. Articles to be discussed should be submitted to the Research Unit for approval two weeks prior to the Journal Club meeting.

8. After the approval of the Research Unit, the article should be disseminated to all faculty members.
9. Articles to be presented should be of interest to the presenter and audience.
10. The presentation should be for an hour – the first 20 minutes the presenter will give an overview/critique of the article and the rest of the time for the participants to discuss the article.
11. After the presentation, article critiques should be posted on the college's website.

# Research Application Flow chart



## Strategic Plan

Task	Responsibility	Action plan	Time required	Barriers	Modes of communication

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**Application of Approval of Research Project**

**Kingdom of Saudi Arabia**

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Mr. Ejaz Akbar  
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# Mohammed Al Mana College for Health Sciences



كلية محمد المانع للعلوم الطبية  
Mohammad Al-Mana College for Health Sciences

## Application for Approval Of Research Proposal

## ***RESEARCH PROPOSAL PACKAGE***

### **CONTENTS:**

1. COVER SHEET
2. ABSTRACT
3. PROPOSAL
4. INFORMED CONSENT FORM (where required)
5. RESSUME OF PRINCIPAL INVESTIGATOR/S
6. HUMAN PARTICIPANT PROTECTIONS EDUCATION FOR RESEARCH TEAMS COMPLETION CERTIFICATE ON-LINE NIH COURSE "PROTECTING HUMAN RESEARCH PARTICIPANTS"  
  
<HTTPS://PHRP.NIHTRAINING.COM/USERS/LOGIN.PHP>
7. RESEARCH APPROVAL FORM

<b>Title:</b>	<u>Duration of Study:</u>
---------------	---------------------------

<b>Department or Affiliation</b>	<b>I.D.</b>	<b>Position</b>	<b>* Signatures</b>
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<b>Principal Investigator</b>				
<b>Co-Principal Investigator</b>				
<b>Other Co-Investigators</b>				

**Declaration of Conflict of Interest:**

All investigators must declare any potential conflict of interest with respect to this research proposal.

The presence of such conflict of interest must be explained (see below). The lack of

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such declaration by

investigators involved with this proposal is taken as evidence of the absence of any conflict of interest.

**Conflict of Interest:**

NAME	SIGNATURE	EXPLANATION

**2. ABSTRACT**

Should not exceed 200 words and should include:

- The importance of the research topic
- The research hypothesis, question or statement, specific objectives and the significance of the outcome

- OUTLINE the methods that will be used to accomplish the research specific objectives

### 3. RESEARCH PROPOSAL

**Title of the Proposal:**

---

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**Introduction**

May include background information related to the research topic (Importance of the topic), the purpose in carrying out this research, and the importance of potential (expected) findings.

**Methodology**

May include: Inclusion Criteria and Exclusion Criteria, which will be used in selecting the research participants; Registration, Randomization Process, Data gathering methods, Procedures, Designated Central Laboratories, Follow-up, Safety and Efficacy Parameters, Expected Outcome, and Statistical Methods.

How this project will be helpful to our community and KSA economy :

**Work Plan and Responsibilities**

---

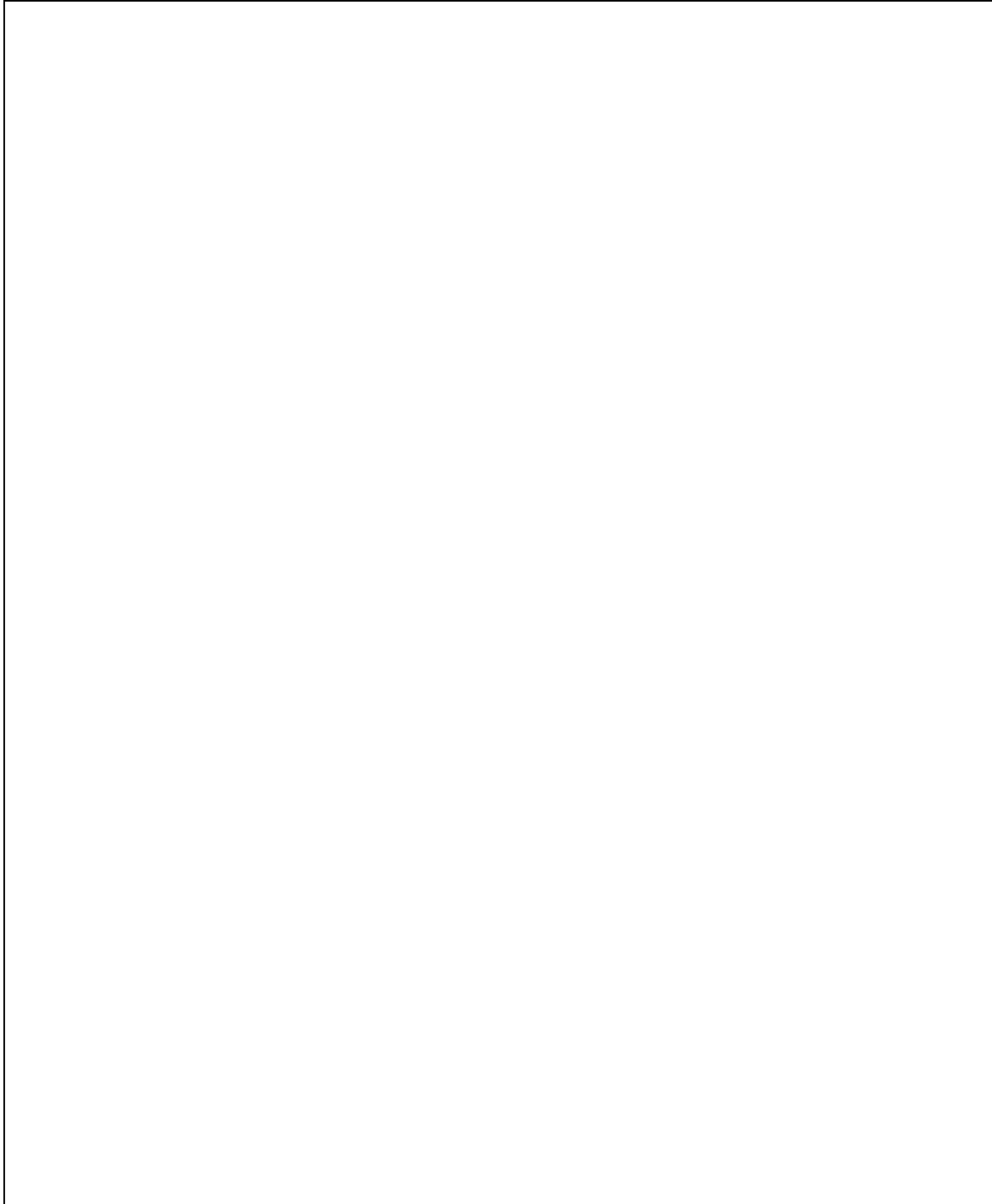
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Detailed description of the protocol work plan is mentioned in the original documentation. Please refer to the submitted documents. The following Table summarizes the job responsibilities of involved members:

<b>Task</b>	<b>Investigator(s)</b>

**References (comprehensive literature review: pages \_\_\_\_\_ )**

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#### 4. INFORMED CONSENT

- For Research involving the administration of Drugs, use of Devices or Performance of procedures

- For Research with no direct benefit to participant

##### Approval - Department:

I have reviewed this proposal and approve the participation of the concerned personnel of my department in it.

PARTICIPANTS	DEPARTMENTAL HEAD	SIGNATURE

## Scientific Research Unit Operational Manual

\* Through their signatures, the investigators affirm that they will: 1) abide by the MACHS-IRB rules and regulations pertaining to the conduct of research; 2) adhere to the scientific protocol as outlined in the submission; 3) exhibit scientific rigor and integrity in the conduct of all phases of the research proposal; 4) include within the authorship, of any scientific articles arising from the research, only those individuals contributing significantly to that research as outlined in the “Guidelines for Manuscript Authorship”; and 5) declare any conflict of interest, or any accrual of financial gain, by virtue of association with the research.

<b>APPROVAL</b>	<b>CHAIRMAN</b>		
		<b>SIGNATURE</b>	<b>DATE</b>
	<b>IRB</b>		

### Approval - Research Unit Committee:

The Committee has reviewed this proposal and attests to its scientific validity.

<b>Chairman (or Designee), Research Unit Committee</b>	Signature	Date



## RESUME

### Personal Data:

<b>Name:</b>	<b>ID No:</b>
<b>Department:</b>	<b>Position:</b>
<b>Email:</b>	<b>Ext:</b>

### Education:

Undergraduate Degree

Post Graduate Degree

Others

---

### Research:

Journal Publications:

Published Abstracts:

**Ongoing research:**

**Grants/ Fund:**





## Consent Form

**Title:**

**NOTE:** A copy of this consent form will be given to the participant, and another copy will remain with MACHS SRU for their records.

I agree to take part in the MACHS research project specified above. I have had the project explained to me, and I have read the explanatory statements, which I will keep for my records.

I understand that any data that this study finds will not contain names or identifying characteristics under any circumstances.

**Participants name:**

**Signature:**

---

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**Date:**