# Kingdom of Saudi Arabia

# Inaya Medical College


# Institutional Review Board (IRB)

# 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"
   HTTP://PHRP.NIHTRAINING.COM/USERS/LOGIN.PHP
7. RESEARCH APPROVAL FORM

**Principal Investigator/s:**

**Name (print)** _____ **Signature:** _____ **Date:** _____

| **Title:** | **Duration of Study:** |
|---|---|
| | |

| | Department or Affiliation | I.D. | Position | * Signatures |
|---|---|---|---|---|
| **Principal Investigator** | | | | |
| | | | | |
| **Co-Principal Investigator** | | | | |
| | | | | |
| **Other Co-Investigators** | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

## Declaration of Conflict of Interest:

**Principal Investigator/s:**

**Name (print)** _____ **Signature:** _____ **Date:** _____

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 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 |
|---|---|---|
| | | |
| | | |

## 1. 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*

## 2. RESEARCH PROPOSAL

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____

**Title of the Proposal:**

## 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.*

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____

# Work Plan and Responsibilities

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:

| Task | Investigator(s) |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____

***References (comprehensive literature review: pages _____ )***

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____

## 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

## 5. Costs Involved in this research

| Item | Details | Expected costs | Details of quotations received | Remarks |
|---|---|---|---|---|
| Equipment | | | | |
| Diagnostic kits | | | | |
| Software | | | | |
| Publication Fees | | | | |
| Conference presentation | | | | |
| Any other | | | | |
| Total | | | | |
| | | | | |

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____

**Approval - Department:**
I have reviewed this proposal and approve the participation of the concerned personnel of my department in it.

| PARTICIPANTS | DEPARTMENTAL HEAD | SIGNATURE |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Approval - Research Unit Committee:**
The Committee has reviewed this proposal and attests to its scientific validity.

| | | |
|---|---|---|
| | | |

* 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.

| | | | |
|---|---|---|---|
| APPROVAL | **Head of IRB** | **SIGNATURE** | **DATE** |
| | | | |

**Principal Investigator/s:**

**Name (print)** _____ **Signature: _____ Date:** _____