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| **General requirements** | **#**  ***IRB APPLICATION CHECKLIST*** | **Items** | **choose** | **notes** |
| **1** | **CV's of research team (required from all investigators)** | **Yes** | Click or tap here to enter text. |
| **2** | **Valid research ethics certificate (required from all investigators)** | **N/A** | Click or tap here to enter text. |
| **3** | **Tools ‘e.g. questionnaire, data collection sheet, interview guide’ (if applicable)** | **No** | Click or tap here to enter text. |
| **IRB required forms** | | | |
| **4** | **IRB Approval Application form (to be completely filled and signed)** | Choose an item. | Click or tap here to enter text. |
| **5** | **Informed Consent form ‘Arabic/English’ (provide translation certificate if other languages)** | Choose an item. | Click or tap here to enter text. |
| **6** | **RS-MOH Data Share Agreement form** | Choose an item. | Click or tap here to enter text. |
| **7** | **Sending biologic sample outside KSA form (if applicable)** | Choose an item. | Click or tap here to enter text. |
| **8** | **Non-disclosure agreement form (if applicable)** | Choose an item. | Click or tap here to enter text. |
| **Only for students** | **Additional required documents for students** | | | |
| **9** | **Supervisor letter** | Choose an item. | Click or tap here to enter text. |
| **10** | **Cultural attaché letter (if studying abroad)** | Choose an item. | Click or tap here to enter text. |
| **11** | **Letter from academic institution** | Choose an item. | Click or tap here to enter text. |
| **12** | **CV of supervisor** | Choose an item. | Click or tap here to enter text. |
| **Only for clinical trial** | **Additional required documents for clinical trials** | | | |
| **13** | **Study protocol** | Choose an item. | Click or tap here to enter text. |
| **14** | **Investigator brochure** | Choose an item. | Click or tap here to enter text. |
| **15** | **Insurance** | Choose an item. | Click or tap here to enter text. |
| **16** | **Clinical trial agreement** | Choose an item. | Click or tap here to enter text. |
| **17** | **Case report form** | Choose an item. | Click or tap here to enter text. |
| **18** | **GCP certificate** | Choose an item. | Click or tap here to enter text. |

***\*N/A: not applicable***

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| ***Section 1:******SUBMISSION DETAILS*** | | | | |
| **Study title in English:** | Click or tap here to enter text. | | | |
| **Study title in Arabic:** | Click or tap here to enter text. | | | |
| **Submission date:** | 12/4/2021 | **Application number** (filled by IRB): | | **FOR IRB USE** |
| **Protocol number:** | If the protocol number is not available, leave it empty. | **Protocol version** | | If the protocol version is not available, leave it empty. |
| **Study duration:** | **2 monthes maximum** | **Starting date of the study:** | | 7/1/2022 |
| **Research objectives:** | Click or tap here to enter text. | | | |
| **Research Type:** | | | | |
| A. Medical Primary Research  1. Basic Medical Research  2. Clinical Research  3. Epidemiological Research | | | | |
| B. Medical Secondary Research  1. Reviews  2. Meta-Analyses | | | | |
| C. Non-Medical  ***\*If you are unsure about your selection, please refer to this*** [***link***](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2689572/figure/F1/?report=objectonly) ***for clarification.*** | | | | |
| **Health Research Themes:** | | | **Research Site:** | |
| **Dose the study about “Social, Cultural, Environmental, and Population Health Research”?**  ☐ Yes ☐ No  **Dose the study about “Health Services Research”?**  ☐ Yes ☐ No | | | Inside MOH Institutions  Outside MOH Institutions  Both inside and outside MOH Institutions | |
| **Purpose of Research:** | | | **Research Site Affiliation:** | |
| Academic purposes MD  Professional purposes | | | Single Site or Center  Multi Sites or Centers | |
| **Research Specialty** (*please select one from the dropdown list*): | | | **Research Site Name/s** (e.g., hospitals or locations) | |
| General Surgery  ***If others, please specify:*** Click or tap here to enter text. | | | |  |  | | --- | --- | | # | Site | | # | # | ***King abdulaziz specialist hospital (Taif)***  ***Alhada armed force hospital (Taif)***  ***King Abdullah medcal city (Makkah)*** |   **\* You can expand the table to add sites as necessary.** | |
| **Previous IRB approval** | | | | |
| **Did you apply to another IRB for this study?**  No  **\* *If yes, please attach a copy to the application.*** | | | | |

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| ***Section 2:******RESEARCH TEAM*** | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR (PI)** | | | | | | | | | | | | | | |
| **First Name:** | | Click or tap here to enter text. | | | **Last Name:** | | | Click or tap here to enter text. | | | | **PI Affiliation:** | MOH  Non-MOH, specify Click or tap here to enter text. | |
| **PI ID number** | | Click or tap here to enter text. | | | **PI Specialty:** | | | Click or tap here to enter text. | | | |
| **PI Degree:** | |  | | | **PI E-mail:** | | | Click or tap here to enter text. | | | |
| **PI Phone:** | | Click or tap here to enter text. | | | **Mailing Address:** | | | Click or tap here to enter text. | | | | **Signature** |  | |
| **Supervisor name and degree (for students)** | | | | | | Click or tap here to enter text. | | | | **Supervisor E-mail** | | |  | |
| **Please list co-investigator(s), if any.**  \*If research supervisor is considered as a co-investigator in this study, he/she must be included to this list.  \*signatures are required, by singing this section, all investigators agree to and will be responsible for the assurance section 7. | | | | | | | | | | | | | | |
| # | Name | | Degree | Affiliation | | | Email | | Phone | | Role | | | Signature |
| 1 | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. | | Please specify: Click or tap here to enter text. | | |  |
| 2 | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. | | Please specify: Click or tap here to enter text. | | |  |
| 3 # | Click or tap here to enter text. | | Under graduate of MBBS | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. | | Please specify: Click or tap here to enter text. | | |  |
|  | Click or tap here to enter text. | | Under graduate of MBBS | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. | | Please specify: Click or tap here to enter text. | | |  |
|  | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. | | Please specify: Click or tap here to enter text. | | |  |

***\*You can expand the table and add co-investigators as necessary.***

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| ***Section 3. FUNDING SOURCE*** |
| **A. Is the study funded?**  Study is **not funded** (Continue to Section 4).  Study is **funded**. **Fund number**: Click or tap here to enter text.  Study applied for fund **(under process)**. **Application date**: Click or tap here to enter text. |
| **B. Funding source:**  MOH, *please specify*: Click or tap here to enter text.  Governmental fund, *please specify*: Click or tap here to enter text.  Commercial Sponsorship, *please specify*: Click or tap here to enter text.  Other, *please specify*: Click or tap here to enter text. |

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| ***Section 4. CONFLICTS OF INTEREST*** | | | | | | | |
| **Do any of the research team or members of their immediate families have financial interest related to the research or the research sponsor?** | | | | | | **Yes** | **No** |
| If the answer is yes, please write conflict management plan  Click or tap here to enter text. | | | | | | | |
| ***Section 5. PROPOSAL FORM***  **Part 1: SUMMARY AND BACKGROUND OF THE STUDY** | | | | | | | |
| **A. Summary in English** (max 150 words) | | | | | | | |
| **Introduction:**  Click or tap here to enter text.  **Aim:** Click or tap here to enter text.  **Methods:** Click or tap here to enter text.  **Importance:**  Click or tap here to enter text. | | | | | | | |
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| **B. Summary in Arabic** (max 150 words) | | | | | | | |
| **المقدمة:** Click or tap here to enter text.  **الهدف:** Click or tap here to enter text.  **منهجية البحث:** Click or tap here to enter text.  **أهمية البحث:** Click or tap here to enter text. | | | | | | | |
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| **C. Background (include references)** “Summarize the relevant literature (max 400 words)” | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| **E. Aims and objectives/research question(s)** | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| **D. Rationale and importance** (max 150 words) | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| **Part 2. METHODS** | | | | | | | |
| 1. **Study Design** | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| 1. **Study area and target population** | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| 1. **Sample size and sampling technique** ‘provide justification for the required sample’ | | | | | | | |
| Click or tap here to enter text. | | | | | | | |
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| 1. **List all research sites and indicate the estimated total number of participants for each site (if male/female samples are not determined, then provide the total numbers only for each site).** | | | | | | | |
| # | **Site** | # Male | | # Female | Total | | |
| 1 | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | |
| 2 | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | |
| 3 | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. |  | | |
| TotalClick or tap here to enter text. | | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | |
| ***\* You can expand the table and add research sites as necessary.*** | | | | | | | |
| 1. **RECRUITMENT** | | | | | | | |
| 1. **Planned recruitment procedures** (select all that apply)   Phone call or SMS, *please specify*: Click or tap here to enter text.  Social media, *please specify*: Click or tap here to enter text.  Email distribution  Flyers/brochures  Online announcement, *please specify*: Click or tap here to enter text.  Other, *please specify*: Click or tap here to enter text.  Not applicable (secondary data only) | | | | | | | |
| 1. **Describe the recruitment process details** (for each group of participants, if applicable).   \*please attach copies of advertisement materials, if applicable.  Click or tap here to enter text. | | | | | | | |
| 1. **Study populations** (select who will be recruited) | | | | | | | |
| **Age:**  Adults (≥18 years)  Children (<18 years)  Particular age range, *please specify*: Click or tap here to enter text.  **Gender:**  Both males and females  Targeted gender, *please specify*:  Males or  Females  **Race/Ethnicity:**  All races and ethnicities  Targeted Race/Ethnicity, *please indicate*: Click or tap here to enter text. | | | **Other:**  Pregnant or lactating women, fetuses, and neonates  Prisoners  People with low-income status  People with physical disabilities  People with mental disabilities  People who are illiterate  People who are non-Arabic speaking  Other, *please specify*: Click or tap here to enter text. | | | | |
| 1. **Please provide a scientific rationale if you are targeting one sex, race, ethnic group, or groups from the ‘other’ category.**   Click or tap here to enter text. | | | | | | | |
| 1. **Describe the measures the study will take to protect the rights and welfare of the populations selected above.**   Click or tap here to enter text. | | | | | | | |
| 1. **Describe the ethical issues that may arise from the study and methods to handle it?** | | | | | | | |
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| 1. **INCLUSION/EXCLUSION** (for treatment and control groups “if applicable”) | | | | | | | |
| 1. **Inclusion criteria:**   Any patient who do hemorrhoidectomy over past 2 years   1. **Exclusion criteria:**   none | | | | | | | |
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| 1. **Tools and procedures** | | | | | | | |
| 1. **Select study tools** (all that apply).   Questionnaire(s): [ Paper  Telephone  Online]  Data collection sheet  Interviews  Intervention, *please specify*: Click or tap here to enter text.  Test(s), *please specify*: Click or tap here to enter text.  Other, *please specify*: Click or tap here to enter text. | | | | | | | |
| 1. **Please list and describe all the selected tools** (include references if needed).   Click or tap here to enter text. | | | | | | | |
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| 1. **Analysis plan** | | | | | | | |
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| 1. **Research Timeline** | | | | | | | |
| **Table or Gantt chart** | | | | | | | |
| **Part 3. PAYMENTS &INCENTIVES** | | | | | | | |
| **A. Will you provide financial incentives or compensation to the study participants?**  Yes  No, If no, continue to part 4. | | | | | | | |
| **B. Please describe the payment plan including the amount of money (SAR) to be given to each participant.**  Click or tap here to enter text. | | | | | | | |
| **Part 4. RISKS & BENEFITS** | | | | | | | |
| **A. Does the study present a risk to the participants?**  Yes  No, If no, continue to part 5. | | | | | | | |
| **B. What risks are expected from carrying out this study?** (Examples of risk areas: physical well-being, privacy, emotions, reputation, employability, and/or criminal/legal status.) | | | | | | | |
| **C. How will the risks be minimized?** | | | | | | | |
| **D. What are the expected benefits from the study?** | | | | | | | |
| **E. Balance risks and benefits (Do the benefits outweigh the risks?):** | | | | | | | |

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| **Part 5. INFORMED CONSENT** |
| **A. Select informed consent process that will be used:**  Signing Informed Consent Form by:  Adult  Children  Parent(s) or guardian(s)  **OR**  The PI request waiver of documentation of Informed Consent for:  Adult  Children  Parent(s) or guardian(s)  Explain why:    **OR**  The PI request waiver of Informed Consent for:  Adult  Children  Parent(s) or guardian(s)  Explain why:  Due to that information will not be sensitive. |

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| **Part 6. PRIVACY &CONFIDENTIALITY** |
| **A. Will the participants’ data be identified?**  Yes, with direct identifiers  Yes, with indirect identifiers (e.g. assigning codes)  No, it will be anonymous |
| **B. How will you protect the privacy of research data?** (Select all that apply)  Storage of consent forms and data in separate places.  Data is collected anonymously.  Use of participant codes on all data (codes will be stored in a separate location).  The study data will be stored securely (e.g. secured office, password protected computer), *please explain* Click or tap here to enter text.  Other, *please describe*: Click or tap here to enter text. |
| **C. How long will the study data be kept after completion of the study? (minimum period is 5 years)**  5 years. |

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| **Part 7. DISSEMINATION** |
| **A. How will the study be disseminated?**  Scientific journal  Conference presentation  Other, please describe: Click or tap here to enter text. |
| **B. Will participants’ identifying information be published or shared?**  Yes  No \* If yes, please explain: Click or tap here to enter text. |

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| ***Section 6. INVESTIGATOR ASSURANCE*** | |
| I certify that:   1. the information filled out in this application form is complete and correct. 2. the research team will follow the IRB approved proposal (study details, methods, and procedures), unless amendment(s) are requested and approved by the IRB. 3. the research team will follow MOH and NCBE regulations. 4. the PI will obtain an approval letter from Saudi Food and Drug Authority (SFDA) before starting a clinical trial. 5. the research team will not disclose personally identifiable data of the participants to any other party. 6. the PI will keep the study data securely for at least five years after completion of the study. 7. the collected data will only be used for this proposal. 8. the PI is responsible for the safe and ethical conduct of the research. 9. the PI will perform and/or supervise the conduct of study-related procedures, and monitor the safety of the study subjects and investigational staff. 10. the research team will collect three copies of informed consent forms (unless waived)     1. one copy to be kept with the PI     2. one copy to be kept with the study participant     3. one copy for the IRB committee OR to be kept in the participant’s file in case of clinical research 11. the research team will provide periodic progress reports as requested by the IRB. 12. the PI will notify the IRB as soon as possible in the case of: 13. any amendment to the project protocol, CRF, IC or IB or other related documents. 14. any serious unexpected adverse events in accordance with the NCBE regulations. 15. any event or new information that may affect the benefit/risk ratio of the proposal. 16. the PI will ensure adequate close-out of the study. 17. the final report will be submitted for approval by the IRB before publication. | |
| **The application must be signed by the PI before submission. (Electronic signatures accepted.)** | |
| Principal Investigator Name: Abdullah maiwid salem Alsawat  Signature:  Date 12/4/2021 | Supervisor Name (for students) Click or tap here to enter text.  Signature:  Date Click or tap to enter a date. |

THANK YOU