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| **Exempt Review** |
| **Type:** Observational study (retrospective and prospective), cross-sectional study, case control study, survey, interview, chart review, data collection, registry |
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| ***Please submit the following:*** | **Submitted** | **N/A** |
| 1. Study Submission Cover Sheet
 | [ ]  | [ ]  |
| 1. Request for Exempt Review Form (completed, signed and stamped)
 | [ ]  | [ ]  |
| 1. Survey or Questionnaire Consent (for surveys, questionnaires, interview questions etc.)
 | [ ]  | [ ]  |
| 1. Case Report Consent (for case reports)
 | [ ]  | [ ]  |
| 1. Full Proposal [**in word format**] (includes title, objectives, literature review, methods, etc.)
 | [ ]  | [ ]  |
| 1. Survey / Questionnaire (for surveys, interview questions etc.)
 | [ ]  | [ ]  |
| 1. Case Report or Data Abstract Form or List of Data Variables (for data collections, chart reviews, etc.)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ CV (mandatory)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ Human Subject Protection Training Certificate (NIH, Bioethics, GCP, etc.) (mandatory)
* <https://phrp.nihtraining.com/users/login.php>
* <http://bioethics.kacst.edu.sa/Register/register-resercher.aspx>
* <https://gcp.nidatraining.org/>
* <https://about.citiprogram.org/en/homepage/>
 | [ ]  | [ ]  |
| 1. IRB Review Fee - Proof of Payment (for company sponsored study)
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| ***Additional requirements for External Investigators (for student researchers):*** | **Submitted** | **N/A** |
| 1. External Research Application
 | [ ]  | [ ]  |
| 1. External Investigators' Declaration
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| 1. External Investigators' Statement
 | [ ]  | [ ]  |
| 1. Letter from Institution, College or University or Advisor or Supervisor
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| **IRB Submission Requirements (After Initial IRB Approval)** | **Submitted** | **N/A** |
| 1. Adverse Events, Protocol Deviations and Violations Reporting
 | [ ]  | [ ]  |
| 1. Amendment Submission Request
 | [ ]  | [ ]  |
| 1. Exempt Status Annual Continuation Report
 | [ ]  | [ ]  |
| 1. Final Report for IRB Termination or Study Completion
 | [ ]  | [ ]  |
| 1. Expedited or Full Study Status Report
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| **Expedited Review** |
| **Type:** Observational study (retrospective and prospective), cross-sectional study, case control study, survey, interview, chart review, data collection, registry with minimal risk intervention, genetic research |
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| ***Please submit the following:*** | **Submitted** | **N/A** |
| 1. Study Submission Cover Sheet
 | [ ]  | [ ]  |
| 1. Request for Expedited Review Form (completed, signed and stamped)
 | [ ]  | [ ]  |
| 1. Informed Consent Checklist
 | [ ]  | [ ]  |
| 1. Consent Form for Participation
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| * Consent Form for Participation (High Risk)
 | [ ]  | [ ]  |
| * Consent Form for Participation (Minimal Risk)
 | [ ]  | [ ]  |
| * Consent Form for Participation (Assent for Minor)
 | [ ]  | [ ]  |
| 1. Full Proposal [**in word format**] (includes title, objectives, literature review, methods, etc.)
 | [ ]  | [ ]  |
| 1. Survey / Questionnaire (for surveys, interview questions etc.)
 | [ ]  | [ ]  |
| 1. Case Report or Data Abstract Form or List of Data Variables (for data collections, chart reviews, etc.)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ CV (mandatory)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ Human Subject Protection Training Certificate (NIH, Bioethics, GCP, etc.) (mandatory)
* <https://phrp.nihtraining.com/users/login.php>
* <http://bioethics.kacst.edu.sa/Register/register-resercher.aspx>
* <https://gcp.nidatraining.org/>
* <https://about.citiprogram.org/en/homepage/>
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| 1. IRB Review Fee - Proof of Payment (for company sponsored study)
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| ***Additional requirements for External Investigators (for student researchers):*** | **Submitted** | **N/A** |
| 1. External Research Application
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| 1. External Investigators' Declaration
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| 1. External Investigators' Statement
 | [ ]  | [ ]  |
| 1. Letter from Institution, College or University or Advisor or Supervisor
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| **IRB Submission Requirements (After Initial IRB Approval)** | **Submitted** | **N/A** |
| 1. Adverse Events, Protocol Deviations and Violations Reporting
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| 1. Amendment Submission Request
 | [ ]  | [ ]  |
| 1. Exempt Status Annual Continuation Report
 | [ ]  | [ ]  |
| 1. Final Report for IRB Termination or Study Completion
 | [ ]  | [ ]  |
| 1. Expedited or Full Study Status Report
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| **Full Review** |
| **Type:** Intervention research (clinical trials, clinical research), genetic research |
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| ***Please submit the following:*** | **Submitted** | **N/A** |
| 1. Study Submission Cover Sheet
 | [ ]  | [ ]  |
| 1. Request for Full Review Form (completed, signed and stamped)
 | [ ]  | [ ]  |
| 1. Informed Consent Checklist
 | [ ]  | [ ]  |
| 1. Consent Form for Participation
 |  |  |
| * Consent Form for Participation (High Risk)
 | [ ]  | [ ]  |
| * Consent Form for Participation (Assent for Minor)
 | [ ]  | [ ]  |
| 1. Full Proposal [**in word format**] (includes title, objectives, literature review, methods, etc.)
 | [ ]  | [ ]  |
| 1. Survey / Questionnaire (for surveys, interview questions etc.)
 | [ ]  | [ ]  |
| 1. Case Report or Data Abstract Form or List of Data Variables (for data collections, chart reviews, etc.)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ CV (mandatory)
 | [ ]  | [ ]  |
| 1. PI and Co-PIs’ Human Subject Protection Training Certificate (NIH, Bioethics, GCP, etc.) (mandatory)
* <https://phrp.nihtraining.com/users/login.php>
* <http://bioethics.kacst.edu.sa/Register/register-resercher.aspx>
* <https://gcp.nidatraining.org/>
* <https://about.citiprogram.org/en/homepage/>
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| 1. IRB Review Fee - Proof of Payment (for company sponsored study)
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| ***Additional requirements for External Investigators (for student researchers):*** | **Submitted** | **N/A** |
| 1. External Research Application
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| 1. External Investigators' Declaration
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| 1. External Investigators' Statement
 | [ ]  | [ ]  |
| 1. Letter from Institution, College or University or Advisor or Supervisor
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| **IRB Submission Requirements (After Initial IRB Approval)** | **Submitted** | **N/A** |
| 1. Adverse Events, Protocol Deviations and Violations Reporting
 | [ ]  | [ ]  |
| 1. Amendment Submission Request
 | [ ]  | [ ]  |
| 1. Exempt Status Annual Continuation Report
 | [ ]  | [ ]  |
| 1. Final Report for IRB Termination or Study Completion
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| 1. Expedited or Full Study Status Report
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| ***Additional submission for all types of study, please enumerate:*** | **Submitted** | **N/A** |
| 1. Investigator’s Brochure
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| 1. Pharmacy Services Investigational Drug Service (IDS) Clearance Form
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| 1. Pathology & Clinical Laboratory Medicine Administration (PCLMA) and IRB Consultation Form
 | [ ]  | [ ]  |
| 1. Indemnity Insurance Certificate
 | [ ]  | [ ]  |
| 1. Genetic Consent
 | [ ]  | [ ]  |
| 1. Material Transfer Agreement
 | [ ]  | [ ]  |
| 1. Data Share Agreement
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| For any inquiry or submission, please send to **InstitutionalReviewBoard@kfmc.med.sa**.***You can also contact the following:***1. **Prof. Omar Kasule (IRB Chairman)**

Email: okasule@kfmc.med.saTelephone: 288-9999 extensions 26913Mobile: 05488679161. **Ms. Cecile Arce**

Email: carce@kfmc.med.saTelephone: 288-9999 extension 26943 |