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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 |  |  |
| 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 |  |  |
| * 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/> |  |  |
| 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 |  |  |
| 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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| **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/> |  |  |
| 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 |  |  |
| 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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| ***Additional submission for all types of study, please enumerate:*** | **Submitted** | **N/A** |
| 1. Investigator’s Brochure |  |  |
| 1. Pharmacy Services Investigational Drug Service (IDS) Clearance Form |  |  |
| 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**](mailto:InstitutionalReviewBoard@kfmc.med.sa).  ***You can also contact the following:***   1. **Prof. Omar Kasule (IRB Chairman)**   Email: [okasule@kfmc.med.sa](mailto:okasule@kfmc.med.sa)  Telephone: 288-9999 extensions 26913  Mobile: 0548867916   1. **Ms. Cecile Arce**   Email: [carce@kfmc.med.sa](mailto:carce@kfmc.med.sa)  Telephone: 288-9999 extension 26943 |