# Appendix 6: IERC Application Form for Exemption of Studies from Ethical Review

**INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)**

**THE AGA KHAN UNIVERSITY - KENYA**

**Application Form for Exemption of Studies from Ethical Review**

|  |  |
| --- | --- |
| **Study Details** | Title: |
| Key Words: |
| Study Area: |

|  |  |  |
| --- | --- | --- |
| **2. Principal Investigator** | Name | Department |
|  |  |

|  |  |  |
| --- | --- | --- |
| **3. Co-PI's** | Names | Department |
|  |  |
|  |  |
|  |  |

|  |  |
| --- | --- |
| **4. Signature of PI** |  |

**Please mark the appropriate box as √**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **5. Types of study** | | | | Yes | No |
| a. | Retrospective review of patient's charts | | |  |  |
| b. | Prospective data collection from patient's charts | | |  |  |
| c. | Analysis of laboratory/ radiology data | | |  |  |
| d. | Clinical audit | | |  |  |
| e. | Evaluation of practice guidelines | | |  |  |
| f. | Case reports | | |  |  |
| g. | Others; please specify | | |  |  |
|  |  | | |  |  |
| **6. Period of data collection** | | | | | |
| From | |  | to |  | |
|  | |  |  |  | |
| **7. Starting date of study:** | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **8. Summary of data to be collected** | | Yes | No |
| a. | Demographics of the patients i.e. name addresses, phone numbers, e-mail address |  |  |
| b. | Clinical notes |  |  |
| c. | Photographs |  |  |
| d. | Laboratory data/ radiology data |  |  |
| e. | Management data |  |  |
| f. | Other, please specify |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **9. Utilization of data to be collected: Will it be used for** | | Yes | No |
| a. | Publication of papers in journals / newspapers |  |  |
| b. | Oral / poster presentation in meetings / conferences |  |  |
| c. | Students / residents’ teaching |  |  |
| d. | Planning subsequent larger studies |  |  |

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| --- |
| **10. Summary of Objectives & Methods of Study including selection and exclusion criteria of study subjects, sample size, analysis plan etc.** |

**11. Please answer the following questions and mark the appropriate box as √**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes | No |
| a. | Will any photographs be used/taken for publication? |  |  |
| b. | If yes, has written permission been obtained from study subject or guardian? |  |  |
| c. | Has the study been reviewed be departmental research / review committee |  |  |
| d. | Was any ethical concern raised by departmental committee? |  |  |
| e. | If yes, what were the ethical issues? | | |
|  | | |
| f. | Were those ethical concerns resolved? |  |  |

**EDUCATION/TRAINING**

|  |  |  |  |
| --- | --- | --- | --- |
| Institution And Location | Degree | Completion Date | Field Of Study |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |

Most recent posts held

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Types of posts held** | **Institution** | **Period** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |

|  |
| --- |
| Recent publications: list only five most important and relevant publications or presentations over the last five years (papers in press or submitted for publication are also acceptable). *Please give full bibliographic reference [authors, title, journal, volume, page numbers, and year].* |

**Certificate of review by the Departmental Research/ Review Committee**

**and Chair of the Department**

The Departmental Research / Review Committee (DRC) have reviewed the above study. The Committee members are satisfied that the study falls in the exemption category and has no ethical issue. The study is being submitted to IERC for granting of an exemption letter.

Name of DRC Chair \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Department Chair \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**For IERC**

|  |  |  |  |
| --- | --- | --- | --- |
| **Exemption granted** | **Yes** | **No** | **Signature of Chair IERC** |
|  |  |  |
| If not, then state the reasons |  | | |
| Has the PI been informed about decision of IERC? |  |  |  |
| If yes, has any response been received? |  |  |  |
| If yes, has the response been reviewed by the Chair of IERC? |  |  |  |
| If yes what decision was taken? Was exemption granted? |  |  |  |