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# Government of Pakistan

National Institutes of Health

Health Research Institute

**National Bioethics Committee for Research (NBC-R) Pakistan**

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

**Adapted & Used with Thanks & Permission of Aga Khan University Ethics Review Committee**

**National Bioethics Committee for Research (NBC-R) Pakistan**

|  |  |
| --- | --- |
| **1. Study Title** |  |

|  |  |  |
| --- | --- | --- |
| **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/routine collected data | | |  |  |
| 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 | |  |  |  | |
|  | |  |  |  | |
| **7. Starting date of study** | | | | | |
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| **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 |  |  |

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| --- | --- | --- | --- |
| **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.**  **1. Aim and Objectives:**  **2. Study design:** \  .  **3. Study population:**  **4. Data Sources and Variables:**  **5. Analysis and Statistics:** |

**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. | Is there any ethical concern/issue? |  |  |
| d. | If yes, what were the ethical issues? | | |
|  | | |
| e. | Were those ethical concerns resolved? |  |  |