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#  Government of Pakistan

National Institutes of Health

Health Research Institute

**National Bioethics Committee (NBC) 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 (NBC) 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 |  |  |

|  |  |  |
| --- | --- | --- |
| **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  |  |  |

|  |
| --- |
| **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?  |  |  |