**Institutional Review Board (IRB)**

Dow University of Health Sciences

Baba-e-Urdu Road

Karachi, Pakistan

Tel: 021-32745827

Web: www.duhs.edu.pk **Email:** **irb@duhs.edu.pk**

**IRB Exemption Form**

**Checklist**

Two copies of Research Protocol with checklist.

Two copies of Drug Brochure or any supplementary information enclosed (if applicable).

Two copies of informed consent both in English and Urdu or any other local language of the population study (If applicable).

Two copies of Questionnaire/Test material being administered during the study (if applicable).

Two copies IRB Exemption form.

Soft copy of IRB Exemption form.

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Signature: Principal Investigator Date

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Signature of supervisor (if applicable) Date

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Signature of Chairman/In-Charge Department Date

Institutional Review Board

Dow University of Health Sciences

#### How to complete this form and begin the IRB review process

1. This form must be typed and **NOT** handwritten.
2. Fill all of the questions on this form completely. For any queries please contact the Research Office, Dow University of Health Sciences. Email: irb@duhs.edu.pk (Please wait for 7 – 10 days for the response).
3. Students’ research project has to be signed by the supervisor.
4. Fill and attach the appropriate appendices required in this application.
5. Attach supporting documentation: consent form(s), protocol, survey instruments, interview schedules, advertisements, letters of permission, etc. Consent form and questionnaire should also be submitted in local languages where ever applicable.
6. Complete the accompanied checklists ensure there all requirements for submission are completed so that review is not delayed.
7. Submit this application and appendices along with the supporting documents to the Research Department Dow University of Health Sciences, Baba-e-Urdu Road Karachi Pakistan.

**Principal Investigator Information:**

|  |  |
| --- | --- |
| Title:  | Name: |
| Designation:  | Department or Unit:  |
| Mailing address (Office): |
| Phone:  | Email:  |
| Signature of PI:  | Date: |

**Co Investigators Information:**

**1.**

|  |  |
| --- | --- |
| Title:  | Name:  |
| Designation: | Department or Unit:  |
| Mailing address (Office):  |
| Phone:  | Email:  |
| Signature of Co-Investigator:  | Date: |

**2.**

|  |  |
| --- | --- |
| Title:  | Name:  |
| Designation:  | Department or Unit: |
| Mailing address:  |
| Phone:  | Email:  |
| Signature of Co-Investigator:  | Date: |

If, there are more than three authors, please write down only the names and institution for of remaining other authors.

1. Title of the Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Please confirm before filling the form:

Is Your study:

* In Vitro, with no human or animal involvement
* Comprises ONLY on pre-collected clinical or laboratory data and no new information would be gathered
* Comprises on data already in Public Domain
* Involves only Passive observation of human or animal behavior
* Involves routine academic performance measures in a class room
* Other

If “Other”, Please specify why do you think an exemption should be given:

1. **Please provide one-page summary of the, research, project, including details of research methodology (use simple language but give details of how study will take place).**
2. **What are the aims and objectives of this research?**
3. **What is the scientific justification for this research?**
4. **Describe the how would the material/organisms/data would be obtained:**
5. **If using already collected data, where was data collected and by whom? Which time period does it comprise of? What was the purpose for original collection? How would you ensure the quality of data, which has been collected? Are Data collectors involved in this study? If not, will they be acknowledged or given authorship?**

**(While being tabulated for the research, data must be anonymized completely, without any identifiers)**

1. **Explain the complete methodology of your project:**
2. **What sampling technique and sample size will you use? How was it Calculated?**
3. **If you are using medical records, what are your exclusion or inclusion criteria?**
4. **If you are using biological material or living microorganisms for in-vitro study, please identify the risks or hazards involved. What precautions would you take to avoid any safety hazards?**

1. **What is the estimated cost of this project? Who will bear this cost?**
2. **What are the primary outcomes of this study?**
3. **Are there any external collaborators involved? What is their role and Who will retain the ownership of the data?**