

**Republic of Iraq**

**Ministry of Health & Environment**

**Approval form of a Research Protocol/ Ministry of Health & Environment (Form number 02/2021)**

**استمارة الموافقة على مشروع بحث في وزارة الصحة والبيئة (استمارة رقم 02/2021)**

* This form should be filled in electronically (Manually filled in form will not be accepted) by the researcher and submitted manually to the research unit at the relevant Health Directorate to be displayed at its Research committee. No research is allowed to be conducted at the institutions of Ministry of Health without having in advance the committee’s approval.
* This form can be downloaded from the official website of Ministry of Health & Environment/ Iraq: ***https://moh.gov.iq/***

1. PERSONAL INFORMATION

**1.1 Principal Investigator**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Specialty** | **Place of work** | **Phone number** | **E mail** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**1.2 Other investigators**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Specialty** | **Place of work** | **Phone number** | **E mail** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. RESEARCH INFORMATION

2.1 Is the research title from the Ministry of Health’s list of priorities:

**2.1**: The list is issued every year and found on MoH website.

**Yes  No**

2.2 The purpose of doing the research: Choose an item.

**If the answer is others, please, specify**: Click or tap here to enter text.

1. RESEARCH TOPIC

3.1 The Research Title:

**3.1**: Write down the title of your research.

Click or tap here to enter text.

3.2 The Research Question:

**3.2**: Write down the smart research question.

Click or tap here to enter text.

3.3 Research Background (with references in Vancouver style):

**3.3**: Write concisely the scientific bases of your research question. Use updated and new references.

Click or tap here to enter text.

3.4 Justification of Choosing this topic (Rationale):

**3.4**: Show the rationale of choosing this research question and what are the expected gab that this research is going to fill.

Click or tap here to enter text.

3.5 The Objective/s of the Research:

**3.4**: Write down primary and secondary objectives

1. Research Setting

4.1 When will the sample be collected?

Start8 January 2021End15 April 2021

4.2 Where will the study be implemented?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name of Institution** | **Name of authorized person** | **Signature** | **Date and stamp** |
| **1** | Click or tap here to enter text. |  |  |  |
| **2** | Click or tap here to enter text. |  |  |  |
| **3** | Click or tap here to enter text. |  |  |  |
| **4** | Click or tap here to enter text. |  |  |  |
| **5** | Click or tap here to enter text. |  |  |  |

4.3 The resources needed from the institution selected to implement the research?

|  |  |  |
| --- | --- | --- |
| **The resource needed** | **tick** | **Amount and types** |
| **Laboratory sample (Blood, urine, ….)** |  | Click or tap here to enter text. |
| **Devices, instrument, tools ……** |  | Click or tap here to enter text. |
| **Patients’ or firm’s records** |  | Click or tap here to enter text. |
| **Persons (patients, employers)** |  | Click or tap here to enter text. |
| **Others specified** |  | Click or tap here to enter text. |

4.4 Who will fund the research?Choose an item.

**If the answer is others, please, specify**:

Click or tap here to enter text.

5. RESEARCH METHODOLOGY

**5.1**: write the design of the study that is going to answer your research question

5.1 Study Design: choose one from below

Choose an item.

**If the answer is others, please, specify**: Click or tap here to enter text.

5.2 Case Definition:

**5.2**: It is the operational definition used to enroll participants in the study

Click or tap here to enter text.

5.3 Exclusion Criteria:

**5.4**: the method used to select the participants of the sample from the targeted sample.

**5.3**: the participants that fulfil case definition, but excluded from the study due to a specific cause

Click or tap here to enter text.

5.4 Sampling Methods:

**5.5**: Write details about how to allocate participants in study arms or blinding them if the study design is relevant

Click or tap here to enter text.

5.5 Randomization and Blinding Methods (If relevant):

Click or tap here to enter text.

5.6 Selection of Participants in control group (If Relevant):

**5.7**: Variables used to answer the research question. Write them in details; how do you measure them, when and by whom.

**5.6**: Criteria of enrolling participants in the control group

Click or tap here to enter text.

5.7 Definition of Outcomes and how to measure it:

Click or tap here to enter text.

5.8 The Procedure (steps) of the Study:

**5.8**: Steps of performing the study.

Click or tap here to enter text.

5.9 Statistical Analysis and sample size:

**5.9**: define types of variables. What are the statistical tools used to measure p value? How are you going to show your results? … etc

Click or tap here to enter text.

1. ETHICAL CONSIDERATION

**6**: Write down the type of consent and provide a copy of it. Show how you abide by the terms of Code of ethics in research.

Click or tap here to enter text.

1. ATTACHED DOCUMENTS (Tick the appropriate box)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Participants’ Consent Form** |  | **Questionnaire & Data Retrieving form** |  | **University letter (Student)** |
|  | **Professional ID** |  | **Others:** Click or tap here to enter text. | | |

1. SIGNING A PLEDGE

We, the undersigned researcher/ researchers, pledge to:

1. Implement the research project as described in this version, and that we do not perform any changes or modifications, after it was approved by the research committee, only with the written agreement of the Research Committee in the Health Directorate that approved the mentioned project.
2. That the preliminary approval was obtained from (Click or tap here to enter text.) to undertake research in the aforementioned hospital and to take advantage from the facilities it provides to the researcher based on what is mentioned in this project, and we herein certify the validity of the signature and stamp set out paragraph (2-4).
3. That we will abide by all orders, instructions and regulatory directives issued by the management of the health institution in which the research will be implemented.
4. That we will maintain all the property of the health institution, including premises, devices, machines, tools, material and documents, and not to misuse it physically or morally, not to impede or disrupt the daily work of the institution as well while we are inside it to accomplish the research.
5. To obtain only what we are entitled to by the approval decision in order to conduct research based on the preliminary approval of the health institution in which the research will be conducted.
6. That we have read the **Code of Ethics in Research** approved by the Ministry of Health and that we will adhere to its entire provisions in all stages of implementing the research and that it is seen as complementary to the decision of the Research Committee.
7. That we will brief the health institution on the research results for the purpose of taking advantage of them.

Principal researcher's name, signature, date: Click or tap here to enter text.

Researcher's name, signature, date: Click or tap here to enter text.

Researcher's name, signature, date: Click or tap here to enter text.

Researcher's name, signature, date: Click or tap here to enter text.