***Note:***

1. *Please read and follow the guidance notes (italic font) provided at the top of each form field. Failure to comply may result in delays processing the application.*

# Title

*[Please provide the project title. The title should reflect what the proposal is all about, where, why, when, who and what is studied]*

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# **Background**

## **Literature Review**

*[Please provide a background (with cited references) describing what’s known (or not known) about the topic including definitions. In addition, include a critical review of weaknesses and gaps (in the method used, for example) in the literature reviewed]*

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## **Study Rationale**

*[Please provide a justification to undertake the study and also outline its potential value]*

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## **Study Aim**

*[State the focus of your research as concisely as possible]*

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## **Objectives**

*[Please ensure that the objectives are linked to the aim of study and follow the SMART style, preferably numbered or in bullet points. Use active verbs like identify, establish, describe, determine, estimate, develop, compare, analyze, collect, assess, measure…. etc. and refer to specific variables and outcome measures]*

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# Materials and Methods

## Details of Study Design

*[Please use the textbox below to elaborate on study design]*

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## Study Setting

*[Please provide a general description of the study place or context such as health centers (or a specific place or clinic inside), online (internet based), stored data … etc]*

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## Study Population

*[Please specify characteristics that describe your study subjects]*

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### What are the inclusion criteria for the study?

*[Please provide a list if possible]*

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### What are the exclusion criteria for the study?

*[Please provide a list if possible]*

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## Sampling

### Sampling technique

*[Please describe the sampling type(s), e.g. probability or non-probability, and technique(s) that will be used in the study. Enough details should be provided.* ***Note:*** *if you are targeting the whole study population then this section is “Not Applicable”]*

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### Sample size calculation

*[Please describe the formula used for calculation with input criteria for sample size estimation like existing prevalence rates, previous study data, pilot study results … etc.* ***Note:*** *if you are targeting the whole study population then this section is “Not Applicable”]*

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## Data Collection Methods.

*[Are any of the following involved? Please tick the appropriate checkbox box(es)]*

Stored data (Electronic Medical Records extracted by BHI)

Stored data (Electronic Medical Records extracted by Research team)

Stored data (Other databases)

Self-administered survey (Email)

Self-administered survey (SMS)

Self-administered survey (face-to-face)

Individual Interview (face-to-face)

Individual Interview (phone)

Individual Interview (video)

Group discussions/training/workshops (face-to-face)

Group discussions/training/workshops (phone)

Group discussions/training/workshops (video)

Direct observation/Video recording/tape recording

Covert observation/Covert filming/ Covert recording

Clinical (physical examination)

Non-invasive laboratory investigation

Radiological imaging/working with sources of ionizing radiation

Invasive laboratory investigation (venipuncture/tissue sampling)

Experiment (Interventions using drugs/medical products/medical devices)

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Describe the methods that will be used for data collection and its validation.

*[Please describe the data collection instrument* *and its validity for the proposed study]*

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## Describe the study’s data analysis plan

*[Please provide a summary of how the study data will be organized and list study outcomes that will be calculated. Ensure that these outcome measures are linked with study aim and objectives]*

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## Describe the quality control measures and good practices to be followed during the study

*[Provide details of control measures and good practices that are planned to monitor the safety of the subjects and the data collected. Where possible please provide . details that will be followed to assure quality research. For example, if a data monitoring and safety board be set up etc.]*

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## List and describe the variables required (Complete ONLY if stored data is required from PHCC databases)

*[Please note that only variables and timeframe mentioned in this section will be approved for extraction, based on the inclusion and exclusion criteria mentioned in section 3.3.]*

*[Provide a list of variables required and provide their details in the table below. Examples of variables and how to complete the table are provided below (blue colour text) for reference. Please delete the example text rows in blue text before submission.]*

*[Obtain SPHI department confirmation on data availability by submitting draft proposal (form F003)* [*here*](https://phcqatar.sharepoint.com/teams/PHCCKnowledgeManagement/Lists/Research%20Request%20Form/NewForm.aspx)*. Include SPHI approval reference number below]*

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| **SPHI approval reference number** |  |

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| **Time frame** | **From** dd-mm-yyyy **to** dd-mm-yyyy |

| **Variable** | **Description/ definition/ units/ time point or period** | **Data recode, if required** |
| --- | --- | --- |
| 1. Age | Age of the patient in years | 1- Below 18  0- 18 and above |
| 1. Height | Average of last 3 recorded height measurements (in cm) | No recode |
| 1. Hypertension | Was the patient ever diagnosed with hypertension (blood pressure 140/90 mmHg or higher) | 1- Yes  0- No |
| 1. Date of Diagnosis | First date when the diagnosis was recorded | No recode |
| 1. Systolic bp | Average of last 3 recorded SBP measurements (mmHg) | No recode |
| 1. Diastolic bp | Average of last 3 recorded DBP measurements (mmHg) | No recode |
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# Project Management

## Recruitment plan for prospective participants

**N/A as this is a request for stored data with no intervention or interaction with subjects and without the use of any identifiable private information or identifiable biospecimens**

**Informed consent will be obtained**

*[Please describe in detail how, where and by whom the targeted study population will be approached, whether written, verbal or electronic consent will be obtained and the steps involved in obtaining the consent,]*

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**Waiver of informed consent is requested**

All of the following study conditions must be met to request a waiver of informed consent:

* The research involves no more than minimal risk to the subjects
* The waiver or alteration will not adversely affect the rights and welfare of the subjects
* No sensitive information (drug use, history of sexually transmitted disease) will be collected.
* The research could not practicably be carried out without the wavier or alteration
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation

[*Describe how your study meets each of the regulatory requirements for waivers of consent/assent]*

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## Data Collection Procedure

*[Please describe in detail, who will be collecting the data? where the interaction with participants will take place? the expected duration of participation in the study for each participant and the process of data collection, how long data will be retained after completion of the study, withdrawal criteria]*

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## Time (When will the study be conducted?)

*[e.g., is it during working hours or shift?]*

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## Study Duration

*[Please tick the appropriate checkbox box]*

1 year  2 years  3 years  4 years  5 years  > 5 years

## Describe the role of each key personnel in the project

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| **Designation** | **Role** |
| * Principal Investigator (PI) * Co-Investigator (Co-I) * Site investigator (SI) * Research Coordinator (RC) * Biostatistician (BS) * Student Mentor (SM) * Other (O) | * Obtain informed consent (A) * Obtain data through communication or interpersonal contact or interaction (B) * Obtain private identifiable human subjects’ data or samples (C) * Obtain data through intervention (D) * Access human subjects’ medical records (E) * Other (O) |
| **Affiliation** | **Profession** |
| * Primary Health Care Corporation (PHCC) * Hamad Medical Corporation (HMC) * Sidra Medicine (SM) * Qatar University (QU) * University of Doha for Science and Technology (UDST) * Qatar Bio Bank (QBB) * Ministry of Public Health (MoPH) * Aspetar Hospital (AH) * Hamad Bin Khalifa University (HBKU) * Weill Cornell Medicine – Qatar (WCM-Q) * Doha Institute for Graduate Studies (DIGS) * Other (O) | * Physician (P) * Nurse (N) * Dentist (D) * Pharmacist (PH) * Phlebotomist (PL) * Researcher (R) * Student (S) * Other (O) |

*[Please provide details of the research team members’ role in conducting the study. Use the abbreviations provided in the table above to complete the below table for each research team member. Where ‘other’ is listed, please provide details. Examples of how to complete the table are provided below (blue colour text) for reference.* *Please delete the example text rows in blue text before submission. All research activities involving human subject interaction conducted at PHCC sites must be undertaken or supervised by PHCC staff]*

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| --- | --- | --- | --- | --- |
| **Name** | **Designation** | **Affiliation** | **Role** | **Profession** |
| John Smith | PI | PHCC | A, B, C | P |
| Joe Brown | Co-I | O – University of Oxford | E | R |

## Will the project require the usage of any materials or equipment from PHCC?

*[For example, if the study requires blood test how will the cost be covered?]*

Yes  No

*[If yes, please provide details of materials and/or equipment that will be required and how their costs will be covered?]*

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## Is there any other requirement for the project?

Yes  No  *[Please tick the appropriate checkbox box]*

*[e.g. workshops, meetings, training. If yes, will these interfere with clinic or staff duties?]*

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# Ethical considerations

*[List all possible ethical issues related to the study and the way it’s managed to reduce their risk. All completed forms should be appropriately translated into a language understood by the research participant]*

## Vulnerable population as research participants

*[Please tick the appropriate checkbox box]*

* Children less than 18 years
* Pregnant women or fetuses
* Persons with impaired decision making capacity
* Older adults more than 65 years
* Employees
* Students☐
* Other  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* N/A as this is a request for stored data and does not involve any interactions or interventions with research subjects ☐

## Describe the measures that you will take to protect any vulnerable populations in your study.

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## How is the study addressing the principle of justice?

*[How will you ensure fair subject selection for participation? Please tick the appropriate checkbox box*]

The recruitment of study participants follows strict inclusion and exclusion criteria to assure unbiassed enrollment.

The study uses some form of random sampling to assure equitable selection of prospective participants.

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## How is the study addressing the principle of beneficence?

*[How will the study minimize harm or discomfort and what possible benefits are there for participants? For example detecting a medical condition will be promptly addressed by the medical services. Please tick the appropriate checkbox box]*

Is there any direct benefit to study participants? Yes  No

Is there any potential harm to study participants? Yes  No

*Please select the type of harm to individual/ group/ society from the list below. [tick the appropriate checkbox]*

Psychological (e.g., lowered self-esteem; emotional distress; embarrassment; misperceptions of the research purpose could raise false expectations of gain to participants).

Physical (Illness/accident consequent on participation in study).

Social (Unwarranted exclusion from society; ostracised by neighbours/ friends/ family/ significant reference or peer group).

Economic (Economic deprivation as consequence of answering questions).

Legal (Legal penalties ensuing from answering questions in survey).

The study addresses sensitive topics (e.g., sexual activity or preference, drug use, mental problems, politics).

The study involves invasive, intrusive, or potentially harmful procedures of any kind.

The study may cause harm consequent on: Participation, Exclusion, or Dissemination of findings.

N/A as this study only involves request for stored data and does not involve any interactions or interventions with research subjects

***Please describe any attempts to minimize risk of potential harm and other comments in the text box below.***

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## Privacy/Autonomy of study participants

*[Explain how you will maintain privacy of study participants at all time? What options will you provide to allow participants to make voluntary decisions? Can you identify sources of undue coercion and show how to address this ethical risk?].*

*[Please tick the appropriate checkbox box and complete the box below with details]*

Privacy of a personal interview about sensitive topics is secured by keeping it exclusive to the interviewed individual.

Privacy of the participants in a personal interview is maintained by selecting their home or a private office instead of a public place. Securing a private room is a plausible alternative.

Assuring anonymous submission of surveys and questionnaires.

The study involves participants who cannot give informed written consent.

There is an existing power relationship between the researcher(s) and the participant(s) that needs to be considered. For instance, a lecturer researching his/her students, or a manager interviewing her/his staff.

The participants will be asked to confirm that they have received and read the information about the study.

The information will be provided in formats other than standard type (eg Braille, large font).

The “waiver of authorization” form was completed to allow for the use of PHI (Protected Health Information) in order to identify and recruit individuals who may be eligible to participate in the specific research

N/A as this study only involves request for stored data and does not involve any interactions or interventions with research subjects

***Please describe other plans to protect the privacy/autonomy of study participants in the textbox below.***

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## Confidentiality/Anonymity of study participants

*[How will you maintain confidentiality/anonymity of study participants? Outline all of the precautions that will be used to maintain the confidentiality of identifiable information. Who will have access to confidential research information, where will the data/specimens be stored…etc.?)]*

(Please tick the appropriate checkboxes and complete the box below with details)

A password protected computer system is used to assure secure data storage.

Only encrypted systems are used for storing research data on laptops.

A locked file cabinet is used to store research related paper forms.

Access to study data is limited to only a few members of the study team.

Plans are set to destroy all research generated data after 3 years of completion of the study according to PHCC regulations.

The study report / publication will show only aggregate results with no identifiers.

Only deidentified study data is stored.

Only coded study data is stored.

A code number is used instead of the participant’s real name on study data and blood/tissue samples.

Research generated data will be shared with a third party. In this case describe a plan to protect participants confidentiality in the textbox below.

The study requires the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g., health center manager, school principal). In this case describe a plan to protect participants confidentiality in the textbox below.

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## Engagement of targeted population/ service users/ their family and the public in developing the current study proposal

*[How will you ensure that service users, service user families and the public were provided with opportunities to be involved in the design, conduct and dissemination of research, unless otherwise justified. Examples may include polling the opinion of few service users in a health center about the logistics of the study, the data collection tool and their comprehension of the informed consent, providing the contact info of an independent body that monitors the quality of research process or to provide an opportunity for the study participants to provide feedback or raise concerns about the study…..etc.]*

*[Please tick the appropriate Checkboxes]*

The project has been discussed with those likely to be involved (including potential participants or those who may represent their views).

A formal feedback/evaluation of the proposal and/or its tools from potential participants is attached with the submission file.

The participants will receive feedback/ briefing of study findings.

The participants will receive results of tests performed as part of the study.

A provision has been made to respond to queries and problems raised by participants during the course of the study.

*[Please elaborate in the text box below.]*

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# Bibliographic References (Vancouver style is recommended)

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