***For Office Use Only –* HEC Reference:**

**Date Received: Reviewers:**

**Date Approved: Approved: (HEC Chair)**

## Human Ethics Application Coversheet – Student

Please remember that your audience for this application form, as well as all forms for participants, will include community members and scholars from outside your discipline and therefore must be written in everyday language. Please do not delete any part of this form.

This form should be completed after reading the *Research Involving Human Participants* issued by the Human Ethics Committee available at <http://www.canterbury.ac.nz/study/ethics/>

Will another ethics committee review this application?

* If a New Zealand Health and Disability Ethics Committee (HDEC) is reviewing your project, please send your HDEC application to us with this coversheet, and then the approval. You do not need to fill out the full University of Canterbury application form.
* If you have ethics approval from another institutional ethics committee (e.g. another New Zealand or Overseas University ethics committee) and you will conduct your research in the country of that ethics committee, please send this coversheet only with that application and the later approval letter, and an explanatory email. You do not, initially, need to fill out the full University of Canterbury application form.

Please ***Bold*** your answers

**Project Title: Access to primary healthcare and ambulatory care sensitive hospitalisations in the Maldives.**

**Status of Research:** **PhD in health science**

Applicant

Name: **Fazeela Mohamed**

University Programme/ Department: **Health Science**

Applicant’s Email: **fazeela.mohamed@pg.canterbury.ac.nz**

Primary Telephone No: **02108213534**

Primary Supervisor Title, given name and family name

Name: **Arindam Basu**

University Programme/ Department: **Health Science**

Supervisor’s Email: [**arindam.basu@canterbury.ac.nz**](mailto:arindam.basu@canterbury.ac.nz)

Primary Telephone No: **+64 3 369 3509**

Other Supervisors: **Wendy Maddocks**

**Health Science**

[**wendy.maddocks@canterbury.ac.nz**](mailto:wendy.maddocks@canterbury.ac.nz)

**+64 02102701241**

## Researcher’s Signature

I ***Fazeela Mohamed***have considered, the various ethical issues involved in this research and have personally completed the application form; I have discussed this proposal with my supervisor(s), and I will conduct this research within the bounds of any approval given by the Human Ethics Committee of the University of Canterbury.

Signed: **Fazeela Mohamed**  Dated: **17/05/2020**

Is the approval of this application a necessary pre-requisite for the Dean of Postgraduate Studies to formally accept your PhD proposal? **YES**/NO

## Senior Supervisor’s Signature

As the primary supervisor of ***Fazeela Mohamed*** research project I, ***Arindam Basu***consider that the design and documentation are of a standard appropriate for a research project carried out in the name of the University of Canterbury.

Signed: **Arindam Basu** Dated: **17/05/2020**

## Low Risk processes (to be completed by the primary supervisor)

*The low risk process for students differs from a full application only in that it is examined solely by the Chair of the Human Ethics Committee. As a result it may be possible to reply to the applicant in 7 days. It is to be signed only by supervisor(s).*

Please explain why the research is low risk, noting the information overleaf

*If no explanation is provided, the application will be considered a full application.*

Signed (Senior/Primary Supervisor only) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dated:

## Submission instructions.

Please submit ONE electronic file containing all the necessary documents in a PDF format and ONE fully signed hard copy. Exceptions may be made, but must be discussed first with the HEC Secretary. Processing of HEC applications is unable to begin until a hard copy of the application has been received by the Ethics Office.

Electronic copies should be emailed to [human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz).  Hard copies should be sent to the Secretary, Human Ethics Committee (Level 5, Matariki South).

Low Risk application information:

Research may be considered low risk when it arises from

a Masters or PhD theses where the projects do not raise any issue of deception, threat, invasion of privacy, mental, physical or cultural risk or stress, and do not involve gathering personal information of a sensitive nature about or from individuals.

b Masters or PhD level supervised projects undertaken as part of specific course requirements where the projects do not raise any issue of deception, threat, invasion of privacy, mental, physical or cultural risk or stress, and do not involve gathering personal information of sensitive nature about or from individuals.

c Undergraduate and Honours class research projects which do not raise any issue of deception, threat, invasion of privacy, mental, physical or cultural risk or stress, and do not involve gathering personal information of sensitive nature about or from individuals, but do not have blanket approval as specified in Section 4 of the Principles and Guidelines.

1. No research can be counted as low risk if it involves:
2. invasive physical procedures or potential for physical harm
3. procedures which might cause mental/emotional stress or distress, moral or cultural offence
4. personal or sensitive issues
5. vulnerable groups
6. Tangata Whenua (if in doubt please see the comments under question 12 on the application form)
7. cross cultural research
8. investigation of illegal behaviour(s)
9. invasion of privacy
10. collection of information that might be disadvantageous to the participant
11. use of information already collected that is not in the public arena which might be disadvantageous to the participant
12. use of information already collected which was collected under agreement of confidentiality
13. participants who are unable to give informed consent
14. conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
15. deception
16. audio or visual recording without consent
17. withholding benefits from “control” groups
18. inducements (over a nominal amount of $20, for example to recompense travel costs)
19. risks to the researcher

*This list is not definitive but is intended to sensitise the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.*

## Description of the Project

1. What does the project seek to do?

**We know from earlier research that effective primary healthcare reduces hospitalisation among patients with high blood pressure, diabetes, asthma, chronic obstructive pulmonary disease, and chronic heart failure. We know Maldives continues to provide primary healthcare services including:**

* **Health education and awareness**
* **Diagnosis and treatment and**
* **Management of disease condition**

**But we are concerned with the higher rates of hospitalisation for these conditions. There is a concern that poor primary healthcare access may be linked to hospitalisation. Therefore, I would like to study the link between transportation, travel time, and trust in provider and access to primary healthcare services; and assess the association between access to primary healthcare and risk of ambulatory care sensitive hospitalisations.**

The objectives of this research are:

**Objective 1: To test the association between transportation, travel time, and trust in provider and self-reported access to primary healthcare services in the Maldives.**

**Objective 2: To assess the association between self-reported access to primary healthcare services in the Maldives and risk of ambulatory care sensitive hospitalisations.**

1. What is the research question or hypothesis of this project?

* **Hypothesis 1: Low level of transportation, long travel time, and less trust in the provider are associated with low level of self-reported access to primary healthcare among those with ambulatory care sensitive conditions.**
* **Hypothesis 2: Individuals with low level of self-reported access, when compared with those with high level of access to primary healthcare have high risk of ambulatory care sensitive hospitalisations.**

1. Describe how this project arose i.e., please explain the academic area or issue etc. which generated the question(s) to be examined – this is to allow lay members of the committee some context for the research.

**Ambulatory care sensitive hospitalisations are diseases that can be managed in the outpatients and community setting. These diseases include asthma, chronic obstructive pulmonary disease, diabetes, chronic heart failure, and hypertension.**

**Hospitalisation due to these diseases is a growing problem in the world, regardless of countries with developed or developing health care systems. To illustrate, ambulatory care sensitive hospitalisations accounts for higher levels of hospitalisations in the Maldives compared with other island nations (36% of total hospitalisations in 2016 in the Maldives compared with about 24-25% in NZ, the UK, and Singapore).**

**These hospitalisations are preventable or avoidable where the setting of avoidance is in the primary healthcare. Theoretically, in a healthcare system that has high rates of ambulatory care sensitive hospitalisations indicate that people in that system have low levels of primary healthcare access and usage, or that the system fails to meet the needs of people to provide these services or both. In any case, patients have low levels of access to primary healthcare in the community.**

**Primary healthcare based interventions are effective in reducing ambulatory care sensitive hospitalisations; while primary healthcare in the Maldives continue to provide these interventions, it remains to be explained relatively higher rates of ambulatory care sensitive hospitalisations in the Maldives.**

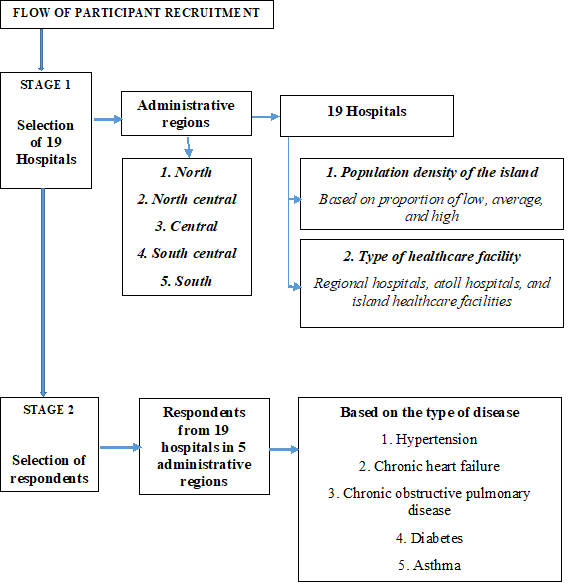
**Island nations such as the Maldives have physical access barriers to healthcare services. Besides, in the Maldives, people also do not trust healthcare providers. As a result in the Maldives and likely in similar island countries, transportation, travel time, and trust are factors that possibly explain the variation in primary health care access.**

1. How will you go about answering the research question?

**The association between transportation, travel time, and trust in provider and self-reported access to primary healthcare services in the Maldives will be tested by cross-sectional survey. Following the cross-sectional survey, a measurement will be constructed as to how people were able to access primary healthcare. This will be achieved by using a median cut-off score to define low verses high self-reported access. This measurement low and high level of self-reported access will be used to assess the association between self-reported access to primary healthcare services in the Maldives and risk of ambulatory care sensitive hospitalisations. This will be done on the basis of a case control study.**

## Information about the Participants

1. Who are the participants and why have they been chosen to be asked to participate?

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**Selection of hospitals:**

**A total of 184 public hospitals were identified from twenty atolls of the Maldives, clustered into six administrative regions. These include Male', north, north central, central, south central, and south regions. Male' region was excluded from the study since major health care facilities (tertiary health care facilities) are located in capital city Male'.**

**Nineteen hospitals of primary units were estimated in a convenience proportion of 1:10. This is above 10% of total hospital units. It is to include maximum number of hospitals resources may allow, particularly funding. Also, this is to draw an operationally manageable sample; and for feasible, timely, and cost effective data collection. Hospitals were selected based on population density of the islands and hospital type.**

**Population density of the islands were based on the proportion of low, average, and high populations in the region. Low populations were over sampled for the primary units due to great differences in number of people living in these islands, in comparison to islands with high populations. For example: In upper north, high category - Kulhudhufushi has a population of 9366, in comparison to low category - Hirimaradhoo 540.**

**Hospitals in islands with populations above 5000 were considered for the high population category from each administrative division. These hospitals include: Kulhudhuffushi regional hospital, Naifaru atoll hospital, Gan regional hospital, and Hithadhoo regional hospital. Since islands of central region have populations below 5000, no hospital was selected for this category.**

**Hospitals in islands with populations from 1000 to 5000 were considered for average population category from each administrative division. These hospitals include: Dhidhdhoo atoll hospital, Un'goofaaru regional hospital, Rasdhoo atoll hospital, Veymandoo atoll hospital, and Viligili atoll hospital.**

**Hospitals in islands with populations below 1000 were considered for low population category from each administrative division. These hospitals include: Utheemu health centre, Hirimaradhoo health centre, Fainu health centre, Olhuvelifushi health centre, Mathiveri health centre, Felidhoo health centre, Kan'doodhoo health centre, Mundoo health centre, Kodey health centre, and Kandhuhulhudhoo health centre.**

**In selecting the population density proportions, the following were taken into consideration:**

* **Populations relocated to other islands under population consolidation program,**
* **Populations displaced to other islands due to tsunami,**
* **Newly inhabited islands under population consolidation program, and**
* **Populations inhibited in islands given for agricultural, industrial and tourism purposes.**

**Hospital types were categorised into regional, atoll and island health centres. Regional and atoll hospitals belong to secondary care. Four regional hospitals were selected from north, north central, south central, and south region. These include Kulhudhuffushi regional hospital, Un'goofaaru regional hospital, Gan regional hospital, and Hithadhoo regional hospital. Five atoll hospitals were picked from all administrative divisions excluding Male'. They were Dhidhdhoo atoll hospital, Naifaru atoll hospital, Rasdhoo atoll hospital, Veymandoo atoll hospital, and Viligili atoll hospital. 10 health centres from all regions were added to the sample. These include Utheemu health centre, Hirimaradhoo health centre, Fainu health centre, Olhuvelifushi health centre, Mathiveri health centre, Felidhoo health centre, Kan'doodhoo health centre, Mundoo health centre, Kodey health centre, and Kandhuhulhudhoo health centre.**

**Selection of respondents:**

**Patients diagnosed with hypertension, chronic heart failure, chronic obstructive pulmonary disease, asthma, and diabetes will be selected for the research. These patients will be registered in the above 19 hospitals. The number of patients from a particular hospital will be proportionately allocated based on the number of patients in that region and hospital.**

1. How many participants will be involved (of each category where relevant)? Please include statistical justification where necessary.

***Respondents for cross-sectional study:* A population of 71940 was estimated to have diabetes, chronic obstructive pulmonary disease, asthma, and cardiovascular diseases in the Maldives. The estimated sample size was derived by computing a minimal sample size required for accuracy on OpenEpi website. A sample of 450 was estimated with a confidence level of 95% and power 80% with prevalence odds ratio of 2 assuming that those with low levels of transportation, long travel time, and less trust in the provider are two times more likely to have low level of access to primary healthcare. An additional 20% samples were added assuming that not every potential respondent will participate in the study. This rounds to a figure of 540 samples.**

**The sample units for the administrative regions will be proportionately allocated based on the number of patients with these diseases (identified from the hospitals from that particular region).**

***Respondents for case control study:* The cases for case-control study will only be patients with ambulatory care sensitive conditions hospitalised for consequences of these conditions. These patients include those who has been hospitalised due to deteriorated health conditions related to given diseases. All acute episodes will be excluded from the study. The controls for case-control study will be patients with ambulatory care sensitive conditions not hospitalised for consequences of these conditions. These two categories of patients will be identified from the cross-sectional survey.**

**The maximum number of cases identified by cross-sectional survey will be studied in a ratio of 1:1 with controls that will also be identified from the cross-sectional study.**

1. What selection criteria and/or exclusion criteria will you use? i.e., randomly, by age, gender, ethnic origin, other – please give details. What plans do you have if the recruitment phase is too successful, or does not recruit enough participants?

**The study population will be situated in the Maldives. Population aged 20 years and above diagnosed with hypertension, chronic obstructive pulmonary disease, chronic heart failure, asthma, and diabetes from five regions of the Maldives has the probability of inclusion in the sample. Individuals aged below 20 years will be excluded from the study. Individuals with hypertension and diabetes only during pregnancy; and asthma only during childhood will be excluded from the study. Because these diseases are temporary diseases and does require life-time treatment. The data requires participants to recall past incidents, patients diagnosed with cognitive disorders and mental retardation will be excluded from the study. Patients admitted in rehabilitation centres and institutionalised populations such as military bases and prisons will be excluded from the study due to restrictions in paperwork that may apply. Populations living in foreign countries at the time of survey will be excluded from the study due to difficulties that might arise in reaching and communicating with them. These populations will be given a final weight of zero. They would not be counted for weighted estimates.**

Plan if the recruitment phase is too successful**: Respondents will be selected randomly from the pool of patients who show interest to participate in the survey. Those not selected will receive a letter of appreciation by the research team.**

Plan if the recruitment phase does not recruit enough participants**: It is assumed that not every potential respondent will participate in the study. Therefore, 20% were added to the sample size.**

1. Describe how potential participants will be identified and recruited?

**The project requires approval from Ministry of Health to contact the patients diagnosed with ambulatory care sensitive conditions. All island hospitals are under Ministry of Health. Therefore, no separate approval is required from island hospitals.**

**Approval from Ministry of Health is contingent upon receiving University of Canterbury Ethics Committee approval. A separate ethics application is not required from the Maldives. This is because University of Canterbury falls under the Association of Commonwealth Universities.**

**Following ethics approval, a formal online request will be mailed to policy planning and international health division of the Ministry of Health. This is to identify the pool of patients diagnosed with these conditions and to obtain permission to contact these patients. Once approved, Ministry of Health will inform the patients about the research through island hospitals. Island hospitals will provide information sheet to all potential participants.**

**Any potential respondent willing to participate will share the contact details with the researcher. From this pool of patients, respondents will be selected randomly through lottery. All patients selected via lottery will be contacted to participate voluntarily in a survey via face-to-face. Others will receive a letter of appreciation from the research team.**

1. Does the project involve recruitment through advertising? **NO**
2. How much time are participants asked to contribute to the research?

**30 minutes**

1. Is any form of inducement to be offered? **NO**
2. How will the participants be treated? Describe in practical terms how the participants will be treated, what tasks they will be asked to perform, etc. Indicate how much time is likely to be involved in carrying out the various tasks.

**Island hospitals will provide information sheet to all potential participants. The information sheet will let the participants know that**

* **They will receive a call by the researcher to arrange a suitable date and time for interview.**
* **They will be answering a set of questions.**
* **They will take 30 minutes of their time to answer the questions.**
* **Standardized precautions will be taken to ensure their safety. These include:**
  + **Prior to the interview, researcher will have a telephone conversation with them. They will be asked if they are unwell, travelled overseas recently, or been in contact with anyone that is suspected to have, or has had Covid-19.**
  + **At the time of face to face interview, the interviewer and they will be separated by a distance of 1 meter.**
  + **Interviewer will wear face mask at all times during interview.**
  + **They will be advised to use face mask. Hand sanitiser will be provided in any case they requests for it. These will be provided by the researcher.**
* **Their participation is voluntary and they have the right to withdraw before commencement of the interview and during the interview. If a participant withdraw during the interview, interviewer will remove the information relating to him/her. Once the interview is complete and entered to the system it will remain anonymous. Therefore, research team will be unable to locate his/her specific information and delete it.**
* **Their information will be stored securely in an electronic format, and research team will make sure his/her identity is not revealed to anyone and all information he/she share with the research team will remain confidential. Any information they provide will be used for research only.**
* **If they become concerned about their condition, research team recommends to discuss this with their primary provider.**
* **The results will be published as a doctoral thesis. The electronic version of the thesis is a public document and will be available free of cost through University of Canterbury Library. As participant’s information is collected anonymous his/her contribution will not be identified. The information they provide will be stored for next 10 years.**
* **If they have any questions, they can contact me Fazeela Mohamed and my supervisory team Arindam Basu and Wendy Maddocks by the addresses and contact numbers provided on the information sheet. We will be pleased to discuss any concerns they may have about participation in the project.**

**Respondents willing to participate in the research will share their contact details with the researcher. From this pool of patients, participants will be selected randomly through lottery. Those not selected through the lottery will receive a letter of appreciation by the research team.**

**Those patients selected via lottery will be contacted to participate voluntarily in the survey. The researcher will contact them over phone to arrange a time of interview. If a respondent is a ‘non-contact’, then the lottery process will be repeated till 540 samples are collected. Researcher will make up to four calls on different hours of the day and on different days of the week to decide a potential participant is a 'non-contact'. Researcher will first make two calls. If a potential respondent is not able to be contacted, she will make another call after two weeks gap. This will be followed until fourth call is over. The initial two calls would be recorded between at least four hours of gap, to be considered as a new event. This will help to contact the potential participants who might not be in the island or in contact at the initial call for data collection.**

**Field workers who will collect data from the respondents will be from same atoll but different island to lessen the issues around anonymity, beneficence, and comfort of the participants. These field workers will travel between islands by atoll ferry. The ferry services are available during the day and vary between 5 to 7 days a week depending on the island. This will be considered in arranging a suitable time and date for interview. It is to control the costs of the research. In case of extreme weather condition and rough sea, interview may have to be postponed to a different date and time. This is for safe travel between islands.**

**The interview will be in-person in a suitable public place at his or her island. The participant will decide the interview spot that he/she feels safe and comfortable.**

**During the interview process field workers will strictly treat the participants ethically and equally. The field workers will keep appropriate pace, and the respondent focused to complete the questionnaire within the timeframe. Field workers will apply same standardised technique in asking the questions. Field workers will instruct the participants what type of questions will be asked in each section prior to answering every section of the questionnaire. Field workers will instruct the participants to take time before answering questions and to provide accurate response to the best of his/her of knowledge.**

1. Will forms for participants need to be translated? **YES**  If yes, what language?

**A semi-structured questionnaire will be delivered in English and Dhivehi languages. The questionnaire translation will be carried out by 2 lecturers of Faculty of Arts of the Maldives National University. The researcher will compare the original English version and the translated version and the process will be repeated till maximum match is achieved.**

1. Will the project require engagement and consultation with iwi Māori? **NO**

• Will the design, implementation or outcomes of the project have implications for iwi Māori?

• Will there be significant Māori content, use of culturally sensitive material or knowledge?

• Will the research require access to Māori sites, or sampling of flora/fauna?

• Will there be Māori participants or subjects?

• Will the ethnicity of participants be recorded and likely to result in different treatment for Māori participants during the study or result in statements specifically about Māori in the results?

*If the answer is yes to any of the questions above, you should contact your College’s Māori research advisors. Contact details for the Maori advisors in your College and other important information and advice regarding engaging with Māori are available at* <http://www.research.canterbury.ac.nz/maoriresearch/ntceg.shtml>

*The advisor will be able to help you assess whether you need to seek further consultation and engagement, and whether you need to contact the Kaiārahi Maori research in order to access the Ngāi Tahu Consultation and Engagement Group. Should you have already organised a Māori steering group/senior Māori advisor to work with you on your project, please check with them on the need for consultation.*

## Other parties with an interest in the research

1. Does the project require permission of an organisation, other people, to access participants or information? **YES** e.g., parents, guardians, school principals, teachers, boards, responsible authorities including employers, etc. If yes, please explain how this approval has been or will be obtained, enclosing copies of relevant correspondence. *Please ensure forms make the employers/organisations aware that even once they have given permission in principle to give you access to participant information, they will not be able to provide this until you have obtained agreement from the participants themselves.*

**The project requires approval from Ministry of Health to contact the patients diagnosed with ambulatory care sensitive conditions. All island hospitals are under Ministry of Health. Therefore, no separate approval is required from island hospitals.**

**Approval from Ministry of Health is contingent upon receiving University of Canterbury Ethics Committee approval. A separate ethics application is not required from the Maldives. This is because University of Canterbury falls under the Association of Commonwealth Universities. Following ethics approval, a formal online request will be mailed to policy planning and international health division of the Ministry of Health. This is to obtain permission to contact the patients.**

**Once approved, Ministry of Health will inform the patients about the research through island hospitals. Island hospitals will provide information sheet to all potential participants. Any potential respondent willing to participate will share the contact details with the researcher.**

**If in any case, Ministry of Health denies, I will discuss with my supervisory team and come up with a second plan.**

1. Will the project require Community consultation? **NO** i.e., will it involve largely one community or that community’s resources, or is it likely to result in different treatment for a community or result in statements specifically about a community in the results (e.g., a geographically bounded community, a community of like-minded individuals, a community of hobbyists, employees)? A useful, though not exhaustive test of whether a community ought to be consulted, is whether that community has a leadership group that can be consulted. Once approvals are obtained please forward copies to HEC. *Please note: the HEC understands that in many cases consultation is informal, and does not produce official approval documents. In such cases, simply note with whom consultation has taken place, why it is those particular bodies, and include their contact details of those with whom you have consulted.*
2. Is the project funded externally? **NO**. If yes, please provide details and discuss any conflict of interest issues that may arise.
3. Is the project commissioned by or carried out on behalf of an external organisation(s)? **NO.** If yes, please identify the organisation(s) andany Intellectual Property agreements. This includes ownership of data, results and publications.
4. Is the project to be part of the CEISMIC digital archive? **NO** If so, please ensure all participants are made aware of this, and have filled in the UC CEISMIC Quake Studies consent form. See [www.ceismic.org.nz](http://www.ceismic.org.nz).

## Data collection

1. Does the project involve a questionnaire? **YES - the project involves a semi-structured questionnaire.** If yes, please include a copy. The HEC does not normally approve a project which involves a questionnaire without seeing the questionnaire, although it may preview applications in some cases where the production of the questionnaire is delayed for good reason. If there is a questionnaire please answer the following questions:

**The project involves a semi-structured questionnaire. The semi-structured questionnaire will be delivered in English and Dhivehi languages. The questionnaire translation will be carried out by 2 lecturers of Faculty of Arts of the Maldives National University. The researcher will compare the original English version and the translated version and the process will be repeated till maximum match is achieved.**

**The delivery of questionnaire will only be by face-to-face. All answers will be entered directly to computer or tablet during face-to-face interview. No interview will be carried out by telephone. If a respondent chooses to be interviewed in English language, the answers will be entered directly to Qualtrics. If a respondent chooses to be interviewed in Dhivehi language, the questionnaire will be in Excel format. Therefore, answers will be entered to spreadsheet by the interviewer. This information will be later transferred to Qualtrics by the researcher.**

**Note:**

**A copy of this questionnaire is provided with this form. The questionnaire will be entered to Qualtrics following the final comments and suggestions provided by ethics committee.**

1. Explain how and why the questionnaire(s) will be anonymous or confidential (Anonymous: you could ***not*** conceivably know who completed it; Confidential: not anonymous, but you will not reveal the identity of the participants to anybody outside the research team)

**The identity of the participant will be kept confidential. Participant’s identity will not be shared even with the supervisors. Each participant will be given a study code at the interview process. Patient’s identification, this includes name and contact details will not be entered to Qualtrics or Excel sheet. Therefore, this study code will have no link to patient’s name or contact details. Any information given by the participant will be entered under this particular study code. Therefore, the information given by the participants will remain anonymous, once the data is entered in the system. This data will only be accessible to researcher and supervisors.**

1. Explain how the questionnaire will be distributed and collected.

**The questionnaire will be interviewer-administered. It will be by face-to-face. This will be carried out by three field workers who will be directed by the researcher.**

***Note: The field workers will be selected from the pool of field workers who collected national demographic and health survey 2017 data and national tobacco control 2018 data. They will not have any direct link with Ministry of Health and island hospitals. They will undergo an interview process prior to selection. Field workers will receive training on how to conduct the survey. This includes questionnaire administration, communication, entry of responses to laptop computer or tablet, cultural competency, and field procedures. Training will be targeted to familiarise field workers with the questionnaire. Demo presentations and field practice by each field worker will be carried out to ensure that they are prepared for field work. This will also minimise the differences in responses by applying same standardised technique in asking the questions.***

1. Does the project involve a structured or semi-structured interview? **YES semi-structured interview**. If yes, please list the topics or the specific questions to be covered.

* **Demographics**
* **Health information**
* **Information about hospitalisation**
* **Health service utilisation**

1. Does the project involve an unstructured interview? **NO**. If yes, please list the topics to be covered.
2. Does the project involve focus groups? **NO.** If yes, please include a copy of the confidentiality agreement all participants will sign or explain the way that you will protect the confidentiality of participants.
3. Does the project involve recording of Audio, Video or Images? **NO.** If yes, please explain the purpose and describe the recording. Please ensure information sheets fully inform participants of the extent and nature of the recording, and explain the legal and ethical issues of ownership of these recordings and how you have resolved them.
4. Will participants will be given the opportunity to check the transcript and/or notes of their interview/focus group? **YES** **– It is a semi-structured interview. The field workers will go through the answers with the respondent on interview spot. Participant will be given the opportunity to change any answer or delete any entry before interviewer completes the interview.** It is normal practice to give participants the opportunity to review their transcription. If this is not to be the case, please explain why you believe it is not necessary. Participants must be informed of interview recording both in the information sheet and at the time of the recording, and the process by which they can review the related transcription. *Please note that transcripts of focus groups may raise privacy issues (particularly if the participants are children, since other parents will see comments by children who are not their own).*

**It is a semi-structured interview. The field worker will go through the answers with the respondent on interview spot.**

## Informed and Voluntary Consent

Please note: The HEC recommends that participants receive an information sheet, which they must be able to retain, unless there are good reasons for not adopting such a procedure.

The information sheet(s) and the consent form(s) should be separate. Projects which **only** involve an anonymous questionnaire may not necessarily require a separate information sheet, provided that the questionnaire includes your name and contact number as well as the other points contained in the information and consent templates available on the HEC website. *Please note: so that participants can retain a copy of the information sheets, the information sheet(s) and the consent form(s) should be separate.*

1. By whom and how will information be given to potential participants? Please attach a copy of the information sheet and consent form (if email/internet, please provide a screen shot), or the oral briefing script. Also, please set out in precise detail the processes used to obtain consent, and ensure that those processes allow the participant the opportunity to say no or withdraw without stress, embarrassment or difficulty. Where you do not intend to gain written consent, (i.e., where you will rely on oral consent etc.) please justify and explain how you will gain consent.

**The island hospitals keep a record of patients diagnosed with ambulatory care sensitive conditions in every island. These island hospitals will share information sheet with all patients diagnosed with these conditions. The information sheet will let know the participants that**

* **They will receive a call by the researcher to arrange a suitable date and time for interview.**
* **They will be answering a set of questions.**
* **They will take 30 minutes of their time to answer the questions.**
* **Standardized precautions will be taken to ensure their safety. These include:**
  + **Prior to the interview, researcher will have a telephone conversation with them. They will be asked if they are unwell, travelled overseas recently, or been in contact with anyone that is suspected to have, or has had Covid-19.**
  + **At the time of face to face interview, the interviewer and they will be separated by a distance of 1 meter.**
  + **Interviewer will wear face mask at all times during interview.**
  + **They will be advised to use face mask. Hand sanitiser will be provided in any case they requests for it. These will be provided by the researcher.**
* **Their participation is voluntary and they have the right to withdraw before commencement of the interview and during the interview. If a participant withdraw during the interview, interviewer will remove the information relating to him/her. Once the interview is complete and entered to the system it will remain anonymous. Therefore, research team will be unable to locate his/her specific information and delete it.**
* **Their information will be stored securely in an electronic format, and research team will make sure his/her identity is not revealed to anyone and all information he/she share with the research team will remain confidential. Any information they provide will be used for research only.**
* **If they become concerned about their condition, research team recommends to discuss this with their primary provider.**
* **The results will be published as a doctoral thesis. The electronic version of the thesis is a public document and will be available free of cost through University of Canterbury Library. As participant’s information is collected anonymous his/her contribution will not be identified. The information they provide will be stored for next 10 years.**
* **If they have any questions, they can contact me Fazeela Mohamed and my supervisory team Arindam Basu and Wendy Maddocks by the addresses and contact numbers provided on the information sheet. We will be pleased to discuss any concerns they may have about participation in the project.**

**Any patient willing to participate will share the contact details with the researcher. From this pool of patients, respondents will be selected randomly through lottery. All patients selected via lottery will be contacted to participate voluntarily in a survey via face-to-face.**

**Prior to answering any question at the interview process, the field workers will give time to ask questions about the information sheet respondents have received by island hospitals. Field workers will answer any question respondents have. Field workers will make respondents aware that they can withdraw from the survey at the commencement of interview and during the interview process; do not have to answer every question; can ask questions about the study at any time; and contact the researcher for further information. Field workers will inform the participants that once the information is entered into the system, it will remain anonymous. Therefore, researcher will be unable to locate and delete a particular participant’s information. Once field workers clarify any doubts or questions about the survey, they will obtain consent from the participants. Participants will sign the consent paper prior to answering the questions. The field worker will photograph the signed consent form and upload to the system on interview spot. The participant will be given the hardcopy of the consent form.**

1. Are all participants competent to give consent on their own behalf? **YES** As a rule, children and young adults under the age of 16 years (or 18 years if still at school) will require parental consent to participate in your research, as do adults who have impairments that limit their capacity to represent themselves. All such participants unable to give consent should still receive a suitable information sheet and assent form where practicable. It is possible in some cases that respect for the autonomy will override concerns over ethical and legal competency, but these are rare and require much justification, and usually only arise in the context of a general community approval to waive competency requirements.

If no, please explain,

1. why they are not competent to give informed consent on their behalf?
2. how consent will be obtained in the absence of that competency?
3. if applicable, how will assent to participate be gained?

## Privacy and Confidentiality

1. Will information pertaining to or about the participants be obtained from any source other than the participant? **NO – No third party involved** If yes please state:
   1. The identity of the third party or parties.
   2. Why such information is needed.
   3. How will you obtain consent from the participant and the third party/parties) to gather that data. Please ensure the information sheet is very clear about any data gathered about participants from third party participants, and how you intend to gain permission to see the data.
   4. The processes you will use to obtain that data. If you are using recruitment strategies that access potential participants via a third party please discuss your specific methods here. In general, it is not legal for your participants to give private contact details of other people to you. Usually, should you wish to snowball recruit, you should give your participants an information sheet or advertisement that they can give to others, in the hope that those third parties will then contact you.

It may happen that by virtue of your job, you have right of access to information concerning the participants. Where information has been collected from individuals for a purpose other than your research, it is probable that potential participants will need to be informed that their agreement to participate may involve such use. Guidance on privacy can be found in the policies of the University, and on the website of the Privacy Commissioner.

1. Is information that identifies participants to be given to any person outside the research team, or if identification of or attribution of comments by participants is sought, please explain how and why. **NO**. If yes, please explain how and why and include this in the information and consent forms.
2. Please explain how confidentiality of the participants’ identities will be maintained in the treatment and use of the data. e.g., the HEC expects that researchers will attempt to ensure that stored data is separated into identifying data (e.g., consent forms, coding forms), and de-identified (e.g., coded data, de-identified transcripts): typically this is done by assigning participants a code on the consent form, and using that code on any data, transcripts, etc. Where this is too difficult, please explain why. Backups of the data should be stored on the UC server.

**Confidentiality will be assured by using participants study codes on all documents.**

**The identity of the participant will be kept confidential. Participant’s identity will not be shared even with the supervisors. Each participant will be given a study code at the interview process. Patient’s identification, this includes name and contact details will not be entered to Qualtrics or Excel sheet. Therefore, this study code will have no link to patient’s name or contact details. Any information given by the participant will be entered under this particular study code. Therefore, the information given by the participants will remain anonymous, once the data is entered in the system. This data will only be accessible to researcher and supervisors.**

1. Is an institution (e.g., school, business, etc.) to which participants belong to be named or be able to be identified in the publication or presentation of this project? **NO.** If yes, please explain whether you have made the institution aware of this or why you have decided not to do so.
2. Where will the project be conducted? It is recommended that interviews be conducted in public spaces, not in private homes. *The committee appreciates that in some cases there may be good academic reasons for conducting research in private homes. If you believe this applies to your project, we ask you to provide (a) a concise justification of why research in the home is necessary for your project, what alternative locations were considered, and why they were discounted, and (b) detail how you anticipate and will seek to mitigate potential risks to both participants and researchers when undertaking research in a private home(s).*

Please note: in the case of research involving children, young adults and participants who need particular care, an adult other than the researcher is required to be present.

**This survey is only going to be conducted in a public place in respondent’s island. No survey will be conducted in a private home. The participant will decide the interview spot that he/she feels safe and comfortable. This can be a park, jetty area, or café.**

## Risk

If the answer to any of the following questions is “Yes”, please indicate briefly the nature of the risk and what actions you could take, or support mechanisms you could rely on, if a participant should become injured, distressed or offended while taking part in this project. In order to maintain a distinction between the researcher and other roles, support should not be undertaken by researcher. At the very least, a list of support services should be included in the information sheet and also participants made aware of the possibility in the information sheet.

1. Is there any risk to physical well-being? **NO**. If yes, describe processes in place to mitigate this/these risk(s).
2. Could participation involve mental stress or emotional distress? **NO**. If yes, describe processes in place to mitigate this/these risk(s).
3. Is there a possibility of causing moral or cultural offence, inadvertently or otherwise? **NO.** If yes, describe processes in place to reduce the possibility of causing such offence, and any consultation/awareness training undertaken.
4. Is deception involved at any stage of the project? **NO.** If yes, please describe the deception, justify its use.

Please note: the HEC considers the use of title in the documents for the participants that is designed to hide the real aim of the project, a deception however mild.

Please attach the debriefing sheet or script that you will use to debrief each participant after they have participated in the project or at the end of the project itself. Ensure that the debriefing sheet includes an explicit reminder that the participant can withdraw without penalty given the deception involved.

1. If yes, please describe the deception, justify its use and attach the debriefing sheet or script that you will use to debrief each participant after they have participated in the project or at the end of the project itself. Please ensure that the debriefing sheet includes an explicit reminder that the participant can withdraw without penalty given the deception involved. The use in the information sheet or consent form or questionnaire of a title that differs from the project title given in this application form, in order not to reveal the real aim of the project, is considered to be a form of deception however mild.

## Data Storage and Future use

1. Please provide details of how the data will be securely stored, and how you will separate identifying and non-identifying data. i.e., what steps will be taken to ensure that information given by participants is safe and protected? All storage facilities including electronic equipment should be in rooms that can be locked. All data should be stored in password-protected files and, where on computers, the computers should be password protected. Data should be backed up or stored on the University servers. If you intend to store the data in cloud services please provide a justification and documentary proof that the data will be secure (e.g., relevant sections of the terms of service of the provider).

**Data will be collected electronically. Electronic data will be password protected. It will be stored in cloud storage services via university server. To prevent accidental loss, back-up data will be stored on transportable media such as flash memory and external hard drives. This will be stored securely in separate lockable cabinets given for individual PhD students.**

1. Who, apart from the researcher and their supervisor (where applicable) will have authorised access to the data? Research Assistants and transcribers need their own confidentiality forms and their participation needs to be made known to participants.

**Field workers for interview process. Field workers will sign confidentiality agreements prior to data collection. The field workers will not be selected from the same community. They will be selected from a different island.**

1. What will happen to the raw data at the end of the project? Standard HEC principles are that data from research projects will be kept safely and then destroyed as follows:
2. At the completion of an Honours or similar project
3. After 5 years for an MA
4. After 10 years for a PhD or staff research

Please discuss and justify any variations to these guidelines that your project requires (for instance, if the data is to be kept permanently).

This information should be contained in all information sheets and consent forms.

**Data will be stored for ten years.**

1. What plans do you have for the publication of the data? Please note, and include in your information sheets, that Master’s thesis and PhDs are public documents available via the UC library database. Also, participants should be offered summary of results.

**Research will be published in the form of a thesis.**

1. Please describe plans for future use of the data beyond those already described above.

**Journal publications**