**Appendix 1: Shows the principles of self-administered questionnaire.**

**Participant Information Sheet - Phase1**

#### Lesson Plan for Questionnaire Administration Procedure

**Lesson Title:** Principles of self-administered questionnaire related to a pilot study **Date:** 2nd week of October 2015

**Presenter**: Waleed Al Rajhi

**Rationale:**

This is a 2-3 hours session is designed for the key individuals (nephrology nurses) from hemodialysis units, Oman, whom agreed to assist in conducting the pilot study which is a part of main study of Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: meaning, level and predictors within an Omani Context. It is presented very much as a practical introduction to the assistants and consists of a mixture of a series of short lectures interspersed with practical activities. The areas of discussion will include aims and objectives of study, consent form, and principles and procedure of administering the questionnaire.

**Prescribed Learning Outcome(s):**

Attendants will be able to:

1. Administer effectively the study questionnaire pertaining to phase 2 of Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context.
2. Maintain confidentiality and sounds ethical principles throughout the process of administering, following-up, and collecting back the questionnaires.
3. Respond to participant’s enquiries that might arise related to study questionnaire.

**Instructional Objective(s):**

At the end of this session, attendants will be able to:

1. Gain an insight into the aims and objectives of the pilot study
2. Understand and practice the method for obtaining consent form related to the pilot study
3. Understand and practice the method of self-administered questionnaire
4. Understand and practice the method of following-up and handling questionnaire after completion by participants
5. Recognize and discuss the special issues that might arise in self-administered questionnaire.

**Prerequisite Concepts and Skills:**

It is essential for nurses who will assist in administering the study questionnaire that have/are: self-interest to assist; qualified nephrology nurses registered at Ministry of Health, Oman; permitted by authorities of hemodialysis unit; and their participation would not negatively affect their clinical role and tasks.

**Materials and Resources:**

|  |  |
| --- | --- |
| Presenter | **Attendant** |
| Sample of the study questionnaire Flip chart  Laptop  Overhead projector | Notebook and pencil |

**Lesson Activities:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Presenter Activities** | **Attendant Activities** | **Time** | **Venue** |
| 1. Introduction to the study aims and objectives 2. Discussion on ethical principles applied to the study 3. Demonstration for obtaining consent form 4. Demonstration of questionnaire administration 5. Discussion and distribution of the key instructions to administer a questionnaire 6. Wrap-up | 1. In all the activities, attendants are expected to engage in discussion and enquire about aspects that are not clear. | 09-12  am | Dialysis unit: Seminar room, meeting room. |

**Key Instructions to Administering Pilot Study Questionnaire**

1. Participant should complete the questionnaire independently without assistance from health professionals or family members. If the patient is unable to complete/read the questionnaire themselves, the questions can be read out for them and/or their responses recorded. The questionnaire is designed to assess the patient’s perception so their answers should not be influenced in anyway.
2. Ensure that consent form has been signed and handed over along the questionnaire.
3. Express the importance of the research that they are contributing to, and that the answers they give on the questionnaires may be an important contribution to the health of others.
4. Emphasize that the questionnaire’s scientific value is contingent on carefully and thoughtfully given answers.
5. The questionnaire must be completed with a dark blue or black pen.
6. Tell the participant that if they have any uncertainty about how to answer a question, they should select what they think is the most appropriate answer.
7. Remind the participant to answer all of the questions.
8. Instruct the participant on how to correct mistakes, if necessary, by crossing out the wrong answer, filling in the correct answer, and circling the correct answer.
9. Thank the participant for completing the questionnaires.
10. REMEMBER: confidentiality is vital throughout the process. Quality assurance of the self-administered questionnaires
11. Before participant leaves the hemodialysis unit, a quality assurance check of the questionnaire must be done. Remind the participant with the following items:
12. Completeness: that all questions have been answered.
13. Accurate identification: make sure that the questionnaire has a printed code on the cover page.
14. Coherence: that only one answer is given for each question. If the participanthasmadeanycorrectionsonthequestionnaire,tosurethatthe intended answer is clearly marked.

**Resources for additional information**

If you have questions related to this or during the questionnaire administration, please contact Waleed Khalid Alrajhi (Researcher) through telephone number: 00968 99636344 Alternatively, You may contact the Study supervisor on0096899885711, who will be happy to discuss it with you.

**Appendix 2: Shows the participant information sheet-phase 1.**

**Participant information sheet– Phase1**

**Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: Meaning, level and predictors within an Omani Context**

You are being invited to take part in a research study that will assess quality of life (QoL) and health related quality of life (HRQoL) in patients with end stage kidney disease (ESKD) in an Omani context. Before you decide to take part, it is important that you understand firstly why the research is being done and what it will involve. Please take time to read the following information, and carefully consider whether you want to take part. Please ask the researcher or nurse involved in this study if there is anything that is not clear or if you would like more information.

**Aim**

The aims of this phase are to explore your thoughts about quality of life, and to identify the areas of life which are most important to you and rate your level of satisfaction with each of them. This phase of the study will help the researcher to explore the understanding of the meaning of quality of lifeline Omani context. This will then inform the next phase of the study in terms of ensuring that we use the appropriate study questionnaires suitable to Omani patients.

**Why have I been invited?**

You are being asked to participate as you are an adult with ESKD and on hemodialysis therapy on a regular basis. Your dialysis nurse has identified that you are eligible to participate in this study. I hope that 12 patients will agree to take part in this study.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical or nursing care.

**What will happen if I agree to help?**

If you agree to take part in this study, it will involve you completing two questionnaires related to quality of life during an interview while your presence in dialysis unit for your regular hemodialysis sessions. You are required to think out loud while completing the questionnaires, and following the completion of items/questions, I will explore the basis of your answers. I might also ask you to nominate the areas of life which are most important, rate your level of satisfaction with each, and indicate the relative importance of each to your overall quality of life.

The time is expected to finish the interview around one hour. The interview will take place in the dialysis unit, pre-dialysis waiting room, or a place you prefer. There will be a private room for conducting the interview to maintain privacy. If you like, you can ask a relative or friend to be present during the interview but not contribute.

With your permission, I would like to audio record this interview so that I have an accurate account of what was said. You can ask me to stop to take a rest at any point during the interview.

We do not anticipate that there will be any disadvantages or risks if you choose to participate in the study. The information will be gathered may not benefit you directly, but I hope that it will help individuals with the same condition in the future.

**What if there is a problem?**

If you have a concern about any aspects of the study, you should speak to the researcher who will do his best to answer your questions. The contact details are listed below. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint to the Dialysis Unit In-charge or to the Call Centre, Ministry of Health. To do so, you can phone the Ministry of Health Call Centre on number 24441999. Working hours: 7:30am to 9.30pm, and during public holidays: 9:30am until 4:30pm.

**Who will disclose, use and/or receive my health information?**

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you (name, address, phone number, direct quotes and locations) that is obtained from you either during the interview or through the questionnaires will be anonymized for publication purposes (e.g. trial report research paper, conference presentation) so that you cannot be recognized from it. All study data will be kept separately from the consent forms and personal contact information so that no connection can be made between the data and your-identify. Personal contact information (e.g. name, phone number, etc.) will be stored as a hard copy separately in a secure location for at least 5 years after the study has ended. All study data will be stored safely and securely either on a password protected file, on a secure, password protected PC. If you decide to withdraw from the study, all identifiable data will be withdrawn; however, any unidentifiable data already collected prior to your withdrawal will be retained and used in the study.

The Ethical Committee on Medical Research at Ministry of Health, Oman, which has responsibility for scrutinizing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Ethical Committee, MinistryofHealth,Oman,whoseroleistocheckthatresearchisproperlyconductedand the interests of those taking part are adequately protected. Once the results are ready, I hope to publish them in a medical journal so that other healthcare professionals can benefit from the results. At the end of the study, results will be disseminated to the key stakeholders.

**Contact**

Thank you for taking time to consider taking part in this study. If you would like to find out more about it, please contact:

Waleed Khalid Alrajhi (Researcher) can be contacted by telephone: 00968 99636344 Alternatively, You may contact the Study supervisor on 0096899885711, who will be happy to discuss it with you.

# Thank you for taking the time to consider taking part in this study.

**Appendix 3: Shows participant informed consent form.**

**Participant Informed Consent Form-Phase 1**

Please take some time to read the following statements. If you agree with the statements, please put your initials in each box, thus indicating your consent to take part in the study. Thank you.

**Study Title**

Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context.

|  |  |  |  |
| --- | --- | --- | --- |
| **Statement** | | | **Initial each box** |
| 1. | I confirm that I have read and understood the patient information sheet dated 15 March 2015 (final version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |  |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected. | |  |
| 3. | I understand that data collected during the study may be looked at by the study supervisors, where it is relevant to my taking part in this research. I give permission for them to have access to these data. | |  |
| 4. | I give permission that personal information (e.g. telephone number) will be used by the researcher only to contact me during this study. | |  |
| 5. | I understand that if I choose to withdraw from the study, any information provided till this moment will be included in the study, with my personal data remaining confidential. | |  |
| 6. | I give permission for all the information I provide during the study to be used for research purposes (including reports, publications and presentation), with strict preservation of anonymity. |  |
| 7. | I understand that any information I provide will be treated in strict confidence. The information will be held securely for at least 5 years and will only be available to the research team. The information will be destroyed thereafter. |  |
| 8. | I agree that personal contact information (e.g. name, phone number) will be stored as hard copy separately in a secure location for at least 5 years after the study has ended. |  |
| 9. | I give permission for the researcher to audio record the interview for the purpose of study only. |  |
| 10 | I agree to take part in this study. |  |

Name of participant Date Signature

Name of person taking consent Date Signature

When complete, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

**Appendix 4: Shows the coding form for cognition interview appraisal.**

**Question Appraisal System: Coding Form**

Instructions. Use one form for each question to be reviewed. In reviewing each question:

1. Write or type in question number. Attach question.

Question number or question here:

1. Proceed through the form - Circle or highlight YES or NO for each Problem Type.
2. Whenever a YES is circled, write detailed notes on this form that describe the problem.

|  |  |
| --- | --- |
| STEP 1 - READING: Determine if it is difficult for the interviewers to read the question uniformly to all respondents. | |
| 1a. WHAT TO READ: Interviewer may have difficulty determining what parts of the question should be read. | YES NO |
| 1b. MISSING INFORMATION: Information the interviewer needs to administer the question is not contained in the question. | YES NO |
| 1c. HOW TO READ: Question is not fully scripted and therefore difficult to read. | YES NO |
| STEP 2 - INSTRUCTIONS: Look for problems with any introductions, instructions, or explanations from the respondent’s point of view. | |
| 2a. CONFLICTING OR INACCURATE INSTRUCTIONS, introductions, or  explanations. | YES NO |
| 2b. COMPLICATED INSTRUCTIONS, introductions, or explanations. | YES NO |
| STEP 3 - CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent. | |
| 3a. WORDING: Question is lengthy, awkward, ungrammatical, or contains complicated syntax. | YES NO |
| 3b. TECHNICAL TERM(S) are undefined, unclear, or complex. | YES NO |
| 3c. VAGUE: There are multiple ways to interpret the question or to decide what is to be included or excluded. | YES NO |
| 3d. REFERENCE PERIODS are missing, not well specified, or in conflict. | YES NO |
| STEP 4 - ASSUMPTIONS: Determine if there are problems with assumptions made or the underlying logic. | |
| 4a. INAPPROPRIATE ASSUMPTIONS are made about the respondent or about his/her living situation. | YES NO |
| 4b. ASSUMES CONSTANT BEHAVIOR or experience for situations that vary. | YES NO |
| 4c. DOUBLE-BARRELED: Contains more than one implicit question. | YES NO |
| STEP 5 - KNOWLEDGE/MEMORY: Check whether respondents are likely to not know or have trouble remembering information. | |
| 5a. KNOWLEDGE may not exist: Respondent is unlikely to know the answer to a factual question. | YES NO |
| 5b. ATTITUDE may not exist: Respondent is unlikely to have formed the attitude being asked about. | YES NO |
| 5c. RECALL failure: Respondent may not remember the information asked for. | YES NO |
| 5d. COMPUTATION problem: The question requires a difficult mental calculation. | YES NO |
| STEP 6 - SENSITIVITY/BIAS: Assess questions for sensitive nature or wording, and for bias. | |
| 6a. SENSITIVE CONTENT (general): The question asks about a topic that is embarrassing, very private, or that involves illegal behaviour. | YES NO |
| 6b. SENSITIVE WORDING (specific): Given that the general topic is sensitive, the wording should be improved to minimize sensitivity. | YES NO |
| 6c. SOCIALLY ACCEPTABLE response is implied by the question. | YES NO |
| STEP 7 - RESPONSE CATEGORIES: Assess the adequacy of the range of responses to be recorded. | |
| 7a. OPEN-ENDED QUESTION that is inappropriate or difficult. | YES NO |
| 7b. MISMATCH between question and response categories. | YES NO |
| 7c. TECHNICAL TERM(S) are undefined, unclear, or complex. | YES NO |
| 7d. VAGUE response categories are subject to multiple interpretations. | YES NO |
| 7e. OVERLAPPING response categories. | YES NO |
| 7f. MISSING eligible responses in response categories. | YES NO |
| 7g. ILLOGICAL ORDER of response categories. | YES NO |
| STEP 8 - OTHER PROBLEMS: Look for problems not identified in Steps 1 - 7. | |
| 8. Other problems not previously identified. | YES NO |

**Participant Informed Consent Form-Phase 2 And 3**

Please take some time to read the following statements. If you agree with the statements, please put your initials **in each box**, thus indicating your consent to take part in the study. Thank you.

**Study Title**

Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: an Omani Context.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Statement** | | | **Initial each box** | |
| 1. | I confirm that I have read and understood the patient information sheet dated 15 March 2015 (final version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |  | |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected. | |  | |
| 3. | I understand that data collected during the study may be looked at by the study supervisors, where it is relevant to my taking part in this research. I give permission for them to have access to these data. | |  | |
| 4. | I give permission that personal information (e.g. telephone number) will be used by the researcher only to contact me during this study. |  | |
| 5. | I understand that if I choose to withdraw from the study, any information provided till this moment will be included in the study, with my personal data remaining confidential. |  | |
| 6. | I give permission for all the information I provide during the study to be used for research purposes (including reports, publications and presentation), with strict preservation of anonymity. |  | |
| 7. | I understand that any information I provide will be treated in strict confidence. The information will be held securely for at least 5 years and will only be available to the research team. The information will be destroyed thereafter. |  | |
| 8. | I agree that personal contact information (e.g. name, phone number) will be stored as hard copy separately in a secure location for at least 5 years after the study has ended. |  | |
| 9. | I agree to take part in this study. |  | |

Name of participant Date Signature

Name of person taking consent Date Signature

When complete, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

**Appendix 5: Shows the participants information sheet-phase 2 and 3.**

**Participant information sheet- Phase1**

#### Lesson Plan for Questionnaire Administration Procedure

**Lesson Title:** Principles of self-administered questionnaire related to a pilot study **Date:** 2nd week of October 2015.

**Presenter**: Waleed Al Rajhi

**Rationale:**

This is a 2-3 hours session is designed for the key individuals (nephrology nurses) from hemodialysis units, Oman, whom agreed to assist in conducting the pilot study which is a part of main study of Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: meaning, level and predictors within an Omani Context. It is presented very much as a practical introduction to the assistants and consists of a mixture of a series of short lectures interspersed with practical activities. The areas of discussion will include aims and objectives of study, consent form, and principles and procedure of administering the questionnaire.

**Prescribed Learning Outcome(s):**

Attendants will be able to:

1. Administer effectively the study questionnaire pertaining to phase 2 of Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context.
2. Maintain confidentiality and sounds ethical principles throughout the process of administering, following-up, and collecting back the questionnaires.
3. Respond to participant’s enquiries that might arise related to study questionnaire.

**Instructional Objective(s):**

At the end of this session, attendants will be able to:

1. Gain an insight into the aims and objectives of the pilot study
2. Understand and practice the method for obtaining consent form related to the pilot study
3. Understand and practice the method of self-administered questionnaire
4. Understand and practice the method of following-up and handling questionnaire after completion by participants
5. Recognize and discuss the special issues that might arise in self-administered questionnaire.

**Prerequisite Concepts and Skills:**

It is essential for nurses who will assist in administering the study questionnaire that have/are: self-interest to assist; qualified nephrology nurses registered at Ministry of Health, Oman; permitted by authorities of hemodialysis unit; and their participation would not negatively affect their clinical role and tasks.

**Materials and Resources:**

|  |  |
| --- | --- |
| **Presenter** | **Attendant** |
| Sample of the study questionnaire Flip chart  Laptop  Overhead projector | Notebook and pencil |

**Lesson Activities:**

|  |  |  |  |
| --- | --- | --- | --- |
| Presenter Activities | Attendant Activities | Time | Venue |
| 1. Introduction to the study aims and objectives 2. Discussion on ethical principles applied to the study 3. Demonstration for obtaining consent form 4. Demonstration of questionnaire administration 5. Discussion and distribution of the key instructions to administer a questionnaire 6. Wrap-up | 1. In all the activities, attendants are expected to engage in discussion and enquire about aspects that are not clear. | 09-12  am | Dialysis unit: Seminar room, meeting room. |

**Key Instructions to Administering Pilot Study Questionnaire**

1. Participant should complete the questionnaire independently without assistance from health professionals or family members. If the patient is unable to complete/read the questionnaire themselves, the questions can be read out for them and/or their responses recorded. The questionnaire is designed to assess the patient’s perception so their answers should not be influenced in anyway.
2. Ensure that consent form has been signed and handed over along the questionnaire.
3. Express the importance of the research that they are contributing to, and that the answers they give on the questionnaires may be an important contribution to the health of others.
4. Emphasize that the questionnaire’s scientific value is contingent on carefully and thoughtfully given answers.
5. The questionnaire must be completed with a dark blue or black pen.
6. Tell the participant that if they have any uncertainty about how to answer a question, they should select what they think is the most appropriate answer.
7. Remind the participant to answer all of the questions.
8. Instruct the participant on how to correct mistakes, if necessary, by crossing out the wrong answer, filling in the correct answer, and circling the correct answer.
9. Thank the participant for completing the questionnaires.
10. REMEMBER: confidentiality is vital throughout the process. Quality assurance of the self-administered questionnaires

Before participant leaves the hemodialysis unit, a quality assurance check of the questionnaire must be done. Remind the participant with the following items:

1. Completeness: that all questions have been answered.
2. Accurate identification: make sure that the questionnaire has a printed code on the cover page.
3. Coherence: that only one answer is given for each question. If the participant has made any corrections on the questionnaire, to sure that the intended answer is clearly marked.

**Resources for additional information**

If you have questions related to this or during the questionnaire administration, please contact Waleed Khalid Alrajhi (Researcher) through telephone number: 00968 99636344 alternatively, You may contact the Study supervisor on0096899885711, who will be happy to discuss it with you.

**Participants information sheet-phase 2 and 3**

**Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: an Omani Context.**

Youarebeinginvitedtotakepartinaresearchstudythatwillassessqualityoflife(QoL) and health related quality of life (HRQoL) in patients with end stage kidney disease (ESKD) in an Omani context. Before you decide to take part, it is important that you understand firstly why the research is being done and what it will involve. Please take time to read the following information, and carefully consider whether you want to take part. Please ask the researcher or nurse involved in this study if there is anything that is not clear or if you would like more information.

**Aim**

Theaimsofthisstudyaretoidentifythelevelofqualityoflifeforpatientswithendstage renal disease on dialysis by using a number of questionnaires. These will tell us how well these questionnaires are accepted by Omanis; and to what extant disease symptoms, social spiritual factors affect quality of life in Omani patients. The findings from the present study will improve our understanding of the ESKD patients’ perceptions about their disease, which can be then incorporated into their future medical and nursing care.

**Why have I been invited?**

You are being asked to participate as you are an adult who has been diagnosed with ESKD and on hemodialysis therapy on a regular basis. Your dialysis nurse has identified that you are eligible to participate in this study. I hope that 400 patients will agree to take part in this study.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical or nursing care.

**What will happen if I agree to help?**

If you agree to take part in this study, it will involve you completing 6 questionnaires during your presence in dialysis unit for your regular hemodialysis sessions. The estimated time to complete these questionnaires will be around 30-40 minutes, but it may take less or more time for some individuals.

The questionnaires to fill out are:

1. Three questionnaires to assess your experience with three symptoms associated with your ESKD disease and how these may affect your everydayactivities.
2. A questionnaire to assess what you think about your healthstatus.
3. A questionnaire to assess the impact of ESKD on your socio-economic activates.
4. A questionnaire to assess the impact of ESKD on your spiritualaspects.
5. You will also be asked some background questions related to your age, gender, education level, marital status, monthly income.

A clinical data will be collected from your medical record (e.g. total hours of hemodialysis per week; malnutrition status, anemia status) to examine its impact and association with your level of QoL.

Once you have finished completing the questionnaires, you will hand it over to your nurse who in turn will seal it and hand it over to the researcher.

We do not anticipate that there will be any disadvantages or risks if you choose to participate in the study. The information will be gathered may not benefit you directly, but I hope that it will help individuals with the same condition in the future.

**What if there is a problem?**

If you have a concern about any aspects of the study, you should speak to the researcher who will do his best to answer your questions. The contact details are listed below. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint to the Dialysis Unit In-charge or to the Call Centre, Ministry of Health. To do so, you can phone the Ministry of Health Call Centre on number 24441999. Working hours: 7:30am to 9.30pm, and during public holidays: 9:30am until 4:30pm.

**Who will disclose, use and/or receive my health information?**

All information which is collected about you during the course of their search will be kept strictly confidential. Any information about you (name, address, phone number, direct quotes and locations) that is obtained from you either during the interview or through the questionnaires will be anonymized for publication purposes (e.g. trial report, research paper, conference presentation) so that you cannot be recognized from it. All study data will be kept separately from the consent forms and personal contact information so that no connection can be made between the data and your identify. Personal contact information (e.g. name, phone number, etc.) will be stored as a hard copy separately in a secure location for at least 5 years after the study has ended. All study data will be stored safely and securely either on a password protected file, on a secure, password protected PC. If you decide to withdraw from the study, all identifiable data will be withdrawn; however, any unidentifiable data already collected prior to your withdrawal will be retained and used in the study.

The Ethical Committee on Medical Research at Ministry of Health, Oman, which has responsibility for scrutinizing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Ethical Committee, Ministry of Health, Oman, who serole is to check that research is properly conducted and the interests of those taking part are adequately protected. Once the results are ready, I hope to publish them in a medical journal so that other healthcare professionals can benefit from the results. At the end of the study, results will be disseminated to the key stakeholders.

**Contact**

Thank you for taking time to consider taking part in this study. If you would like to find out more about it, please contact:

Waleed Khalid Alrajhi (Researcher) can be contacted by telephone: 00968 99636344 Alternatively, You may contact the Study supervisor on0096899885711, whowillbe happy to discuss it with you.

# Thank you for taking the time to consider taking part in this study.

**Appendix 6: Shows the participant information consent form-phase 2 and 3.**

**Participant Informed Consent Form-Phase 2 And 3**

Please take some time to read the following statements. If you agree with the statements, please put your initials **in each box**, thus indicating your consent to take part in the study. Thank you.

**Study Title**

Quality of Life and Health Related Quality of Life in Individuals with End Stage Kidney Disease: an Omani Context.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Statement** | | | **Initial each box** | |
| 1. | I confirm that I have read and understood the patient information sheet dated 15 March 2015 (final version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |  | |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected. | |  | |
| 3. | I understand that data collected during the study may be looked at by the study supervisors, where it is relevant to my taking part in this research. I give permission for them to have access to these data. | |  | |
| 4. | I give permission that personal information (e.g. telephone number) will be used by the researcher only to contact me during this study. |  | |
| 5. | I understand that if I choose to withdraw from the study, any information provided till this moment will be included in the study, with my personal data remaining confidential. |  | |
| 6. | I give permission for all the information I provide during the study to be used for research purposes (including reports, publications and presentation), with strict preservation of anonymity. |  | |
| 7. | I understand that any information I provide will be treated in strict confidence. The information will be held securely for at least 5 years and will only be available to the research team. The information will be destroyed thereafter. |  | |
| 8. | I agree that personal contact information (e.g. name, phone number) will be stored as hard copy separately in a secure location for at least 5 years after the study has ended. |  | |
| 9. | I agree to take part in this study. |  | |

Name of participant Date Signature

Name of person taking consent Date Signature

When complete, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

**Appendix 7: Shows the risk assessment plan.**

**Appendix Risk assessment plan**

|  |  |  |
| --- | --- | --- |
| **Risk** | **Action to Prevent** | **Action to Manage** |
| University and Ministry of Health, Oman, ethics approval takes longer than anticipated | Study documentation is prepared as early as possible. Check slots for ethics review as early as possible. | Engage in discussion with Research office and Directorate of Research, Oman. |
| Recruitment to cognitive interviews proves challenging | Patients are invited to take part when next in clinic. Flexibility in dates is allowed. | A minimum of 3 interviews is allowed. An extra month of recruitment is allowed. |
| Attendance of patient to cognitive interview proves challenging and creates delay | Patients are invited to take part when next in clinic. Patients are given the option to participate at different times and dates. | An extra month of recruitment is considered. |
| Responses to pilot study survey are fewer than required | Oversampling technique is pursued. Two weekly reminders are sent by the researcher. | Additional 2 reminders will be sent if required. Additional invitations are sent by the researcher. |
| Responses to main study survey are fewer than required | Oversampling technique is pursued. Two weekly reminders are sent. | Additional reminders are sent if required. Additional invitations are sent. |
| Nephrology nurses or clinical site is not engaging as planned | Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians. | Engage in discussion and negotiation with clinicians. Identify source of sub- optimal engagement. Examine alternatives to increase engagement. |
| Nephrology nurses or clinical site withdraws early | Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians. | Start negotiations with another clinical site. Inform other clinical sites about development and request support with recruitment until a new clinical site comes onboard. |
| Recruitment to main study survey proves challenging | Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians. | Offer to support clinicians during recruitment. Consider adding a new clinical site. |
| Patient withdraws early | Ensure patient fully understands the purpose and procedures of the study. | Replace patients who withdraw. Intensify recruitment. Set minimum number of patients required. |
| **Risk** | **Action to prevent** | **Action to manage** |
| Recruiting clinicians for the study proves challenging | Set intense recruitment strategy, ensuring study advertisements are widely available. | Relax requirements set in the job description. An additional month of recruitment is allowed. Explore possible availability within research group. |
| Data collection rates are lower than expected | Ensure that questionnaires have been adequately prepared. Ensure that participants fully understand procedures. | Administering questionnaires as an interview base. |