1. Purpose:

1.1 To organize and generate the informed consent from patients to have permission to carry out certain procedures and treatments by the Home Medical Care professionals in the patients home.

2. Definition:

2.1 ***"Consent"*** is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), verbally, or in writing. For the consent to be valid, the patient must:

- 2.1.1 Be competent to take the particular decision.
- 2.1.2 Have received sufficient information to take it.
- 2.1.3 Not be acting under duress.

2.2 Patients Who Lack the Capacity to Consent

When the term *"a person who lacks capacity"* is used, it means a person who lacks capacity to make a particular decision or take a particular action at the time the decision or action needs to be taken (British Medical Association).

2.3 The Principles Identified in Mental Capacity Act 2005 Code of Practice States:

- 2.3.1 A person must be assumed to have capacity unless it is established that they lack capacity.
- 2.3.2 A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
- 2.3.3 A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
- 2.3.4 An act done or decision made, under this (Mental Capacity Act) for/or on behalf of a person who lacks capacity must be done, or made in his best interests.
- 2.3.5 Before the act is done, or the decision is made, regard must be made to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

2.4 Written Informed Consent:

2.4.1 A written form to document that the patient has received information necessary to make consent; and to document his/her agreement (signature or fingerprint).

2.4.2 Consent is often wrongly equated with a patient's signature on a consent form.

2.4.3 A signature on a form is evidence that the patient has given consent, but is not proof of valid consent.

2.4.4 If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature.

2.4.5 Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent giving, not a binding contract.

2.5 Procedures/tests for which a written informed special consent is needed include:

2.5.1 Wound Debridement

2.5.2 Initial insertion of Nasogastric Tube

2.5.3 HIV Testing

2.5.4 Initial Insertion of Indwelling Urinary Catheter

2.5.5 Patients Taking Part in Clinical Research/Study

2.5.6 Photographic or Video Recording of a Patient Specifically For Education, Publication or Research Purposes.

3. Policy:

3.1 Patients should be a fully competent adult to provide consent for his care.

3.2 If the patient is not fully competent the legal guardian will provide the consent.

3.3 Patients should be provided information (see procedure) before providing any consent.

3.4 Patients consent forms should be placed in the patient's medical record and include the date and time that consent was given.

3.5 All patients/family members of a patients who are accepted for HMC services should sign the HMC General Consent Form [form 1]

3.6 Patient's informed consent should be obtained by trained staff whenever there is a high risk procedure or treatment and/or taking part in research/study involving human subjects.

3.7 Patient's informed consent should be valid as long as services are provided; except in the circumstance of special consent when the intervention should be done within two weeks of the patient/guardian signing the special consent form.

3.8 Patient's informed consent should be invalid in case of patient request to be discharged from the services; and if the patient will be readmitted to the services a new consent form MUST be filled up.

3.9 If services are interrupted due to hospital admission for more than three(3) months or on vacation for more than six (6) months. There will be a need to reassess patient's needs and a new consent form MUST be filled up.

4. Procedures:

4.1 Health Care Professionals must always start from the assumption that the person has the capacity to make the decision in question.

4.2 All Health Care Professionals must always bear in mind that just because someone lacks capacity to make a decision on one occasion, that does not mean that they will never have capacity to make a decision in the future, or about a different matter.

4.3 Only adult patients whom are fully competent can provide informed consent.

4.4 Before taking any informed consent the Health Care Provider should check the patient's competency.

4.5 Competency is checked using the mini-mental examination tool, which is part of the doctors' initial patient assessment.

4.6 Patient whose ***score 8*** or more on the **6CIT** assessment tool will be considered with impaired cognitive function and cannot provide informed consent.

4.7 An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. The Health Care Provider should involve appropriate colleagues in making such assessments of incapacity, (such as specialist learning disability teams and speech and language therapists), unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

4.8 If the patient is not competent his legal guardian should provide consent as follows:

Patients to be consented	Who will provide the consent
Children below the age of 18 years	Parents
Adults older than 18 years whom are fully competent.	The patient will provide the informed consent
Adults older than 18 years whom are not competent.	The following will provide consent by descending order: 1. Wife/Husband 2. Eldest son (should be older than 18) 3. Eldest daughter (should be older than 18) 4. Parents 5. Eldest brother

4.9 Upon enrollment into the Home Medical Care, the social worker must ensure that the patient/guardian understands and has signed the HMC General Consent Form [form1] and the agreement form (form2)

4.10 For significant procedures, it is essential for the Health Care Provider, to document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement. This should be done through the use of the Consent for procedure Form [form 3] with further details in the patient's HMC medical record if necessary (if the procedure carries significant risk) otherwise; it should only be documented in the patient's HMC medical record that he/she has given verbal consent to carry out the intervention.

4.11 **Procedures/tests for which a written informed special consent is needed include:**

4.11.1 Wound Debridement
4.11.2 Initial insertion of Nasogastric Tube
4.11.3 HIV Testing
4.11.4 Initial Insertion of Indwelling Urinary Catheter
4.11.5 Patients Taking Part in Clinical Research/Study
4.11.6 Photographic or Video Recording of a Patient Specifically For Education, Publication or Research Purposes.

4.12 Completed consent forms [forms1,2] should be kept in the patient's medical record. Any changes to a form, made after the patient has signed the form, should be initialed, timed and dated by the patient/family and the Health Care Provider.

4.13 It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. (See HMC waived testing policy) However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined or become very distressed about similar care in the past) it would be helpful to do so.

4.14 When a patient formally gives their consent to a particular intervention, this is only the endpoint of that consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or

over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

4.15 If a proposed procedure carries significant risks, it will be appropriate to seek *written informed consent*, and Health Care Provider must take into consideration whether the patients havehad sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the Health Care Provider may then proceed.

4.16 The Consent for procedure Form [form3] provides space for a Health Care Provider to provide information to patients and to sign confirming that they have done so. The Health Care Provider providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

4.17 In case of emergencies, the two stages of obtaining consent (discussion of options and confirmation that the patient wishes to go ahead with the procedure) will be conducted instantaneously, and it may often be appropriate to use the patient's medical record to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

4.18 When infants or children are being cared for, their parents give consent on their behalf. Where an infant/child is undergoing a high risk procedure or treatment, the Health Care Provider should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that he has their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, the Health Care Provider must do so, unless the delay involved in contacting them would put the infant/child's health at risk.

4.19 The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about the following:

4.19.1 The Patient's Condition

4.19.2 The Proposed Care and Services

4.19.3 The Name of the Person Providing the Care and Services

4.19.4 Potential Benefits and Drawbacks
4.19.5 Possible Alternatives
4.19.6 The Likelihood of Success
4.19.7 Possible Problems Related to Recovery
4.19.8 Possible Results of Non-Treatment.

4.20 The Health Care Provider carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done. It is the Health Care Provider who will be held responsible in law if this is challenged later.

4.21 If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment.

4.22 The following conditions apply for consent refusal:

4.22.1 If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their medical records. The health care provider should use Patients Refusal of Care Against Medical Advice Form [form 4]

4.22.2 If the patient has already signed a consent form, but then changes his/her mind the Health Care Provider (and where possible the patient) should note which aspect of care the patient is refusing this on the consent form.

4.22.3 Where a patient has refused a particular intervention the Health Care Provider must ensure that he/she continues to provide any other appropriate care to which they have consented.

4.22.4 Health Care Provider should ensure that the patient realizes that they are allowed to change their mind and accept treatment if they later wish to do so.

4.22.5 Where delay may affect their treatment choices, they should be advised accordingly and sign the Patients Refusal of Care Against Medical Advice Form [form 4]

4.23 Clinical photography and conventional or digital video recordings:

4.23.1 Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that

they make clear in advance if any photographic or video recording will result from that procedure.

4.23.2 Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the written informed consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

4.23.3 Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognized, may be used within the clinical setting for education or research purposes with verbal consent from the patient as long as this policy is well publicized. However, express consent must be sought for any form of publication.

4.23.4 Health Care Providers who wish to take a photographic or video recording of a patient specifically for education, publication or research purposes, must first seek the patients' written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

4.24 All participants involved in research/study involving human subjects should give explicit consent prior to involvement in research. Provision of information regarding the objective of research, tools used in research, confidentiality of information and benefits and harms of taking part in research, should be obtained and documented in the patient medical file.

4.25 Training of Health Care Workers on how to obtain valid consent:

4.25.1 Employees will be made aware of the policy and procedure at local induction and followed up through ongoing training relevant to their roles and responsibilities.

4.25.2 Doctors in-charge are responsible for identifying training needs for staff and discussing with the education and training department in order that consent training can be implemented.

4.25.3 Where practicable, procedure specific training relevant to the department and clinical setting must occur for staff that the consent process is delegated to,but are not capable of performing it. This must occur on local induction or as soon as possible thereafter

4.25.4 .HMC in-charge must keep records of any local training on consent and follow it up as part of the staff development review process.

4.25.5 All staff is responsible for attending training events and working within their level of competence when gaining consent.

5. Responsibilities:

5.1 All home Medical Care professionals

6. Forms:

6.1 General Consent for initiation HMC services Form/ HMC-PRR-Form-05.1

6.2 Agreement of HMC services form/ HMC-PRR-Form-05.2

6.3 Patient Consent for Procedure/Test/Study Form/HMC-PRR-Form-05.3

6.4 Patients Refusal of Care Against Medical Advice Form/HMC-PRR-Form/05.4

7. References:

7.1 Policies and procedures guidelines of Home Medical Care Centre, Home Medical Care Administration, Medina Munwara Region, 2016

7.2 Policies and procedures guidelines of Home Health Care Unit, Family and Community Medicine Department at Riyadh Military Hospitals,2014

7.3 Joint Commission International Accreditation Standards for Home Care, 2012

7.4 MOH Home Medical Care Standard, 2015

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