PROTOCOL FOR OBTAINING INFORMED CONSENT/TEMPLATE OF INFORMED CONSENT

NOTE: THIS PROTOCOL IS ALSO USED AS A GUIDELINE TO COUNSEL PATIENTS/BY-STANDERS IN EMERGENCIES/EVENTUALITIES

Sl No.	Activity	Remarks
1	Request that patient should be spoken to in the presence of the by-standers Resp: CNL	Speaking to the patient, with the by-standers puts the patient at ease. Once all of the by-standers have been explained it reassures them and ensures a lesser degree of their anxiety. The doctor should ensure that the patients and by-standers are conveyed the message in a language that they comprehend.
2	Explain the diagnosis Resp: CNL	Patient and By-standers are explained the diagnosis. It is the doctors responsibility to ensure that a scientific approach has been adopted and that the history, clinical findings, investigation reports point towards the diagnosis.
3	Explain investigation reports Resp: CNL	At times certain investigation reports i.e. Radiology reports are a graphical representation of the patients bones/soft tissues. These can be shown and explanations offered.
4	Management options Resp: CNL	Patient and by-standers are explained about the management options of a certain disease and also explained the consequences of not treating the disease. Patient's sentiments must be respected, but at the same time a firm approach is needed since the doctor with his expertise knows what is best and works with the patients' best interest in mind.
5	Intervention planned Resp: CNL	The intervention planned is clearly explained. This also encompasses the anesthesia used, position on table, incision made, brie steps of procedure, post-operative discomfort if any, pain management, uses of tubes and drains.
6	Complications Resp: CNL	Complications of the procedure, anesthesia, blood transfusion, drains, tubes, and prostheses are explained.
7	After-care Resp: CNL	Physiotherapy, Sitz baths, steam inhalation, hot-fomentation etc. are explained to reduce the anxiety and improve compliance.
10	Maintaining decorum and poise; Resp: CNL	The doctor at all times maintains his/her poise and decorum, remembering that the GRH staffs are service providers.
11	Document the findings Resp: CNL & SN	All the documents must be noted in the likely event that the records might be needed as evidence in the court of Law. Non-compliance of patients or obliging the patients their demand for an investigation is also documented. MRD F must be filled if patient by-standers have been informed as a proof of discussing with them. Consent form is filled in all aspects as per MRD F
12	Witnesses Resp: SN	Two witnesses are to sign in the consent form, also stating their relation ship with the patient.
13	Important point to be noted at all times	The patient and the by-standers must not be put under duress, pressure or force. It should also be ensured that the patient is in compos mentis – a clear state of mind. If the patient is unable to give consent, the by-standers are banked on. If both are indecisive, , "life-saving interventions" is the moral and legal responsibility of the doctors, even if it means putting themselves

		at stake, since the patient at near-death situation is unable to comprehend the gravity of the situation and thus indecisive about procedures that are needed to rescue his life.
14	Maintaining the confidentiality of the patient	Above all the interaction between the doctor and the patient is a privileged communication; and kept confidential and private.
15	Emergency procedures	Emergency procedures are carried out immediately.

HIGH RISK CONSENT FOR EMERGENCY LAPAROTOMY AND PROCEED -15th September 2009

I Mr._____ aged _____years, address _____, from _____island, have been explained that I have sustained an injury by falling from a height and the present clinical status is that I have

a) Pneumoperitoneum (air in the peritoneal cavity) as a result of rupture of the bowel
b) Crush injury to the right gluteal region
c) Internal haemorhage (internal bleeding)
d) Class 4 wound (contamination occurring in the wound before operative measures have been taken and likely hood of contamination even after the wound has been treated)
e) Co morbid conditions (hypertension, diabetes , Asthma)

The treatment that is being offered to me **Exploratory laparotomy and proceed under general anesthesia**. I understand that my *present condition makes me a poor candidate for surgery and anesthesia*, but the procedure has to be taken up as a life saving measure. The **surgery involves**

1. Opening the anterior abdominal wall and examining the internal organs
2. Repair of the internal organs (injuries expected are hollow organ injuries and bleeding from solid organs)
3. Placement of drains, Ryle's tube, Foley's catheter -post operatively.
4. Kept NPO for at least 2 days post operatively.
5. Need for a colostomy (Opening the large intestine to the outside through the abdominal wall) if necessary
6. Need for mechanical ventilation if necessary

The operation that has been described above has the following complications (seen in about 5% of population)

a) Haemorrhage (intra and post-operatively)
b) Wound complications (seroma, hemoatoma,dehiscence, poor wound healing, surgical site infections)
c) Anastamotic complications (leak, stenosis, fistula, obstruction)
d) Colostomy complications (Stenosis, prolapse, intrusion, bleeding, para-colosotmy hernia)
e) Peritonitis (infection of the abdominal cavity)
f) Peritoneal abscesses with involvement of solid organs (liver, spleen, kidney), Sepsis.
g) Need for blood transfusion & Complications of blood transfusion
h) Iliac vein thromboembolism
i) Complications due to anesthesia – liver/renal failure (acute), hypothermia, fluid shift, acid-base imbalance, Barotrauma
j) On-table death and peri-operative mortality
k) Unforseen complications

All these have been explained to me by my doctors and in Dhivehi. I understand and accept these risks and give my written informed High-risk consent in compos mentis and good faith, without duress, to permit my doctors to proceed with the operation and anesthesia.

Patient Name: Relative: Relative:
Sign: Sign: Sign:

NOTE: THIS CONSENT IS ONLY A TEMPLATE. IT CAN BE MODIFIED DEPENDING ON THE TYPE OF SURGERY