MEDICAL RECORD	INFORMED CONSENT FOR PERFORMANCE OF PROCEDURE and REQUEST FOR ANESTHESIA

PROPOSED PROCEDURE

1. Name of Procedure:
Colonoscopy Possible Interventions (Moderate Sedation) (Colonoscopy with Possible Interventions (Moderate Sedation))

2. Condition to be treated:
To examine the colon and lower digestive system for disease or abnormality._

3. Description of the procedure:
This procedure involves using an endoscope to see inside your digestive tract. An endoscope is a thin, flexible tube with a light and camera on one end. Your doctor will insert the device through your anus and rectum. It can be moved through your colon as far as where it joins your small intestine. The camera will display images on a screen. Your doctor may use air to inflate your colon. This may allow your doctor to see better.

This procedure also involves placing you in a state of sedation. Sedation helps you feel relaxed. It may be given together with light anesthesia. Anesthesia causes you to sleep and reduce your response to pain. Your provider will monitor your heart rate, breathing and other vital functions.

You will be given moderate sedation. You will be sedated using medicines. Your healthcare provider may give these by mouth, by inhalation, or by injection. The medicine may be injected into a muscle or into your bloodstream. You will be able to respond and breathe as normal. Your ability to move may be impaired. You will be sleepy and relaxed. Your provider may use a device to help your breathe.

Your doctor will examine the lower part of your digestive tract. Your doctor may do any of the following:
* Remove growths (such as polyps), foreign bodies, or other abnormalities.
* Stretch narrowed areas with balloons or other tools.
* Place a hollow tube to keep a narrowed area open. The hollow tube is called a stent.
* Stop and control bleeding. Your doctor may use an electrical current or other heat source, clips, rubber bands, or injection of medicines.
* Take, and save images of your lower digestive system.
* Shrink enlarged veins with rubber bands or injection of medicine(s).
* Drain a fluid collection.
* Mark certain areas to help locate them later. This is done using a special dye.
*Take a tissue sample (biopsy).
*Take and save high frequency sound waves (ultrasound) images of your internal organs.

When the procedure is complete, your doctor will remove the endoscope. The effects of sedation will wear off in a few hours. You may be monitored for a few hours after the procedure.

Additional information, including procedure site. Enter NA if not applicable.

Patient Information
Name: _____
DOB: _____
FMP/SSN: _____

Provider Name: _____

4. Risks of the procedure:
* Bleeding.
* Bloating.
* Confusion, memory loss, or difficulty thinking (impaired cognitive function).
* Headache.
* Nausea and/or vomiting.
* Pain at the administration site.
* Pain, numbness, swelling, weakness or scarring where tissue is cut.
* You may have problems, diseases or abnormalities but this test may not find them.
* You may need additional tests or treatment.
* Your doctor may not be able to make a proper diagnosis.
* Allergic reaction. May include itching, hives, swelling, difficulty breathing, drop in blood pressure, possible loss of consciousness.
* Infection.
* Lowering of blood pressure. This may lead to decreased blood supply to your body. It may cause dizziness, fainting or heart attack.
* Reactions to medicine(s) given or used during or after the procedure.
* Too little sedation. You may experience awareness, pain or discomfort during the procedure.
* Too much sedation. You may become unconscious. You may experience respiratory suppression. You may need additional medication or treatment.
* Breathing problems. You may need a breathing tube or other treatment.
* Discomfort and pain. This can occur due to pressure from the scope or from gas that is put in during the exam.
* A hole or tear in the colon. This happens in about 1 patient in 1000. You will need surgery to repair the hole. You may need a colostomy. A colostomy is an opening in the abdominal wall. It lets waste from your body drain into a bag.
* Bleeding. Bleeding can occur during the procedure or up to 1-2 weeks later. This usually happens when polyps have been biopsied or removed. If polyps are removed, the risk of bleeding is about 1 in 300. If the polyp is very large, the risk is about 1 in 20. If you have serious bleeding, you may need to have blood transfusions, another colonoscopy or an x-ray test. You may need surgery to stop the bleeding. If you have bleeding, you will be asked to give permission for blood transfusions. If you have concerns about blood transfusions, you should talk with the doctor before the procedure.
* Missing cancer or other important problems. About 10% of polyps and 1% of cancers may be missed by the procedure.
* Incomplete examination. In 5-10% of cases, the procedure cannot be finished for some reason. If this happens, you may need to have the procedure tried again on a different day. You may need a different kind of test (for example, a colon X-ray test).
* Death. The risk of death is between 1 in 3,500 and 1 in 5,000.
* Your doctor may not be able to complete the procedure under moderate sedation.
* Damage to the anus or nearby structures. This may be discovered during the procedure, or later.
* Damage to the colon or nearby structures. This may be discovered during the procedure, or later.
* You may have cancer, but this procedure may not find or remove it.
* Death.

Patient Information

Name: _____

DOB: _____

FMP/SSN: _____

Provider Name: _____

5. **Intended results of the procedure:**
This procedure may allow your doctor to find out what is wrong. This information may allow your doctor to provide appropriate treatment. This procedure may remove cancer early before it has spread.

ALTERNATIVES TO PROPOSED PROCEDURE

6. **Recognized alternatives to the proposed procedure:**
* Watching and waiting with your doctor.
* Other imaging methods such as x-ray or ultrasound.
* Barium enema test. This is a specific x-ray test. This involves placing materials into your rectum to make it easier to see on x-ray.
* Virtual colonoscopy. This involves an ultrasound scan along with liquid or air placed into the rectum.
* Colonoscopy without moderate sedation.
* Exploratory surgery.
* You may choose not to have this procedure.

7. **Risks and benefits associated with the alternatives:**

8. **Risks associated with not undergoing any treatment or procedure:**
If you choose not to have this treatment, your doctor may not be able to find out what is wrong. You and your doctor may not be able to plan appropriate treatment. If you have cancer, your cancer may grow or spread. It may be more difficult or impossible to remove at a later time.

9. I request the administration of such anesthesia as may be considered necessary or advisable in the judgment of the professional staff of Tripler Army Medical Center.

10. Exceptions to surgery or anesthesia, if any are (if "none", so state): None

11. I request the disposal by the medical facility of any tissues or parts which it may be necessary to remove.

12. I understand that photographs and videos may be taken of this operation, and that they may be viewed by various personnel. I consent to the taking and hard copy and electronic storage of such pictures.

13. **CONSENT FOR BLOOD PRODUCTS**: Is there a reasonable chance that human blood products will be given during procedure?

☐	No. It is not expected that blood products will be used in procedure(s).
☐	Yes. During the course of procedure(s) I may need to be given human blood products. Condition to be treated: Low blood counts, blood clotting factors, low blood volume. Procedure description: My physician has explained to me, and I understand, the possible need for transfusion(s) of blood or blood products in connection with my medical care as deemed necessary. It

has been explained to me and I understand the nature of my treatment, the alternatives, the benefits, and the risks involved. I understand blood is received from screened volunteer donors. I understand the alternative, where applicable, of autologous (self) blood donation. I have had the opportunity to ask questions.

Risks: I understand and accept the infrequent but potential risks of transfusion, which include, but are not limited to: Transfusion, Reaction, (fever and chills, skin rash, shortness of breath, low blood pressure clotting, red blood cell breakdown, kidney failure). Infection (hepatitis, cytomegalovirus, HIV (AIDS), HTLV-1, and others) and death.

Intended Results:
Red blood cells: Need to increase oxygen delivery to key tissues.
Platelets: Reduce the risk of severe hemorrhage.
Plasma: Treat clinically significant procoagulant deficiencies.
Cryoprecipitate: Treat specific procoagulant factor deficiencies.

Recognized alternatives: Refusal of transfusion of human blood products.

Risks and benefits associated with the alternatives: Risks include worsening anemia (inability to oxygenate key tissues), bleeding and death. Benefits include the reduced risk of acquiring a blood borne infection or having a transfusion reaction.

Risks associated with not undergoing any treatment or procedure: See above.

SIGNATURES
(All items in this form must be completed before signing)

14. COUNSELING PROVIDER: I have counseled this patient regarding the condition to be treated, the description of the proposed procedure, the intended and anticipated results and the risks of the proposed procedure, alternative treatments, if any, the risks and benefits of the alternative treatments, and the risks of undergoing no treatment.

_____
(Signature of Counseling Provider)

15. I have been informed of the condition to be treated, the description of the proposed procedure, the intended and anticipated results, and the risks of the proposed procedure, alternative treatments, if any, and the risks and benefits of the alternative treatments of the above named proposed procedure. I have been informed of the risks of undergoing no treatment.

I request the performance of the above-named proposed treatment or procedure and of such additional treatments or procedures as are found to be necessary or desirable, in the judgment of the professional staff, during the course of the operation or procedure. I acknowledge that no guarantees have been made to me concerning the results of the treatment or procedure. I acknowledge the above has been explained to my satisfaction, I have had the opportunity to ask my doctor questions, and my questions have been answered.

_____ _____
(Signature of Patient) *(Date)*

16. SPONSOR OR GUARDIAN: (When patient is a minor or unable to give consent) I am the parent, legal guardian, or other surrogate decision maker of the above named individual. I request the performance of the above-named proposed treatment or procedure and of such additional treatments or procedures as are found to be necessary or desirable, in the judgment of the professional staff during the course of the operation or procedure. I acknowledge that no guarantees have been made to me concerning the results of the treatment or procedure. I acknowledge the above has been explained to my satisfaction and I have had the opportunity to ask questions and my questions have been answered.

_____ _____ _____
(Signature of Surrogate Decision Maker) *(Relationship)* *(Date)*

Will procedure(s) be performed outside the operating room?

☐	No
☐	Yes

Patient Information
Name: _____
DOB: _____
FMP/SSN: _____

Provider Name: _____

UNIVERSAL PROTOCOL: NON-OR PROCEDURE VERIFICATION CHECKLIST
For use of this form, see MEDCOM Reg 40-54; the proponent agency is MCHO-CL-Q
Used for Procedures Performed Outside of the Operating Room

Universal Protocol Checklist
Pre-procedure verification: Confirmed correct patient, procedure, consent, positioning, side/site, blood products and special equipment (as applicable).

The procedure site was marked (or used alternative marking method. Note: Not required for obvious wound/lesion, midline, single organ procedures, procedures without intended laterality (e.g., endoscopes and colposcopies) or procedures in which there are no predetermined sites of insertion.

A Time-Out was performed: Immediately before the procedure noting the above as well as confirming the patient's position, relevant images and labs, antibiotics, fluids, and safety precautions IAW MEDCOM Reg 40-54.

Team agrees on procedures to be done:

By: _____

And: _____

Date/Time: _____

Instructions for completing to the Non-OR Procedure Verification Checklist.
Conducting the TIME-OUT prior to incision/procedure

By: Should be signed by the licensed team member who performed the TIME-OUT.

And: Should be the name(s) of at least one member of the team present that participated in the TIME-OUT.

Date/Time: The date and time the TIME-OUT occurred.

Patient Information
Name: _____
DOB: _____
FMP/SSN: _____
Provider Name: _____