

Gastroenterology Department

WRITTEN INFORMATION AND CONSENT FORM

1. **Consent form for colonoscopy, also known as lower digestive endoscopy.**

This document is for you, or whoever, represents you, to authorize the performance of this procedure. This means that you authorize us to perform it. You can withdraw this consent at any time. Signing it does not oblige you to undergo the procedure. Revoking this consent does not imply any adverse consequences that could compromise the quality of the care received. Before signing, please read carefully the following information. Please, let us know if you have any questions or need further information. We will be glad to assist you.

1.1. What is this about? What is this for? The study that you will undergo is called colonoscopy and it consists of the exploration of the rectum and the colon (large intestine), including the last centimeters of the small intestine. It is performed with a flexible tube that is introduced through the anus. The tube (endoscope) has a lighting system and a camera. It is useful for the diagnosis of conditions that affect the large intestine, as well as for the treatment of some of them.

1.2. How is this performed? The study is performed in a comfortable position on the left side of the patient, even though it might be convenient to change the position during the procedure. The duration of the colonoscopy is variable, but it is usually 30 minutes long, total. In order to be better tolerated, you will be given a sedative, and, if necessary, an analgesic. It can also be performed with profound sedation or general anesthesia.

1.3. What effects will it have on you? The passage of the endoscope through the intestine produces malaise and a feeling of being bloated. There can be moments of pain, of short duration. This is due to the passage of the endoscope through the curves of the colon, and because of the air that is being introduced. Once the study is finished, a sensation of gas remains, which passes shortly after. If you have had any treatment performed, or if there are any lesions, such as hemorrhoids, a small strip of blood can be seen in the first deposition after the study.

1.4. What are the benefits? The colonoscopy is always indicated when your physician deems it necessary to know of the existence of a disease in the large intestine. For instance, if there are symptoms such as rectorrhagia (emission of blood through the anus), anemia due to blood loss, recent changes in the intestinal habit, or diarrhea of long course, amongst others.

During the study, some treatments can be performed, such as the extirpation of polyps (polypectomy or extirpation of small benign tumors, and sometimes even malignant as well), destruction of lesions through heat, argon gas or laser, dilation of narrow areas, and placement of prosthetics. In some cases, the study cannot be completed in the exploration of the entire colon, and it is advisable to perform another session.

1.5. Other alternatives available in your situation: an alternative to the colonoscopy, for the diagnosis, is

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the performance of an opaque enema. The latter consists of introducing a contrast medium through the anus and filling up the entire colon. Its diagnostic results are worse, and it does not enable taking biopsies or the performance of treatments. Another alternative, for the diagnosis, is the virtual colonography by means of CT scan. The latter can be necessary as a complement in certain circumstances, or if the colonoscopy has not been complete. For the treatments, the only alternative to the endoscopy is the surgical operation, which implies greater risks.

1.6. What are the risks? Any medical procedure has its risks. Risks do not usually occur and the procedure does not produce damage or undesirable side effects at all. However, this is not always the case. That is why you have to know all risks that this procedure may lead to.

1.6.1.The most frequent ones: the colonoscopy is a very safe technique. The complications are usually mild, and without any repercussions.

- Abdominal pain
- Sweating.
- Bloating or abdominal distention.
- Unwanted reactions to the administered medications.
- The possibility of complications is larger when the endoscope is used to apply treatments, such as polypectomies, destruction of lesions through heat, argon gas, or laser, dilations, or placement of prosthetics.

1.6.2.The most serious ones: the most serious complications are not very frequent, but they are possible.

- Perforation or rupture of the intestine.
- Hemorrhage.
- Severe allergic reactions to medications.
- Cardiopulmonary alterations.
- Rupture of abdominal aneurysm.
- Transmission of infections.
- Exceptionally, an urgent treatment or a surgical operation might be required.

1.6.3.The ones related to your own medical condition:

1.7.Special situations that must be taken into account: drug allergies: it must be known previously if you have any allergies to anesthetics or sedatives, in order to avoid their use in case they are

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contraindicated.

Patients with antiagregant or anticoagulant treatment may have higher risk of hemorrhage, especially if biopsies are taken, or with other maneuvers. Precautions in this regard must be taken.

Heart failure, respiratory failure, kidney failure, recent acute myocardial infarction, and severe inflammatory bowel diseases increase the risk of complications.

1.8. Other information of interest (to be taken into consideration by the healthcare professional):

perform the preparation correctly. It will make the exploration easier, diminish the discomfort, and avoid having to repeat it.

Let us know if you suffer from possible allergies to medications..

Notify us on time (at least a week earlier) if you take any anticoagulant medications (Sintrom®, etc.) or antiagregant ones (aspirin, acetyl- salicylic acid, tromalyl®, iscover®...), for it might be necessary to discontinue their use prior to the study.

Come with another person.

Do not drive or operate dangerous machinery during the rest of the day in case you have been administered sedation.

1.9. Other issues we need your consent for

1.9.1. Sometimes, during the procedure, there are some unexpected findings. These might oblige to change the way for performing the procedure and to use variants of the same that were not initially planned.

1.9.2. Sometimes, it is necessary to take biological samples to better study your case. These samples might be saved and used later for research related to the disease you have. They will not be used directly for commercial purpose. If they were to be used for other purposes rather than the ones stated herein, your previous consent will be requested. If you do not consent for them to be used for research purposes, the samples will be destroyed once your case has been documented, according to the policies of our Healthcare Facility. In any case, your identity will be kept confidential at all times.

1.9.3. It may also be necessary to take images such as photographs or videos. They serve to better document the case. They can also be used for educational purposes or for the diffusion of scientific knowledge. In any case, they will be used only if you give your consent. Your identity will be kept confidential at all times.

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2. Consent form

- In case of patient's disability, the consent form must be obtained from the legal representative.
- In case of minor, when it is considered that he/she lacks sufficient maturity, the consent form must be obtained from the legal representative, although the minor should be always informed in accordance with his/her level of understanding and if he/she is over the age of 12, his/her opinion will be heard.
- If the patient is emancipated or is at least 16 years-old, he/she will be entitled to grant his/her own consent. However, in case of an action implying a severe risk, according to the judgment of the physician, legal representatives will also be informed and their opinion will be taken into account for the decision-making.

2.1. Patient's information and that of his/her legal representative (if required)

Patient's last and first names: ID/NIE:

Legal representative's last and first names: ID/NIE:

2.2. Professionals involved in the information and/or consent process

Last and first names: Date: Signature:

Last and first names: Date: Signature:

2.3. Consent

I, Mr/Mrs, do hereby certify that I agree with the procedure proposed to me. I have read and understood the information contained above. I was able to ask questions and address all my concerns. Therefore, I have consciously and freely decided to authorize the procedure. I am also aware that I can revoke my consent at any time I deem appropriate.

.....I DO....I DO NOT Authorize the performance of all appropriate actions, including modifications to the way of performing the procedure in order to avoid any danger or potential harm to my life or health, which could arise during the procedure.

.....I DO....I DO NOT Authorize the preservation and further use of any biological samples for research related to the disease I suffer.

.....I DO....I DO NOT Authorize that, in the event that the mentioned biological samples were to be used in different investigations, the researchers contact me in order to request my consent.

.....I DO....I DO NOT Authorize the use of the images for educational purposes or diffusion of scientific knowledge.

Location and date.....

PATIENT

Consent/Approval by

THE LEGAL REPRESENTATIVE

Signed by:

Signed by:

2.4. Rejection of the procedure

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I, Mr/Mrs, do not authorize the performance of this procedure. I do hereby assume the consequences that could arise related to my health or my life.

Location and date.....

PATIENT

Consent/Approval by
LEGAL REPRESENTATIVE

Signed by:

Signed by:

2.5.Revocation of consent

I, Mr/Mrs, have freely and consciously decided to revoke my consent for this procedure. I do hereby assume the consequences that could arise related to my health or my life.

Location and date.....

PATIENT

Consent/Approval by
LEGAL REPRESENTATIVE

Signed by:

Signed by: