

# INFORMED CONSENT FORM

Last modified: February 2<sup>nd</sup>, 2018

**1. Study title:** Abnormal Blood Sugar Tests in Diabetic Patients During Colonoscopy Preparation

**2. Principal Investigator:** Myong Ki Baeg, MD, PhD, Department of Gastroenterology, International St. Mary's Hospital, Incheon, Republic of Korea

### **3. What you should know before agreeing to study participation**

We will comply with legal regulations and the Declaration of Helsinki ethics principles. The study will be fully explained to you before signing the study consent form. You may inquire about this study and the informed consent form at anytime. You may decide to participate or not participate in this study of your own free will.. Please take you time before deciding on participation. You may consult with your kin or others before making a decision. There are no repercussions to whichever decision you may make. Your data will be blinded before undergoing analysis, rendering it anonymous.

**4. Study goal:** To discover the incidence of abnormal glucose levels after fasting and bowel preparation for colonoscopy in type 2 diabetes subjects.

**5. Study time:** From colonoscopy preparation to exiting the endoscopy department. Expected to end on December 31<sup>st</sup>, 2019.

**6. How many are expected to enroll in this study:** From 1000 to 2000 subjects.

### **7. How is the study done?**

This informed consent form will be explained to you at the outpatient clinic of the International St. Mary's hospital. If you agree, guidelines about colonoscopy preparation will be explained to you

before colonoscopy. If you have hypoglycemic symptoms during fasting or preparation, please use self-remedies such as candy or juice. If these do not relieve your symptoms, please contact or come to a nearby medical facility or the International St. Mary's hospital. After colonoscopy preparation, when you enter the preparation unit of the endoscopy center, you will have your blood sugar checked and be instructed to fill out a questionnaire. If you have hypo or hyperglycemia, you will be treated for this condition.

#### **8. What must I conform to during the study?**

Please conform to the colonoscopy fasting and preparation medication instructions. Otherwise, there is nothing that you must do.

#### **9. What discomfort and risks do I undergo by participating in this study?**

Fasting and preparation for colonoscopy are done regardless of study participation. Therefore, there are no added risks by enrolling in this study. When we check your blood sugar, there will be a little pinprick.

#### **10. Are there any benefits to participating in this study?**

There are no added benefits by participating in this study.

#### **11. What should I do if I don't want to participate in this study?**

There are no penalties and the colonoscopy will be done as scheduled.

#### **12. Is there any reimbursement for injuries/harm inflicted during this study?**

This study will not cause any additional injuries or harm. Therefore, there will be no reimbursement for any injuries or harm which occur during colonoscopy or colonoscopy preparation.

#### **13. What about dropping out from the study?**

You may request to drop out from the study at any time. Please contact the study investigator or

the IRB whenever you want to drop out from the study.

**14. Who do I contact?**

The institutional review board of International St. Mary's Hospital 032-290-2617

Email: [hkchoi@ish.ac.kr](mailto:hkchoi@ish.ac.kr)

## Informed consent

I have been thoroughly informed about this study and all questions that I may have about this study have been answered. I enter this study of my own free will and confirm that I will have a copy of this consent form given to me after signing.

Participant

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Legal guardian (if needed)

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Investigator

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_