

## Curriculum Vitae of Investigators

**Sofia Isabel Ribeiro – Yadav, RMT, MLS (ASCP)i, MD**

Marilao, Bulacan, Philippines

(+63) 923 743 6532

sisabelribeiro94@gmail.com

### EDUCATION

- General Surgery Residency Training (January, 2020 – *present*)  
Department of Surgery, Bulacan Medical Center  
City of Malolos, Bulacan, Philippines
- Doctor of Medicine (2014 – 2018)  
Our Lady of Fatima University  
Valenzuela City, Philippines
- Bachelor in Medical Laboratory Sciences (2010 – 2014)  
Our Lady of Fatima University  
Valenzuela City, Philippines

### WORK EXPERIENCE

- Resident Physician, General Surgery (January, 2020 – *present*)  
Department of Surgery, Bulacan Medical Center  
City of Malolos, Bulacan, Philippines
- Post Graduate Intern (July, 2018 – July, 2019)  
Bulacan Medical Center  
City of Malolos, Bulacan, Philippines

## **Lucas Riel B. Bersamin, MD, FPSGS, FPCS, FPALES**

Las Piñas, Philippines

(+63) 917 521 3428

ahmcmisfellows2020@gmail.com

### **EDUCATION**

- Advanced Minimally Invasive Surgery Fellowship Training (January, 2020 – December, 2021)  
Department of Surgery, Asian Hospital and Medical Center  
Muntinlupa, Metro Manila, Philippines
- General Surgery Residency Training (January, 2012 – December, 2016)  
Department of Surgery, Ospital ng Maynila  
Manila, Philippines
- Doctor of Medicine (2005 – 2010)  
Pamantasan ng Lungsod ng Maynila  
Manila, Philippines
- Bachelor of Science in Nursing (1998 – 2002)  
University of Santo Tomas  
Manila, Philippines

### **WORK EXPERIENCE**

- Consultant Staff (2022 – *present*)  
Department of Surgery, Bulacan Medical Center  
City of Malolos, Bulacan, Philippines
- Consultant Staff (2022 – *present*)  
Department of Surgery, Asian Hospital and Medical Center  
Muntinlupa, Metro Manila, Philippines
- Consultant Staff (2021 – *present*)  
Department of Surgery, Medical Center Manila  
Manila, Philippines
- Consultant Staff (2021 – *present*)  
Department of Surgery, Ospital ng Maynila Medical Center  
Manila, Philippines
- Consultant Staff (2018 – *present*)  
Department of Surgery, Unihealth Hospital and Medical Center  
Paranaque, Metro Manila, Philippines
- Consultant Staff (2018 – *present*)  
Department of Surgery, Medical Center Taguig  
Taguig, Metro Manila, Philippines

**Penelope Pelczar, MSHE, Dr. rer. nat.**  
Hamburg, Germany  
p.pelczar@uke.de

#### EDUCATION

- Dr. rer. nat. (2009 – 2013)  
Institute of Human Genetics, University Medical Center Göttingen  
Göttingen, Germany
- Master of Science, Study of Human Ecology (2004 – 2006)  
Chungnam National University  
South Korea
- Bachelor of Science in Public Health (1996 – 2001)  
University of the Philippines – Manila  
Manila, Philippines

#### WORK EXPERIENCE

- Postdoctoral Researcher (2014 – *present*)  
UKE  
Hamburg, Germany
- Researcher (2006 – 2009)  
Korea Atomic Energy Research Institute  
South Korea
- Research Assistant (2002 – 2004)  
National Institute of Health  
Manila, Philippines



## APPENDIX 1



### BULACAN MEDICAL CENTER DEPARTMENT OF SURGERY MOJON, MALOLOS CITY, BULACAN

#### **CHAIRMAN**

*Jose Emiliano T. Gatchalian, MD, FPCS FPSGS.*

#### **TRAINING OFFICER**

*Hilda M. Sagayaga, MD, FPSTS, FPCS, FPSGS*

#### **CONSULTANTS**

##### **GENERAL SURGERY**

*Protacio T. Bajao, MD, FPSGS, FPCS*

*Bethoven J. Go, MD, FPSGS, FPCS*

*Jose Ravelo T. Bartolome, MD, FPSGS, FPCS*

*Hjordis Marushka B. Celis, MD, FPSGS, FPCS*

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*Ricardo Riego De Dios, MD, FPSGS, FPCS*

*Raphael Madarcos, MD, FPSGS, FPCS*

##### **MINIMALLY INVASIVE SURGERY**

*Lucas Riel B. Bersamin Jr., MD, DPBS, FPSGS, FPATOS*

#### **CHIEF RESIDENT**

*Sofia Isabel Ribeiro – Yadav, MD*

#### **RESIDENTS**

*Raphael Vistan, MD*

*Erick James Gastardo, MD*

*Mark Joseph Barron, MD*

*Kristan Tyrone Balao, MD*

*Noel Balmoja, Jr, MD*

*Aldrin Paul Reyes, MD*

*Russel Sta. Maria, MD*

*Justine Jan De Rueda, MD*

*Reinino Mendoza, MD*

*Ada Marielle B. Ignacio, MD*

*Joanna Camille A. Luna, MD*

*Ma. Celyn B. Magno, MD*

*Greggy Aaron M. Sison, MD*

*Diana Arabani, MD*

*Wilson Caling, MD*

*Renz Mariano, MD*

*Louie Pueblias, MD*

*Inna Saliot, MD*

### **Informed Consent Form for “Effects of Preoperative Chewing Gum in Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study”**

This Consent Form is for patients undergoing Elective Laparoscopic Cholecystectomy at Bulacan Medical Center. The title of our research project is “Effects of Preoperative Chewing Gum in Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study” to be conducted by Dr. Sofia Isabel Ribeiro - Yadav under the supervision of Dr. Lucas Riel B. Bersamin on behalf of the Department of Surgery, Bulacan Medical Center. This study has no sponsors.

This Informed Consent Form has two parts:

1. Information Sheet - to share information about the research with you
2. Certificate of Consent - for signatures if you agree to take part

You will be given a copy of the full Informed Consent Form

## PART I: Information Sheet

I am Dr. Sofia Isabel Ribeiro – Yadav, working for Department of Surgery, Bulacan Medical Center. We are currently doing research on patients undergoing Laparoscopic Cholecystectomy due to Cholelithiasis or Gall Bladder Polyps which are very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor, or the staff.

Cholelithiasis is one of the most common diseases in this country due to the incidence of the population of younger residents that indulge in fast food and the latest food craze which is “samgyupsal”, better known as Korean barbeque. The best – known management for this disease entails surgery, either open or laparoscopic.

Laparoscopic Cholecystectomy is the gold – standard for the treatment of symptomatic gallstone disease and has a conversion rate of 5 to 10%. The reason we are doing this research is to investigate whether chewing gum can aid in decreasing the rate of conversion due to gastric distention and inaccessible landmarks.

This research will involve chewing a local – brand mint flavored gum 30 minutes prior to your scheduled operation (Laparoscopic Cholecystectomy), as well as, two follow up visits to the Out – Patient Department (OPD).

We are inviting all consenting patients that will undergo Elective Laparoscopic Cholecystectomy with the indications of Cholelithiasis and/or Gall Bladder Polyp to participate in this research on Chewing Gum.

Your participation in this research is entirely *voluntary*. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this medical center will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this medical center for Cholelithiasis/Gall Bladder Polyp, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

During the research, you will be admitted to the surgery ward of Bulacan Medical Center for 24 to 28 hours after which you will be discharged and advised to follow up post operatively at the Out Patient Department at the 2<sup>nd</sup> and 4<sup>th</sup> week.

- In the first visit, the suture will be removed from the post operative site and your wounds will be assessed for signs of surgical site infection
- In the second visit, your post operative site will be assessed and your overall wellness will be checked

The research will take place over 19 months in total. During that time, it will be necessary for you to come to the medical center to be admitted for 24 – 48 hours after which you will be discharged and advised to follow up post operatively at the OPD at the 2<sup>nd</sup> and 4<sup>th</sup> week.

In total, you will be asked to come at least 3 times to the medical center during the span of 1 month during these 19 months. At the end of 19 months, the research will be finished.

As previously mentioned, laparoscopic cholecystectomy has a conversion rate of 5 – 10%. It is possible that this may also happen to you even though the incidence of conversion is low. This research

aims to lessen the possibility of such a scenario. However, in case this does happen then rest assured, we will perform the procedure required for the findings presented to us – to the best of our abilities.

If you participate in this research, there may not be any benefit for you but your participation is likely to help us find the answer to the research question which will lead to future benefits to society.

You will not be given any money or gifts to take part in this research.

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no – one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the main investigator.

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. These will be small meetings in the community and these will be announced. After these meetings, we will publish results in order that other interested people may learn from our research.

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. If it your choice and all of your rights will still be respected.

If you do not wish to take part in the research, you will be provided with the established treatment available at the medical center.

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you have contact the following:

- Dr. Sofia Isabel Ribeiro – Yadav
  - sisabelribeiro94@gmail.com

This proposal has been reviewed and approved by La Consolacion Universtiy Philippines Research Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact Naila Mae V. Reyes, LPT at research.ethics.comm@email.lcup.edu.ph

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

## Part II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research

Printed Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

If illiterate;

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Printed Name of Witness \_\_\_\_\_

Signature of Witness \_\_\_\_\_

Date \_\_\_\_\_

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. -
2. -
3. -

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Printed Name of Researcher \_\_\_\_\_

Signature of Researcher \_\_\_\_\_

Date \_\_\_\_\_



## APPENDIX 2



### BULACAN MEDICAL CENTER DEPARTMENT OF SURGERY MOJON, MALOLOS CITY, BULACAN

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Louie Pueblos, MD

Inna Saliot, MD

### Informed Consent Form for “Effects of Preoperative Chewing Gum in Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study”

Ang pahintulot na ito ay para sa mga pasyenteng sumasasilalim sa Elective Laparoscopic Cholecystectomy sa Bulacan Medical Center. Ang pamagat ng aming proyektong pananaliksik ay “Effects of Preoperative Chewing Gum in Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study” na gagawin ni Dr. Sofia Isabel Ribeiro - Yadav sa ilalim ng pangangasiwa ni Dr. Lucas Riel B. Bersamin sa ngalan ng Department of Surgery, Bulacan Medical Center. Ang pag-aaral na ito ay walang mga sponsor.

Ang Pahintulot na ito ay may dalawang bahagi:

1. Impormasyon – upang ibahagi ang impormasyon tungkol sa pananaliksik na ito
2. Pahintulot – para sa mga lagda kung sumasang – ayon kayong lumahok

Ibibigay sa inyo ang isang kopya ng buong Pahintulot

## **BAHAGI I: Impormasyon**

Ako si Dr. Sofia Isabel Ribeiro – Yadav, nagtatrabaho sa Department of Surgery, Bulacan Medical Center. Kami ay kasalukuyang nagsasagawa ng pananaliksik sa mga pasyenteng sumasailalim sa Laparoscopic Cholecystectomy dahil sa Cholelithiasis o Gall Bladder Polyps na karaniwan dito sa bansa. Bibigyan kita ng impormasyon at anyayahan kang maging bahagi ng pananaliksik na ito. Hindi mo kailangang magpasya ngayon kung sasali ka o hindi sa pananaliksik. Bago ka magdesisyon, maaari kang makipag-usap sa sinumang komportableng kausapin tungkol sa pananaliksik.

Maaaring may mga salitang hindi mo maintindihan. Pakiusap itanong mo sa akin kung kailangan mo ng paliwanag habang binabasa natin ang impormasyon at ipapaliwanag ko ito. Kung may mga katanungan ka sa hinaharap, maaari mong itanong sa akin, sa doktor ng pag-aaral, o sa mga tauhan.

Ang Cholelithiasis ay isa sa pinakakaraniwang sakit sa bansa dahil sa mataas na insidente ng mga kabataang residente na mahilig sa fast food at sa pinakabagong pagkain na "samgyupsal", na kilala rin bilang Korean barbecue. Ang pinakamahusay na kilalang paraan ng pamamahala para sa sakit na ito ay operasyon, maaaring bukas o laparoscopic.

Ang Laparoscopic Cholecystectomy ang gold standard para sa paggamot ng symptomatic gallstone disease at may conversion rate na 5 hanggang 10%. Ang dahilan ng aming pananaliksik ay upang imbestigahan kung makakatulong ang pagnguya ng gum sa pagbaba ng rate ng conversion dahil sa gastric distention at hindi maabot na mga landmark.

Ang pananaliksik na ito ay kinabibilangan ng pagnguya ng lokal na tatak ng mint flavored gum 30 minuto bago ang iyong nakatakdang operasyon (Laparoscopic Cholecystectomy), gayundin ng dalawang follow up na pagbisita sa Out-Patient Department (OPD).

Inaanyayahan namin ang lahat ng consenting na pasyenteng sasailalim sa Elective Laparoscopic Cholecystectomy na may indikasyon ng Cholelithiasis at/o Gall Bladder Polyp na lumahok sa pananaliksik na ito tungkol sa Chewing Gum.

Ang iyong pagsali sa pananaliksik na ito ay boluntaryo. Nasa iyo ang pagpili kung lalahok o hindi. Kung pipiliin mong lumahok o hindi, magpapatuloy ang lahat ng serbisyong natatanggap mo sa medical center na ito at walang magbabago. Kung pipiliin mong hindi lumahok sa proyektong ito ng pananaliksik, iaalok sa iyo ang karaniwang paggamot na inaalok sa medical center na ito para sa Cholelithiasis/Gall Bladder Polyp, at ipapaliwanag namin ito sa iyo. Maaari mong baguhin ang iyong isip at tumigil sa paglahok kahit na sumang-ayon ka dati.

Sa panahon ng pananaliksik, ikaw ay ma-admit sa surgery ward ng Bulacan Medical Center ng 24 hanggang 28 oras pagkatapos nito ay makaka-discharge ka at papayuhan na mag-follow up sa OPD sa ika-2 at ika-4 na linggo.

- Sa unang pagbisita, aalisin ang tahi sa post-operative site at susuriin ang iyong mga sugat para sa mga palatandaan ng surgical site infection.
- Sa ikalawang pagbisita, susuriin ang iyong post-operative site at ang iyong kabuuang kalusugan.

Ang pananaliksik ay magtatagal ng 19 buwan sa kabuuan. Sa panahong iyon, kinakailangan mong pumunta sa medical center para ma-admit ng 24 hanggang 48 oras pagkatapos nito ay makaka-discharge ka at papayuhan na mag-follow up sa OPD sa ika-2 at ika-4 na linggo.

Sa kabuuan, inaasahan kang pumunta ng hindi bababa sa 3 beses sa medical center sa loob ng isang buwan sa panahon ng 19 na buwan. Sa pagtatapos ng 19 buwan, matatapos na ang pananaliksik.

Tulad ng nabanggit, ang laparoscopic cholecystectomy ay may conversion rate na 5-10%. Posibleng mangyari rin ito sa iyo kahit na mababa ang insidente ng conversion. Layunin ng pananaliksik na ito na bawasan ang posibilidad ng ganoong sitwasyon. Gayunpaman, kung mangyari ito, makakaasa kang gagawin namin ang kinakailangang pamamaraan ayon sa mga natuklasang ipinakita sa amin - sa abot ng aming makakaya.

Kung lalahok ka sa pananaliksik na ito, maaaring wala kang makukuhang benepisyo ngunit ang iyong paglahok ay malamang na makatulong sa amin na mahanap ang sagot sa tanong ng pananaliksik na magdudulot ng mga benepisyo sa lipunan sa hinaharap.

Wala kang matatanggap na pera o regalo para lumahok sa pananaliksik na ito.

Sa pananaliksik na ito, may kakaibang ginagawa sa iyong komunidad. Posible na kung malaman ng iba sa komunidad na ikaw ay lumalahok, maaari silang magtanong sa iyo. Hindi namin ibabahagi ang pagkakakilanlan ng mga lumalahok sa pananaliksik.

Ang impormasyong makukuha namin mula sa proyektong ito ng pananaliksik ay mananatiling kumpidensyal. Ang impormasyon tungkol sa iyo na makokolekta sa panahon ng pananaliksik ay itatago at walang makakakita nito kundi ang mga mananaliksik. Anumang impormasyon tungkol sa iyo ay magkakaroon ng numero imbes na pangalan mo. Tanging ang mga mananaliksik ang makakaalam kung ano ang iyong numero at itatago namin ang impormasyon na iyon nang may kandado. Hindi ito ibabahagi o ipapasa sa iba maliban sa pangunahing mananaliksik.

Ang kaalamang makukuha namin mula sa paggawa ng pananaliksik na ito ay ibabahagi sa iyo sa pamamagitan ng mga pulong sa komunidad bago ito gawing malawak na magagamit sa publiko. Ang kumpidensyal na impormasyon ay hindi ibabahagi. Ito ay magiging maliit na pulong sa komunidad at ipapahayag ito. Pagkatapos ng mga pulong na ito, ilalathala namin ang mga resulta upang ang iba pang interesadong tao ay maaaring matuto mula sa aming pananaliksik.

Hindi mo kailangang lumahok sa pananaliksik na ito kung ayaw mo. Maaari ka ring tumigil sa paglahok sa pananaliksik anumang oras na piliin mo. Nasa iyo ang pagpili at lahat ng iyong mga karapatan ay igagalang pa rin.

Kung hindi mo nais na lumahok sa pananaliksik, ikaw ay bibigyan ng itinatag na paggamot na magagamit sa medical center.

Kung mayroon kang mga katanungan, maaari mo itong itanong ngayon o sa hinaharap, kahit na nagsimula na ang pag-aaral. Kung nais mong magtanong sa hinaharap, maaari kang makipag-ugnayan sa mga sumusunod:

- Dr. Sofia Isabel Ribeiro – Yadav
  - sisabelribeiro94@gmail.com

Ang proposal na ito ay nirepaso at inaprubahan ng La Consolacion University Philippines Research Ethics Committee, na isang komiteng ang tungkulin ay tiyakin na ang mga kalahok sa pananaliksik ay protektado mula sa pinsala. Kung nais mong malaman ang higit pa tungkol sa IRB, makipag-ugnayan kay Naila Mae V. Reyes, LPT at research.ethics.comm@email.lcup.edu.ph

Maaari mo akong tanungin ng higit pang mga tanong tungkol sa anumang bahagi ng pag-aaral ng pananaliksik, kung nais mo. Mayroon ka bang mga tanong?

## **BAHAGI II: Pahintulot**

Nabasa ko ang impormasyong nabanggit sa itaas, o ito ay nabasa sa akin. Nagkaroon ako ng pagkakataong magtanong tungkol dito at ang anumang mga tanong na itinatanong ko ay nasagot nang kasiya-siya. Kusang-loob akong pumapayag na lumahok bilang isang kalahok sa pananaliksik na ito.

Printed Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

Kung hindi marunong magbasa;

Napatunayan ko ang wastong pagbasa ng form ng pahintulot sa potensyal na kalahok, at ang indibidwal ay nagkaroon ng pagkakataong magtanong. Pinatunayan ko na ang indibidwal ay kusang nagbigay ng pahintulot.

Printed Name of Witness \_\_\_\_\_

Signature of Witness \_\_\_\_\_

Date \_\_\_\_\_

Nabasa ko nang tama ang impormasyon sa potensyal na kalahok, at sa abot ng aking makakaya ay sinigurado ko na nauunawaan ng kalahok na ang mga sumusunod ay gagawin:

1. –
2. –
3. –

Pinatunayan ko na ang kalahok ay binigyan ng pagkakataong magtanong tungkol sa pag-aaral, at lahat ng mga tanong na itinatanong ng kalahok ay nasagot nang tama at sa abot ng aking makakaya. Pinatunayan ko na ang indibidwal ay hindi pinilit na magbigay ng pahintulot, at ang pahintulot ay ibinigay nang kusang-loob.

Isang kopya ng ICF na ito ay ibinigay sa kalahok.

Printed Name of Researcher \_\_\_\_\_

Signature of Researcher \_\_\_\_\_

Date \_\_\_\_\_

## APPENDIX 3



La Consolacion University Philippines  
Bulihan, City of Malolos, Bulacan 3000



### Research Ethics Committee Protocol Approval

May 27, 2024

**SOFIA ISABEL RIBEIRO – YADAV, MD**  
Principal Investigator

Re: **Effects of Preoperative Chewing Gum on Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study**  
(1062/202405-YadavS00)

Sir/Ma'am,

We wish to inform you that the study protocol entitled, “**Effects of Preoperative Chewing Gum on Gastric Distention in Patients undergoing Laparoscopic Cholecystectomy: A Single Centre Study**” has been reviewed and is hereby granted **Ethics Clearance** for implementation by the LCUP-REC. The study has been assigned study protocol code **1062/202405-YadavS00**, which should be used for all communication to the LCUP- REC related to this study. This ethical clearance is valid for one year until **May 28, 2025**.

The following technical documents were submitted for review on which this approval was based:

1. Study Protocol/Investigator’s Brochure
2. Proposal manuscript
3. A comprehensive review of literature that justified the conduct of the study
4. The procedure of research data gathering was found to be scientific
5. Adherence and observance of ethical standards set for research undertaking as seen in Chapter 2 – Ethical Consideration
6. Reference List
7. Informed Consent Form / Assent Form
8. Appended research instrument
9. Curriculum Vitae illustrating the investigator’s qualification to conduct of the study
10. Budget Proposal using the PRE-REC-FO-011-Detailed Budget Sheet
11. Compliance and justification report on the protocol assessment form

While the study is in progress, the Principal Investigator is requested to submit the following documents:

1. Progress report using the PRE-REC-FO-018 (Continuing Review Application Form) every six months from the date of approval which includes the following: (NOTE: *In view of active ethical clearance, this report is mandatory even if the study has not started or is still awaiting release of funds.*)
  - a. Date covered by the report (if any)
  - b. Protocol summary and status report on the progress of the research
  - c. Number of participants accrued
  - d. Withdrawal or termination of participants
  - e. Complaints on the research since the last LCUP-REC review
  - f. Summary of relevant recent research literature, interim findings and amendments since

- a. the last LCUP-REC review
  - b. Any relevant multi-center research reports
  - c. Any relevant information especially about risks associated with the research
  - d. A copy of the accomplished informed consent document
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the study/trial including changes in personnel, must be submitted or reported using the PRE-REC-FO-017 (Study Protocol Amendment Submission Form).
  3. Revisions in the informed consent form using the PRE-REC-FO-017 (Study Protocol Amendment Submission Form).
  4. Reports of adverse events including from other study sites using the PRE-REC-FO-017 (Serious Adverse Event Report).
  5. Notice of early termination of the study and reasons for such using the PRE-REC-FO-019 (Early Termination Report Form).
  6. Any event which may have ethical significance.
  7. Any information which is needed by the LCUP-REC to do an ongoing review.
  8. Notice of time of completion of the study using the PRE-REC-FO-020 (Final Report Form).
  9. Application for renewal of ethical clearance 90 days before the expiration date of this approval through submission of PRE-REC-FO-018 (Continuing Review Application Form).
  10. Any unreported protocol amendments, deviation, serious adverse events, suspected unexpected serious adverse events, and other gross violations determined by the REC, ethics clearance may be revoked after thorough investigation and determination of REC.

Thank you. Respectfully,



**GERALD LESTER A. CAOILI, PTRP, MSPT, DrPH(c)**  
Chair, LCUP-R