A. PARTICIPANT INFORMATION SHEET

I. STUDY INFORMATION

Protocol Title: **A Double-Blind Randomized Controlled Trial on the Efficacy of Hydrocolloid Dressing vs. Topical Antibiotic on Wound Healing of Post-Punch Biopsy Wounds Among Patients in a Tertiary Hospital in Manila**

Principal Investigator and Contact No.: **Fiona Bianca V. Enriquez, MD / 0905477350**

II. PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to determine the efficacy of using hydrocolloid dressing on wound healing of non-sutured post-punch biopsy sites in comparison to gauze dressing impregnated with topical antibiotics.

You are invited to join this study because you have met our eligibility clause. Your participation in this study is completely voluntary

III. ELIGIBILITY CLAUSE

Adult patients 18 to 64 years old with clean cutaneous lesions who will undergo skin punch biopsy using a 3-mm disposable biopsy puncher.

IV. WHAT WILL YOU HAVE TO DO?

If you agree to take part in this study:

a. Your age, gender, and the anatomic sites of the skin punch biopsy will be recorded.
b. You will be randomly assigned to a treatment plan, either the hydrocolloid dressing or the topical antibiotic.
c. Photographs of the skin punch biopsy sites will be taken to be used as a baseline.
d. On the 5th day after the skin punch biopsy procedure, you are expected to return to the USTH OPD for evaluation of the skin punch biopsy site. The following data will be recorded in the wound evaluation sheet: the presence or absence of infection, the clinical estimate of reepithelialization, the clinical estimate of wound closure, scar formation, pigmentation of scar, and the cosmetic appearance of the wound. Photographs of the skin punch biopsy sites will also be taken.

You are free to ask questions any time during the conduct of the study and we shall answer them the best we can. Should you decide to withdraw from this study at any time, for whatever reason you may have, you will be free to do so, and your decision will not affect the medical care you are receiving.

V. BENEFITS FROM PARTICIPATING IN THE STUDY

The direct benefit that you shall acquire from this study is to have better clinical outcomes at the post-biopsy site. All the dermatologic consultations and medications of the participants for the duration of the study will be free of charge. **Transportation allowance of PHP 100.00 will be provided on the 5th day after the skin punch biopsy.** No **other form of** monetary compensation or incentive shall be given. However, if clinically important findings are noted, you and your attending physician will be informed immediately so that further action may be taken if necessary.

VI. VOLUNTARY PARTICIPATION

Your participation in this study is voluntary and you will be free to withdraw from this study at any time should you wish to do so. You will be given a copy of the signed and dated written informed consent form prior to study participation.

VII. POSSIBLE RISKS TO PARTICIPANTS

There is a possible side effect of irritation of the skin with the use of hydrocolloid dressing. Treatment on patients who will experience any adverse side effects will be immediately stopped. **Management, consultation, and treatment of adverse effects resulting from the participation in this study will be free of charge.**

VIII. WHOM TO CONTACT IF YOU HAVE QUESTIONS

If you have questions about this research study, you may contact the investigator, **Dr. Fiona Bianca V. Enriquez** at cellphone number 09054777350.

If you want an independent opinion of your rights as a research subject, you may contact the UST Hospital – Research Ethics Committee (USTH-REC), which is a committee tasked to make sure that research participants are protected from any form of harm:

JOSEPHINE M. LUMITAO, M.D.
Head, USTH - Research Ethics Committee
6th Floor, Clinical Division, UST Hospital
731-3001 local 2610 / usth_irb@yahoo.com.ph

B. CERTIFICATE OF CONSENT (English version)

Protocol Title: **A Double-Blind Randomized Controlled Trial on the Efficacy of Hydrocolloid Dressing vs. Topical Antibiotic on Wound Healing of Post-Punch Biopsy Wounds Among Patients in a Tertiary Hospital in Manila**

Principal Investigator and Contact Details:
Fiona Bianca V. Enriquez, MD / 0905477350

I voluntarily consent to take part in this study. This study has been explained to me fully in a manner that I've understood. The purpose and significance of this study has been explained to me completely and my questions and queries were directly answered. I was in no way coerced to participate in this study.

_____	_____	_____
Name of Participant/Legal Guardian	Signature	Date

Witness Statement

I, the undersigned, hereby certify that to the best of my knowledge, the participant signing this informed consent form has fully understood the nature, risks, and benefits of his/her participation in the study. He/she was in no way coerced by the investigator to participate in this study.

_____	_____	_____
Name of Witness	Signature	Date

Investigator Statement

I, the undersigned, hereby certify that I have fully explained the study to the participant. To the best of my knowledge, the participant of the study has fully understood the risks and benefits of his/her participation. He/she was in no way coerced to participate in this study.

_____	_____	_____
Name of Person Obtaining Consent	Signature	Date