INFORMED CONSENT FORM
STAGE 1. BASIC SYMPTOM ITEM POOL

1. INTRODUCTION

We are #MentalHealthPH, a community-based mental health organization. We are based in Quezon City, with chapters in Iloilo City, Cebu City, and the Bicol Region. We are doing research, and the principal investigator (PI) for this project is Dr. Ronald Del Castillo. We are developing mental health mobile applications ("apps" or "chatbots") that you could download and use on your phone or tablet. We hope that the apps could help Filipinos with mental health concerns or problems. You are invited to participate.

This information sheet is about our research. We have done our best to make clear what the research involves. If you wish to ask for clarifications or want additional information, you are encouraged to contact anyone in the research team. You do not have to decide right now—or even today—if you will participate in the research. We encourage you to reflect on it. If there is anything you see, read, or notice that you do not understand about the research, you can talk to anyone whom you feel comfortable with about the project. We will assist you.

2. PURPOSE OF THE RESEARCH

This study involves research. The overall goal of this research is to develop mobile apps or chatbots and to test them and see if they can promote mental wellbeing and reduce psychological or emotional distress. This is a multi-year, 8-stage project. Your participation is requested in Stage 1, and this consent applies only to Stage 1. In Stage 1, we hope to create a comprehensive but succinct picture of how Filipinos experience depression and anxiety and to identify interventions that might be used in a phone app.

3. TYPE OF RESEARCH INTERVENTION

In Stage 1, there is no intervention. You will not receive an intervention.

4. PARTICIPANT SELECTION

We are inviting between 75 and 90 adult Filipinos across the Philippines, aged 18 years or older. We are looking for participants who own a mobile device they regularly use and with reasonable and reliable internet access. You must also be able to read or understand Filipino or English.

We are looking for Filipinos with a current or recent clinical diagnosis of a depressive disorder or an anxiety disorder. We also require that you have had at least one depressive episode or anxiety-related episode lasting at least 2 weeks and leading to significant impairment in the past 12 months. Finally, we require that you have had current or recent contact with mental health services or treatment. By agreeing to participate in this research, you are disclosing and affirming that you meet these requirements.
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5. VOLUNTARY PARTICIPATION

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, it does not change anything about the benefits or services you may be currently receiving or will receive in the future. If you choose not to participate in this research project, it does not change anything. You may change your mind later and stop participating even if you agreed earlier.

6. PROCEDURES AND PROTOCOL

Step 1. First, we encourage that you carefully read this Informed Consent Form.

Step 2. When you click “Yes” on the website, you agree to participate and can begin to answer the basic demographic questions. When you click “No,” you decline to participate, and you will be automatically exited from the website.

Step 3. You will then answer two online surveys: (a) one on depression and (b) one on anxiety.

Stage 4. The research team will then contact you by phone, email, or messenger to schedule an online meeting for a semi-structured interview. The interview will cover two broad topics: (a) a follow-up to your responses to the survey questionnaires and (b) a discussion on what you think a useful and helpful mobile app should look like.

Step 5. Finally, there is an emergency phone number should you feel distressed. You should feel free to contact the research team at any point throughout your participation. However, please know that there is no live person monitoring the app. The chat function is a robot, not a person. If you feel distressed and wish to get support, it is best to contact the emergency phone number, to talk to a trusted adult (e.g., a friend or loved one), or to go to the nearest emergency room.

7. RESPONSIBILITIES OF THE PARTICIPANT

Your participation will involve the following:

1. To ask questions or clarification about this Informed Consent Form or any other aspects of the project
2. To respect privacy and maintain confidentiality
3. To answer as honestly as possible

8. RESPONSIBILITY OF THE PROJECT TEAM

Dr. Ronald Del Castillo is the principal investigator. This means that he has oversight of the entire project, ensuring that the data collection, including your participation, is consistent with the data and safety monitoring plan. Along with the project staff as well as #MentalHealthPH, which is the proponent organization for this project, we are responsible for your safety, for you to understand this consent and what your involvement entails, and for answering your questions or concerns.

9. DURATION

The entire research project is 24 months, though your participation is limited. The surveys will take about 10-15 minutes. The interview will take approximately 60-90 minutes. These might take longer or shorter. How often and how long you use the app depend on you. However, the app might prompt you with automated reminders to use it.

10. SIDE EFFECTS

There is no medical intervention or procedure involved in Stage 1. There are no anticipated side effects, although there are risks and possible discomfort, which we describe below.

11. DISCOMFORTS, INCONVENIENCES, AND RISKS

Potential risks associated with participation are unlikely, of low risk, and transient. Answering potentially sensitive questions might lead to psychological distress. For example, unwanted changes in thoughts or emotions may come from answering questions about mental wellbeing, psychological concerns or problems, and other perceived sensitive topics.

To help minimize potential psychological distress and to help ensure confidentiality, the research team uses the following strategies:

1. The research team is trained to listen to your concerns calmly and patiently so that you can be directed to appropriate support.
2. The research team can link you to trained and registered mental health professionals.
3. There is a “get support” page on the research website, on the mobile app, and at the end of this consent form.

12. BENEFITS

Your completion of the surveys and interviews might lead to self-reflection about your own health, behaviors, and community. Bringing these issues to awareness might lead to new information or knowledge. However, you might not experience direct benefits.

13. COMPENSATION, REIMBURSEMENTS, AND EXPENSES

There might be some material costs to you (e.g., internet data while using your phone) as well as other costs (e.g., loss of study or leisure time). You will be given P500 for completing the survey and P150 for the interview.

14. PRIVACY AND CONFIDENTIALITY

With this research, something out of the ordinary is being done. It is possible that if others are aware that you are participating, they may ask you questions. Every effort will be made to remind you and the other participants to respect privacy and keep confidentiality. The research team will not be sharing the identity of those participating in the research.

All data will be automatically uploaded to a secure password-protected database. As required by ethical guidelines, the research team will keep the data for at least 3 years following the submission of the final report to the Ethics Review Board. Please be reminded that the reported data will be aggregated; no individual data can be linked to you. The data will be shredded and/or otherwise destroyed after 3 years.

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. Only the research team will be able to see it. Data will not be shared with or given to anyone except the Ethics Review Board.

15. SHARING THE RESULTS

We will publicly share our research progress on a project website. You and the other participants will not be individually identified in that site. Confidential information will not be shared.

We will publish the results in order that other interested people may learn from our research. This might include publications in research journals, traditional media (e.g., newspapers) and new media (e.g., social media). Our results might also contribute to policies and programs, in both the private and public sector. You will not be individually identified in any of these efforts.

16. PARTICIPANT WITHDRAWAL OR TERMINATION

Please be reminded that your participation is voluntary and that you can withdraw from the research at any time, without penalty.

There might circumstances under which the PI may decide to end your participation regardless of whether you wish to continue participating. The foreseeable circumstances or reasons under which your participation in the study might be terminated include the following:

1. Observable distress in which continued participation is harmful to you and/or to the other participants
2. Observable irritability or agitation in which continued participation is harmful to you and/or the other participants
3. Other observable or foreseeable situations in which your safety and/or the safety of the other participants might be compromised

In these circumstances, questions might arise about whether the PI may use, study, or analyze already collected data about participants who withdraw from the survey or whose participation is terminated by the research team.

Ethical regulations state that the PI can retain and use already collected data on you to the point of your withdrawal. It may not be removed even after you have decided to withdraw or if the research team has terminated your participation. Since it is not possible to link you to a particular survey questionnaire or individual interview after they have been collected, there would be no way of removing your individual data.

No additional data will be collected after your participation is withdrawn or terminated. You will not be individually identified from the already collected data after withdrawal or termination.

17. RIGHT TO REFUSE OR WITHDRAW

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. It is your choice. All your rights will still be respected.

18. WHO TO CONTACT IN CASE OF DISTRESS

Some people might feel some discomfort or distress after completing this survey. This might happen soon after or sometime in the future. This is normal. For some people, they might feel so distressed that it might be helpful to talk to someone.

We encourage you to visit the website below or your local healthcare provider. For emergencies go to the nearest emergency room or clinic.

You may visit our “Get support” page here: https://mentalhealthph.org/support-for-yourself/.

19. WHO TO CONTACT IN THE RESEARCH TEAM

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

Ronald Del Castillo, PsyD, MPH, FRSPH
291 A. Bonifacio San Jose, Quezon City 1115
MentalHealthPH@gmail.com | +639053519620

This informed consent form is consistent with the Philippine Data Privacy Act of 2012.

It follows the National Ethical Guidelines for Health and Health-Related Research. The World Health Organization guidance and explanations for developing informed consent forms has also been extensively reviewed. Finally, the “Guidelines for best practice in cross-cultural surveys” (Institute for Social Research, University of Michigan) was closely reviewed in the developing of the current project’s informed consent form.

This proposal has been reviewed and approved by the University of Santo Tomas, College of Rehabilitation Sciences, Ethics Review Committee, which is a committee whose task it is to make

sure that research participants are protected from harm. If you wish to find more information, the Board can be reached here:

Assoc. Prof. Anna Lea Enriquez, MD (Chairperson, UST-CRS ERC), Room 101 Medicine Bldg., University of Santo Tomas, España Blvd., Manila, 1015
+027409713 | ethicsreview.crs@ust.edu.ph

This is the end of PART I. INFORMATION SHEET.

PART II. CONSENT TO PARTICIPATE

Consent by Participant

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.

Your Name:

E-Signature of Participant:

Date:

- By clicking “Yes,” you agree to participate. Your research participation will start after your click.

- By clicking “No,” you decline to participate. The site will automatically end after you click.

Witness of Participant

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.

Your Name:

E-Signature of Witness:

Date:

STATEMENT BY THE RESEARCHER/PROJECT STAFF TAKING CONSENT

Checkmark.

_____ I, the undersigned, have accurately read out and discussed the information sheet to the potential participant, and to the best of my ability made sure that the participant understands.

_____ 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 participant 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.

PROJECT STAFF:

Print Name of Project Staff Taking Consent

_____

Signature of Researcher/Project Staff Taking Consent

_____

Today's Date

_____
day/month/year

[Participants may download a copy of this consent prior to study participation.]