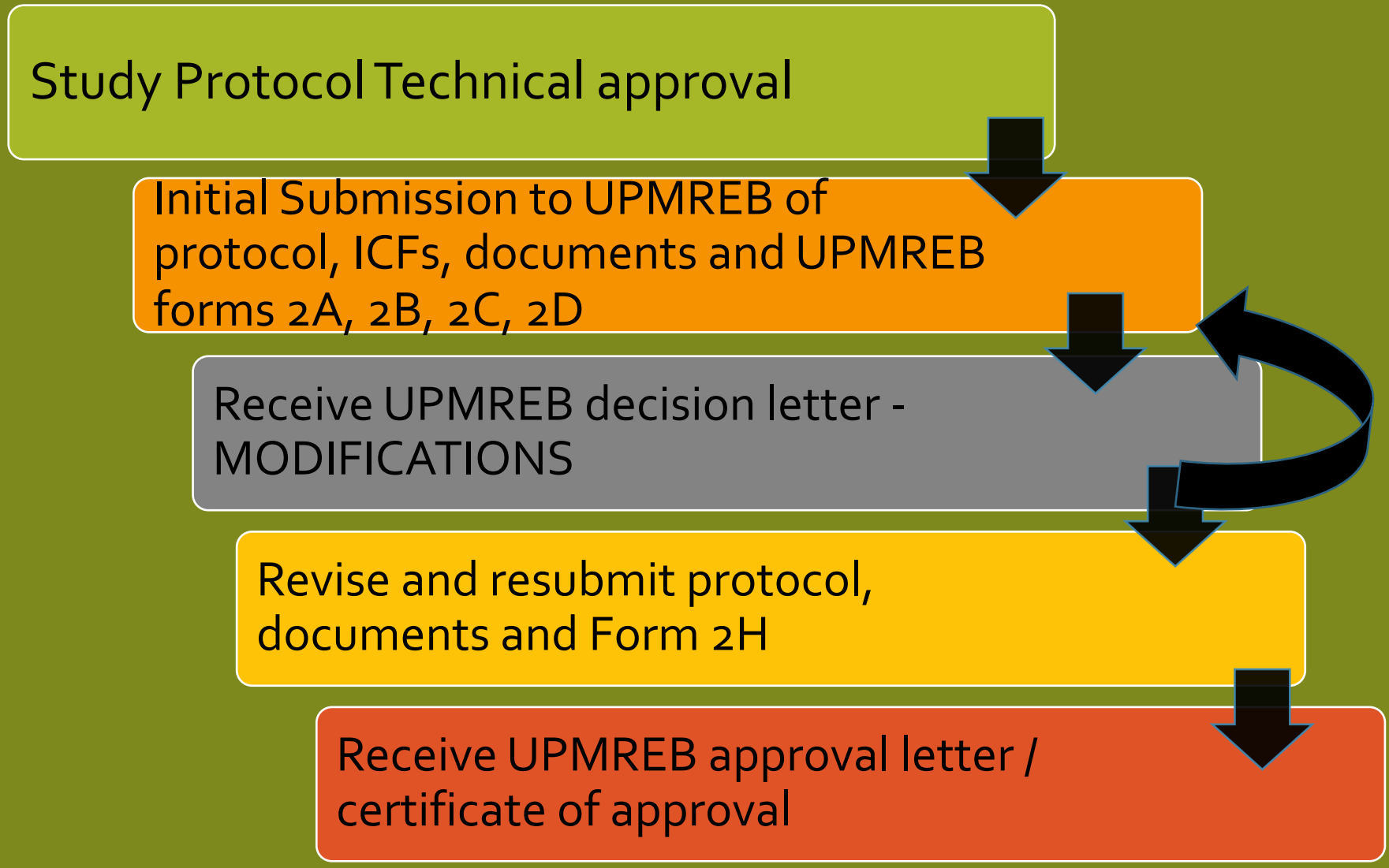
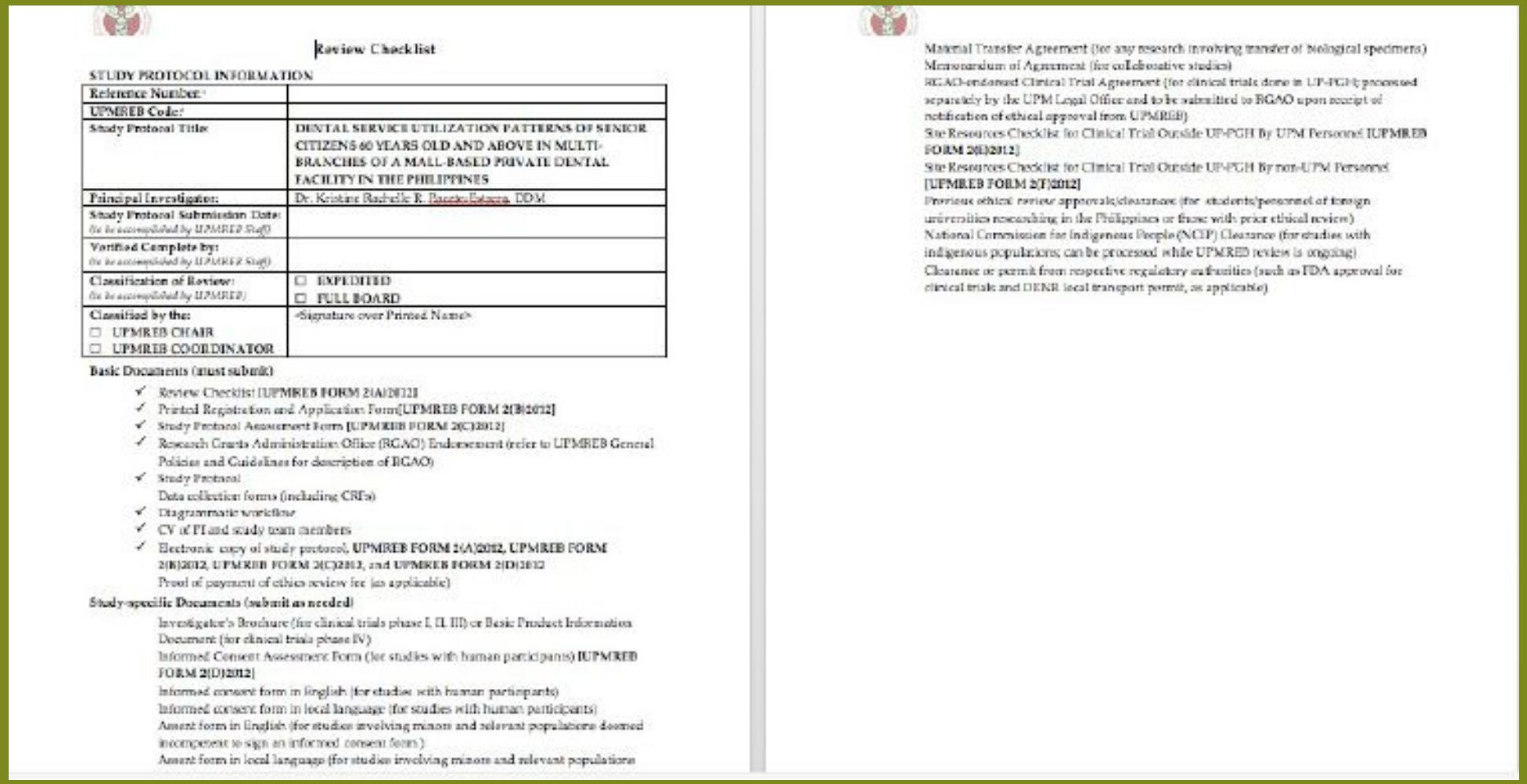
Kristine Rachelle Pacete-Estrera, DDM
Dentistry 197

The REB Process Part 2: FOLLOWING UP AFTER SUBMISSION

Steps in the study protocol ethics review process:





Review Checklist

STUDY PROTOCOL INFORMATION

Reference Number:	
UPMREB Code:	
Study Protocol Title	**DENTAL SERVICE UTILIZATION PATTERNS OF SENIOR CITIZENS 60 YEARS OLD AND ABOVE IN MULTI-BRANCHES OF A MALL-BASED PRIVATE DENTAL FACILITY IN THE PHILIPPINES**
Principal Investigator:	Dr. Kristine Rachelle R. Pareto-Estacio, DDM
Study Protocol Submission Date: *(to be accomplished by UPMREB Staff)*	
Verified Complete by: *(to be accomplished by UPMREB Staff)*	
Classification of Review: *(to be accomplished by UPMREB)*	☐ EXPEDITED ☐ FULL BOARD
Classified by the: ☐ UPMREB CHAIR ☐ UPMREB COORDINATOR	<Signature over Printed Name>

Basic Documents (must submit)

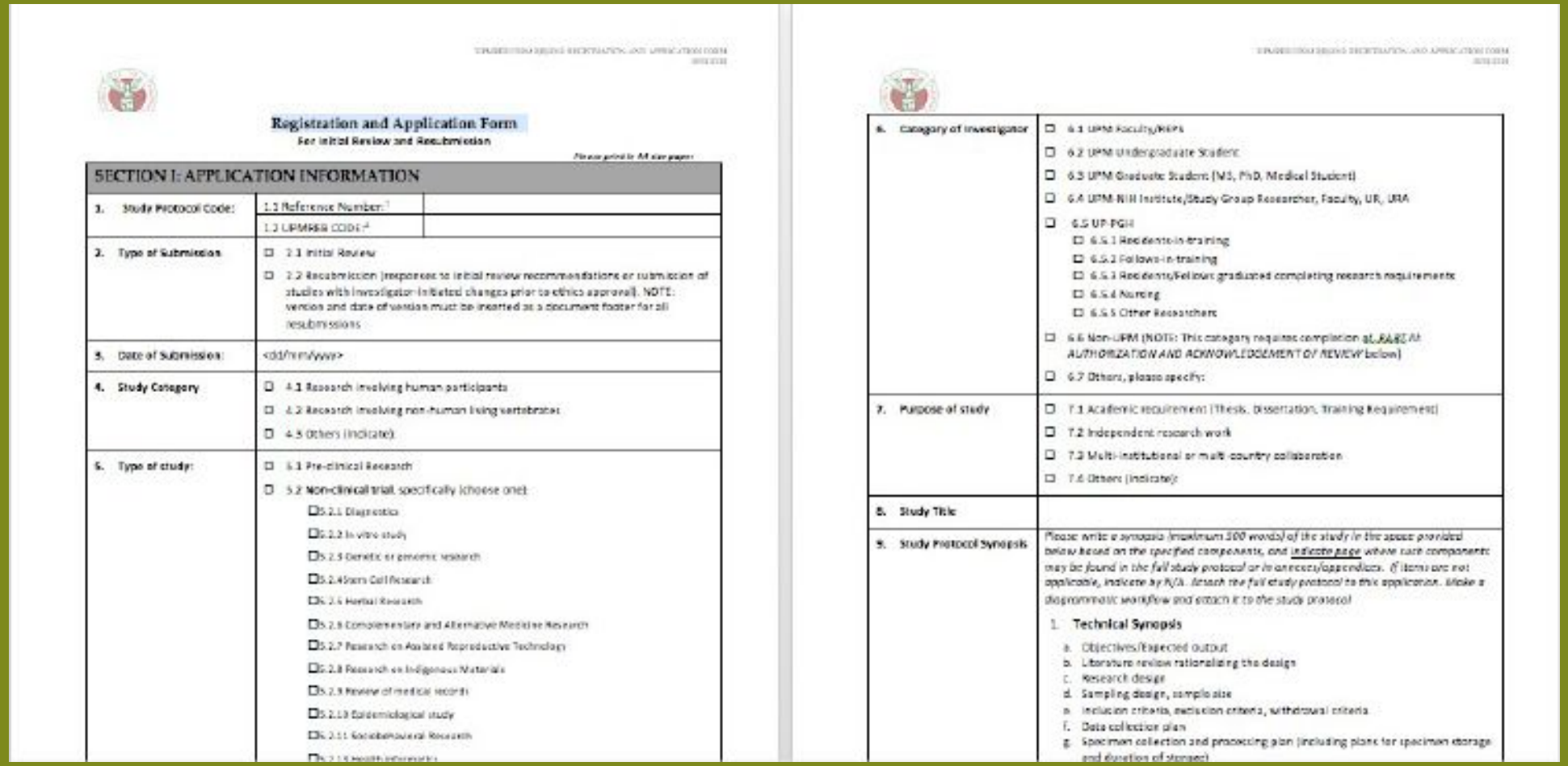
- ✓ Review Checklist [UPMREB FORM 2(A)2012]
- ✓ Printed Registration and Application Form[UPMREB FORM 2(B)2012]
- ✓ Study Protocol Assessment Form [UPMREB FORM 2(C)2012]
- ✓ Research Grants Administration Office (RGAO) Endorsement (refer to UPMREB General Policies and Guidelines for description of RGAO)
- ✓ Study Protocol
  Data collection forms (including CRFs)
- ✓ Diagrammatic workflow
- ✓ CV of PI and study team members
- ✓ Electronic copy of study protocol, **UPMREB FORM 2(A)2012, UPMREB FORM 2(B)2012, UPMREB FORM 2(C)2012, and UPMREB FORM 2(D)2012**
  Proof of payment of ethics review fee (as applicable)

Study-specific Documents (submit as needed)

Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
Informed Consent Assessment Form (for studies with human participants) **[UPMREB FORM 2(D)2012]**
Informed consent form in English (for studies with human participants)
Informed consent form in local language (for studies with human participants)
Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
Assent form in local language (for studies involving minors and relevant populations

Material Transfer Agreement (for any research involving transfer of biological specimens)
Memorandum of Agreement (for collaborative studies)
RGAO-endorsed Clinical Trial Agreement (for clinical trials done in UP-PGH; processed separately by the UPM Legal Office and to be submitted to RGAO upon receipt of notification of ethical approval from UPMREB)
Site Resources Checklist for Clinical Trial Outside UP-PGH By UPM Personnel **[UPMREB FORM 2(E)2012]**
Site Resources Checklist for Clinical Trial Outside UP-PGH By non-UPM Personnel **[UPMREB FORM 2(F)2012]**
Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while UPMREB review is ongoing)
Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

Form 2(A) Review Checklist



Registration and Application Form

For Initial Review and Resubmission

Please print in A4 size paper

SECTION I: APPLICATION INFORMATION

1. Study Protocol Code:	1.1 Reference Number:	
	1.2 UPMREB CODE	
2. Type of Submission	☐ 2.1 Initial Review ☐ 2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions	
3. Date of Submission:	<dd/mm/yyyy>	
4. Study Category	☐ 4.1 Research involving human participants ☐ 4.2 Research involving non-human living vertebrates ☐ 4.3 Others (indicate)	
5. Type of study:	☐ 5.1 Pre-clinical Research ☐ 5.2 Non-clinical trial, specifically (choose one): ☐ 5.2.1 Diagnostics ☐ 5.2.2 In vitro study ☐ 5.2.3 Genetic or genomic research ☐ 5.2.4 Stem Cell Research ☐ 5.2.5 Herbal Research ☐ 5.2.6 Complementary and Alternative Medicine Research ☐ 5.2.7 Research on Assisted Reproductive Technology ☐ 5.2.8 Research on Indigenous Materials ☐ 5.2.9 Review of medical records ☐ 5.2.10 Epidemiological study ☐ 5.2.11 Sociobehavioural Research ☐ 5.2.12 Health Informatics	

6. Category of Investigator	☐ 6.1 UPM Faculty/KKPS ☐ 6.2 UPM Undergraduate Student ☐ 6.3 UPM Graduate Student (MS, PhD, Medical Student) ☐ 6.4 UPM NIH Institute/Study Group Researcher, Faculty, UR, URA ☐ 6.5 UP PGH ☐ 6.5.1 Residents-in-training ☐ 6.5.2 Fellows-in-training ☐ 6.5.3 Residents/Fellows graduated completing research requirements ☐ 6.5.4 Nursing ☐ 6.5.5 Other Researchers ☐ 6.6 Non-UPM (NOTE: This category requires completion of *RABEI AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) ☐ 6.7 Others, please specify:
7. Purpose of study	☐ 7.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 7.2 Independent research work ☐ 7.3 Multi-institutional or multi-country collaboration ☐ 7.4 Others (indicate):
8. Study Title	
9. Study Protocol Synopsis	*Please write a synopsis (maximum 500 words) of the study in the space provided below based on the specified components, and indicate page where such components may be found in the full study protocol or in annex(s)/appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol* 1. **Technical Synopsis** a. Objectives/Expected output b. Literature review rationalizing the design c. Research design d. Sampling design, sample size e. Inclusion criteria, exclusion criteria, withdrawal criteria f. Data collection plan g. Specimen collection and processing plan (including plans for specimen storage and duration of storage)

Form 2(B) Registration and Application Form

for Initial Review and Resubmission

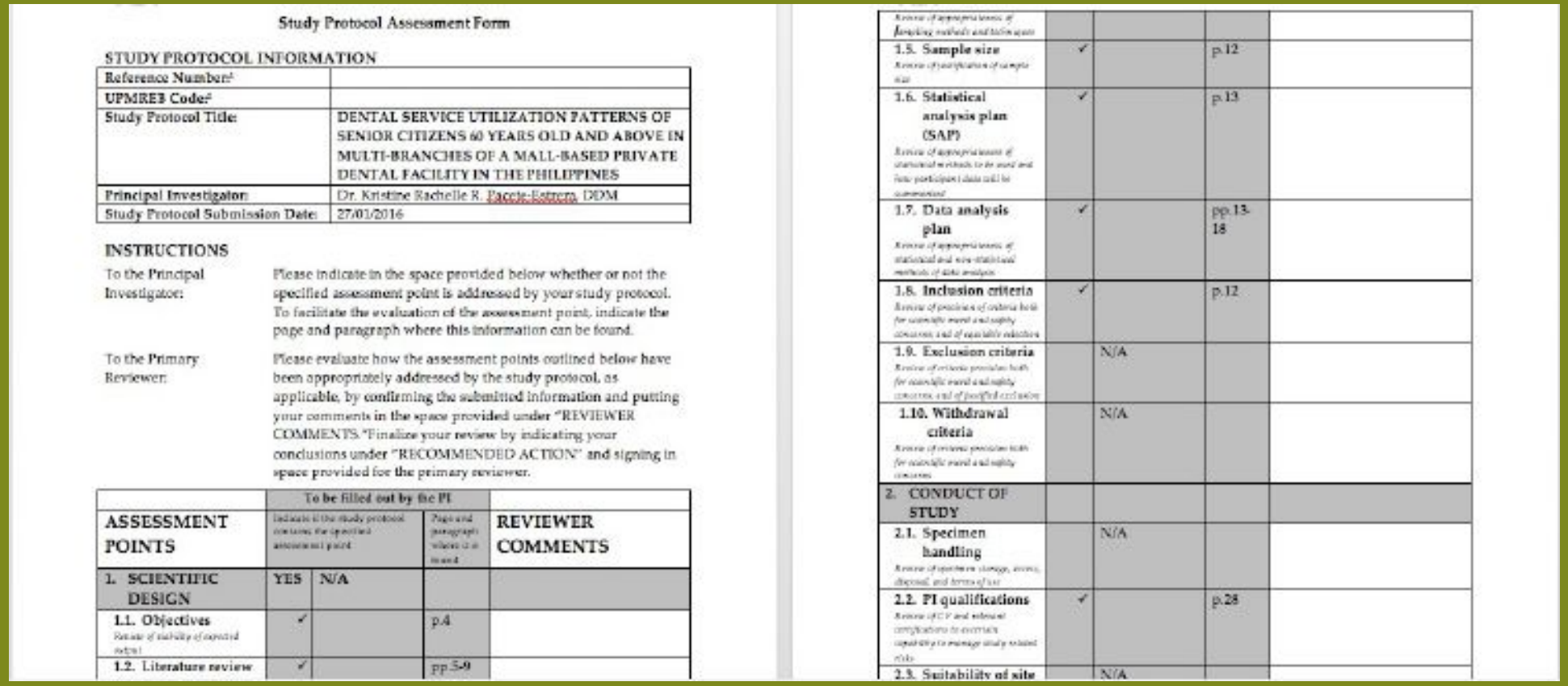
Please print in A4 size paper

SECTION I. APPLICATION INFORMATION		
1. **Study Protocol Code:**	1.1 Reference Number:[1]	
	1.2 UPMREB CODE:[2]	
2. **Type of Submission**	☐ 2.1 Initial Review ☐ 2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions	
3. **Date of Submission:**	<dd/mm/yyyy>	
4. **Study Category**	☐ 4.1 Research involving human participants ☐ 4.2 Research involving non-human living vertebrates ☐ 4.3 Others (indicate):	
5. **Type of study:**	☐ 5.1 Pre-clinical Research ☐ 5.2 **Non-clinical trial,** specifically (choose one): ☐ 5.2.1 Diagnostics ☐ 5.2.2 In vitro study ☐ 5.2.3 Genetic or genomic research ☐ 5.2.4 Stem Cell Research ☐ 5.2.5 Herbal Research ☐ 5.2.6 Complementary and Alternative Medicine Research ☐ 5.2.7 Research on Assisted Reproductive Technology ☐ 5.2.8 Research on Indigenous Materials ☐ 5.2.9 Review of medical records ☐ 5.2.10 Epidemiological study ☐ 5.2.11 Sociobehavioral Research ☐ 5.2.12 Health informatics ☐ 5.2.14 Operations/process research ☐ 5.3 **Clinical Trial Type 1** (drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials) intended for marketing registration ☐ 5.4 **Clinical Trial Type 2** (drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials) **NOT** intended for marketing registration ☐ 5.5 **Post Marketing Surveillance** ☐ 5.6 Others, please indicate:	

[1] To be issued upon RGAO registration

[2] To be issued upon initial processing by UPMREB

6. **Category of Investigator**	☐ 6.1 UPM Faculty, RCE ☐ 6.2 UPM Undergraduate Student ☐ 6.3 UPM Graduate Student (MS, PhD, Medical Student) ☐ 6.4 UPM-NIH Institute/Study Group Researcher, Faculty, UR, URA ☐ 6.5 UP-PGH ☐ 6.5.1 Residents-in-training ☐ 6.5.2 Fellows-in-training ☐ 6.5.3 Residents/Fellows graduated completing research requirements ☐ 6.5.4 Nursing ☐ 6.5.5 Other Researchers ☐ 6.6 Non-UPM (NOTE: This category requires completion of *PART III. AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) ☐ 6.7 Others, please specify:
7. **Purpose of study**	☐ 7.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 7.2 Independent research work ☐ 7.3 Multi-institutional or multi-country collaboration ☐ 7.4 Others (indicate):
8. **Study Title**	
9. **Study Protocol Synopsis**	*Please write a synopsis (maximum 500 words) of the study in the space provided below based on the specified components, and indicate page where such components may be found in the full study protocol or in annexes/appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol.* 1. **Technical Synopsis** a. Objective/Expected output b. Literature review rationalizing the design c. Research design d. Sampling design, sample size e. Inclusion criteria, exclusion criteria, withdrawal criteria f. Data collection plan g. Specimen collection and processing plan (including plans for specimen storage and duration of storage) h. Data analysis plan (including statistical basis for design, as applicable) i. Rationalization for choice of study site (including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable) (Cross reference information with statements provided in the informed consent)
	2. **Ethical Considerations Section** *This should be stated in the study protocol, as applicable.* a. Protection of privacy and confidentiality of research information including data protection plan b. Vulnerability of research participants c. Risks of the study (including social risks) d. Benefits of the study e. Patent related compensations/reimbursements/entitlements f. Informed consent process and recruitment procedures



Study Protocol Assessment Form

STUDY PROTOCOL INFORMATION

Reference Number:	
UPMREB Code:	
Study Protocol Title:	DENTAL SERVICE UTILIZATION PATTERNS OF SENIOR CITIZENS 60 YEARS OLD AND ABOVE IN MULTI-BRANCHES OF A MALL-BASED PRIVATE DENTAL FACILITY IN THE PHILIPPINES
Principal Investigator:	Dr. Kristine Rachelle R. Pacete-Estrera, DDM
Study Protocol Submission Date:	27/01/2016

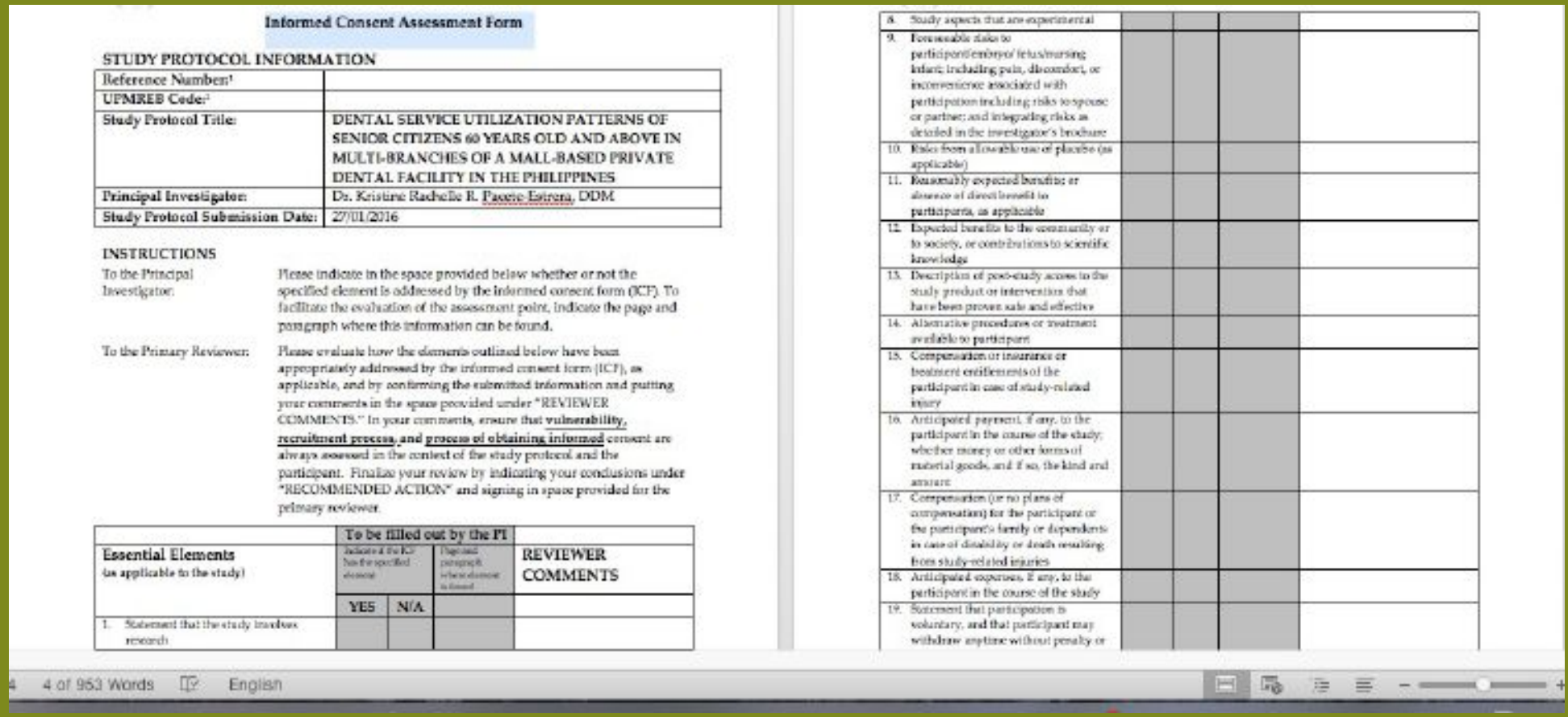
INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the Primary Reviewer: Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS."Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

ASSESSMENT POINTS	To be filled out by the PI			REVIEWER COMMENTS
	Indicate if the study protocol contains the specified assessment point		Page and paragraph where it is found	
1. SCIENTIFIC DESIGN	YES	N/A		
1.1. Objectives	✓		p.4	
1.2. Literature review	✓		pp.5-9	
1.5. Sample size	✓		p.12	
1.6. Statistical analysis plan (SAP)	✓		p.13	
1.7. Data analysis plan	✓		pp.13-18	
1.8. Inclusion criteria	✓		p.12	
1.9. Exclusion criteria		N/A		
1.10. Withdrawal criteria		N/A		
2. CONDUCT OF STUDY				
2.1. Specimen handling		N/A		
2.2. PI qualifications	✓		p.28	
2.3. Suitability of site		N/A		

Form 2(C) Study Protocol Assessment Form



Informed Consent Assessment Form

STUDY PROTOCOL INFORMATION

Reference Number:	
UPMREB Code:	
Study Protocol Title:	DENTAL SERVICE UTILIZATION PATTERNS OF SENIOR CITIZENS 60 YEARS OLD AND ABOVE IN MULTI-BRANCHES OF A MALL-BASED PRIVATE DENTAL FACILITY IN THE PHILIPPINES
Principal Investigator:	Dr. Kristine Rachelle R. Pasete-Estrera, DDM
Study Protocol Submission Date:	27/01/2016

INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the Primary Reviewer: Please evaluate how the elements outlined below have been appropriately addressed by the informed consent form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." In your comments, ensure that **vulnerability, recruitment process, and process of obtaining informed** consent are always assessed in the context of the study protocol and the participant. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

Essential Elements (as applicable to the study)	To be filled out by the PI: Indicated in the ICF has the specified element		Page and paragraph where element is found	REVIEWER COMMENTS
	YES	N/A		
1. Statement that the study involves research				
8. Study aspects that are experimental				
9. Foreseeable risks to participant/embryo/fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure				
10. Risks from allowable use of placebo (as applicable)				
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable				
12. Expected benefits to the community or to society, or contributions to scientific knowledge				
13. Description of post-study access to the study product or intervention that have been proven safe and effective				
14. Alternative procedures or treatment available to participant				
15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury				
16. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount				
17. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries				
18. Anticipated expenses, if any, to the participant in the course of the study				
19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or				

4 of 953 Words English

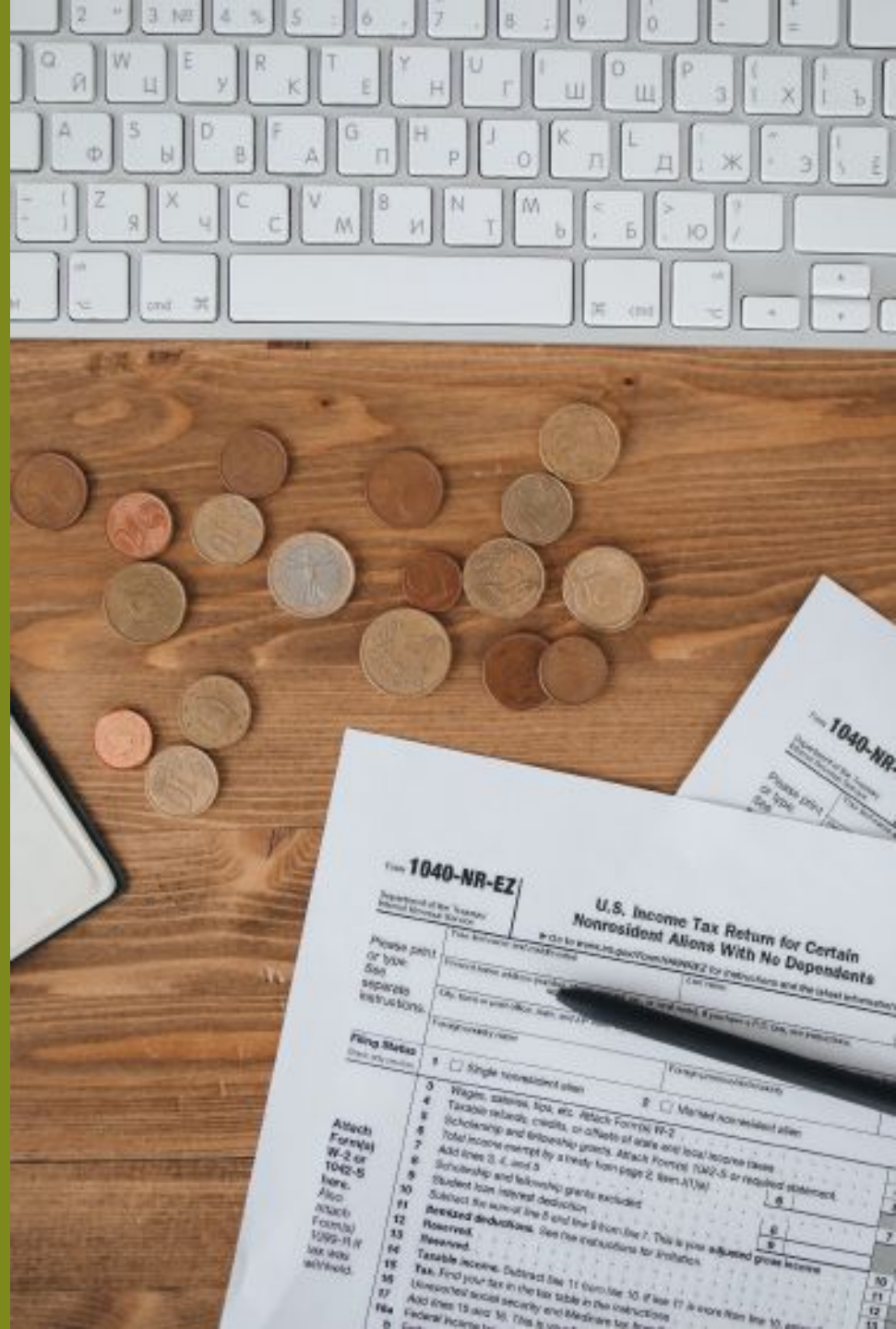
Form 2(D) Informed Consent Assessment Form

Reviewing the steps for submission:

1)Accomplish all forms typewritten and have it checked by your adviser/co-author

2) Prepare your cover letter for submission to REB

3) Register your research to RGAO (Research Grants Administration office) via online and wait for RGAO certificate to be emailed

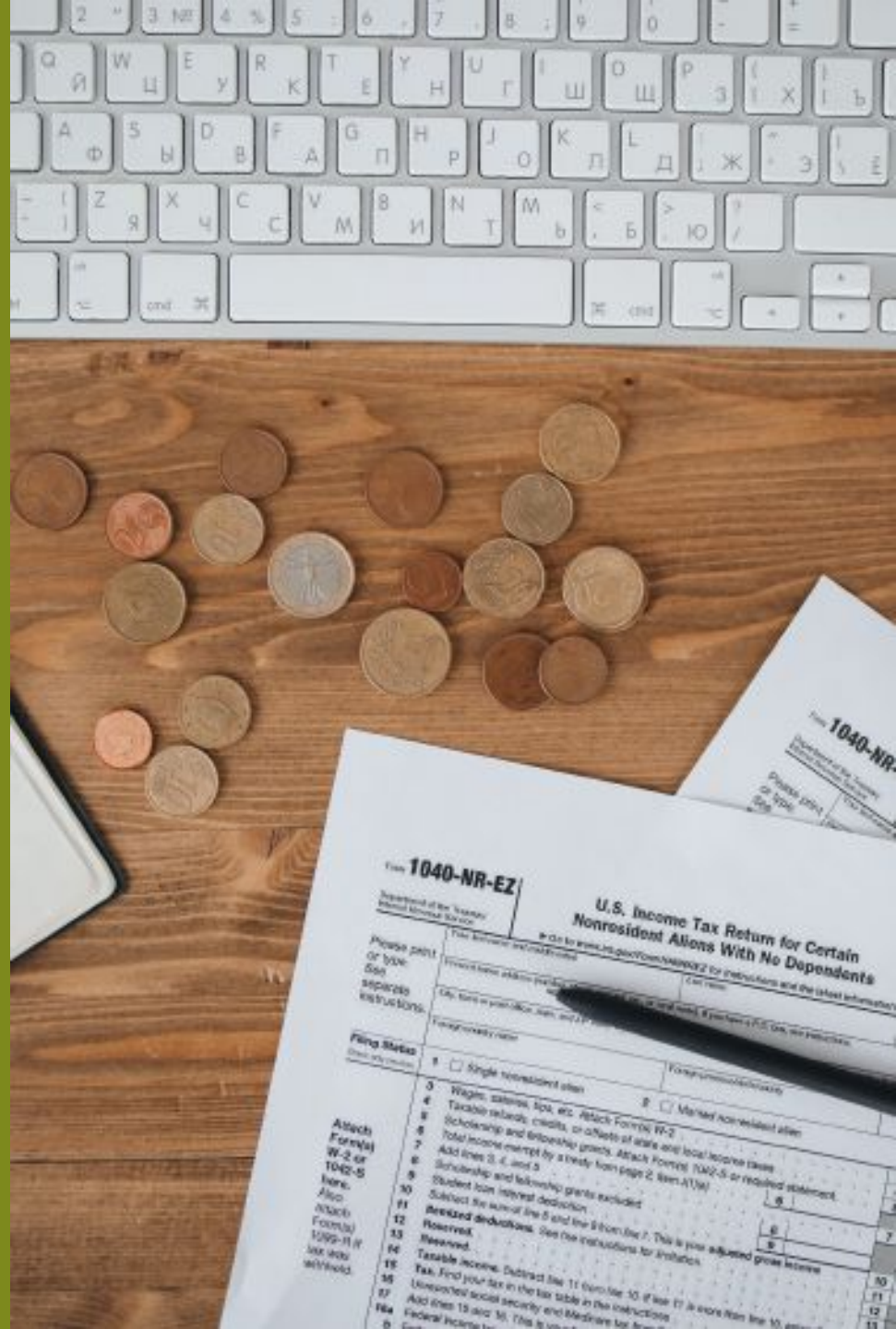


Contd.

4) As soon as RGAO certificate is received, register and submit to i-REB (online submission)

5) Submit the required number of copies to REB after receiving confirmation via email

6) Get instructions from UPM REB staff on next steps for follow up



UPM REB's most recent instructions for initial submission:

Please find below the process for registration with the Research Grants Administration Office (RGAO) and for initial submission to the UP Manila Research Ethics Board (UPMREB) for your reference.

1. Register study with RGAO (Research Grants Administration Office) at http://rgao.upm.edu.ph/registration

The registration certificate with RGAO reference number will be sent to you via email after one (1) working day. A printed copy can be made available at RGAO upon request.

2. Request for an iREB account at https://ireb.upm.edu.ph/account/request

UPMREB will approve the request after one (1) working day so you can access your iREB account. You can do this while waiting for the RGAO reference code.

3. Log in to iREB at https://ireb.upm.edu.ph/login, complete the online forms and upload all the required documents in PDF format. Merge all CVs in one pdf file, and all GCPs in one pdf file.

You may refer to our website at http://reb.upm.edu.ph/ for detailed information on the submission process, cut-off dates, review status, etc. Updated versions of UPMREB forms are downloadable at http://reb.upm.edu.ph/sops-and-forms (see SOP II).

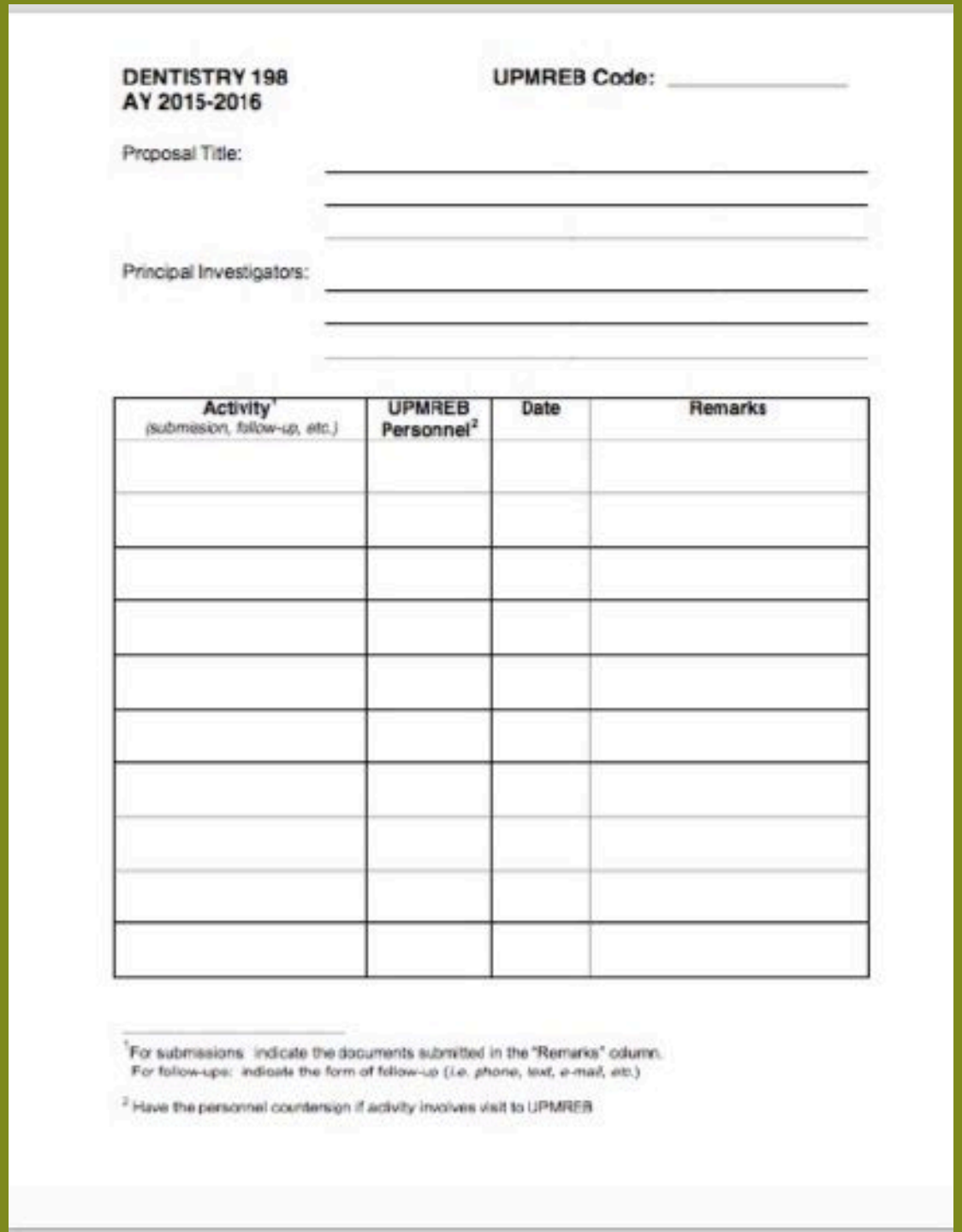
4. Wait for UPMREB's notification before submitting the printed copies

UPMREB will screen your submission. You will be notified through e-mail to either submit the hard copies of your documents or address screening issues.

5. *Submit four (4) complete sets of printed copies of the required forms and basic documents to UPMREB at Room 126, NIH Bldg., UP Manila*

· The last 2 pages of UPMREB Form 2(B) should bear original signatures. UPMREB is accepting submissions for initial review during Mondays and Wednesdays, 9:00AM-12:00NN and 1:00-3:00PM ONLY

Due to the ECQ, this requirement is temporarily lifted and will resume once office work commences.:



DENTISTRY 198
AY 2015-2016

UPMREB Code: _____

Proposal Title: _____

Principal Investigators: _____

Activity[1] (submission, follow-up, etc.)	UPMREB Personnel[2]	Date	Remarks

[1] For submissions: indicate the documents submitted in the "Remarks" column.
For follow-ups: indicate the form of follow-up (*i.e. phone, text, e-mail, etc.*)

[2] Have the personnel countersign if activity involves visit to UPMREB

UPM REB Transaction Form

- ✓ For following up REB review
- ✓ Proof of status updates with Department of Community Dentistry

How often do you follow up?

✓ Weekly?
✓ Monthly?

Note: "Exempted" protocols → in 2 weeks
"Expedited" protocols → in 2-4 weeks
"Full board" protocols → at least 4 weeks (for initial feedback from REB)

How do you do follow up?

✓Personal visit
✓Calling
✓Email

**All methods of follow up may be documented / logged in Transaction Form

University of the Philippines Manila Review Ethics Board (UPMREB)

Decision letter or Notice of Decision

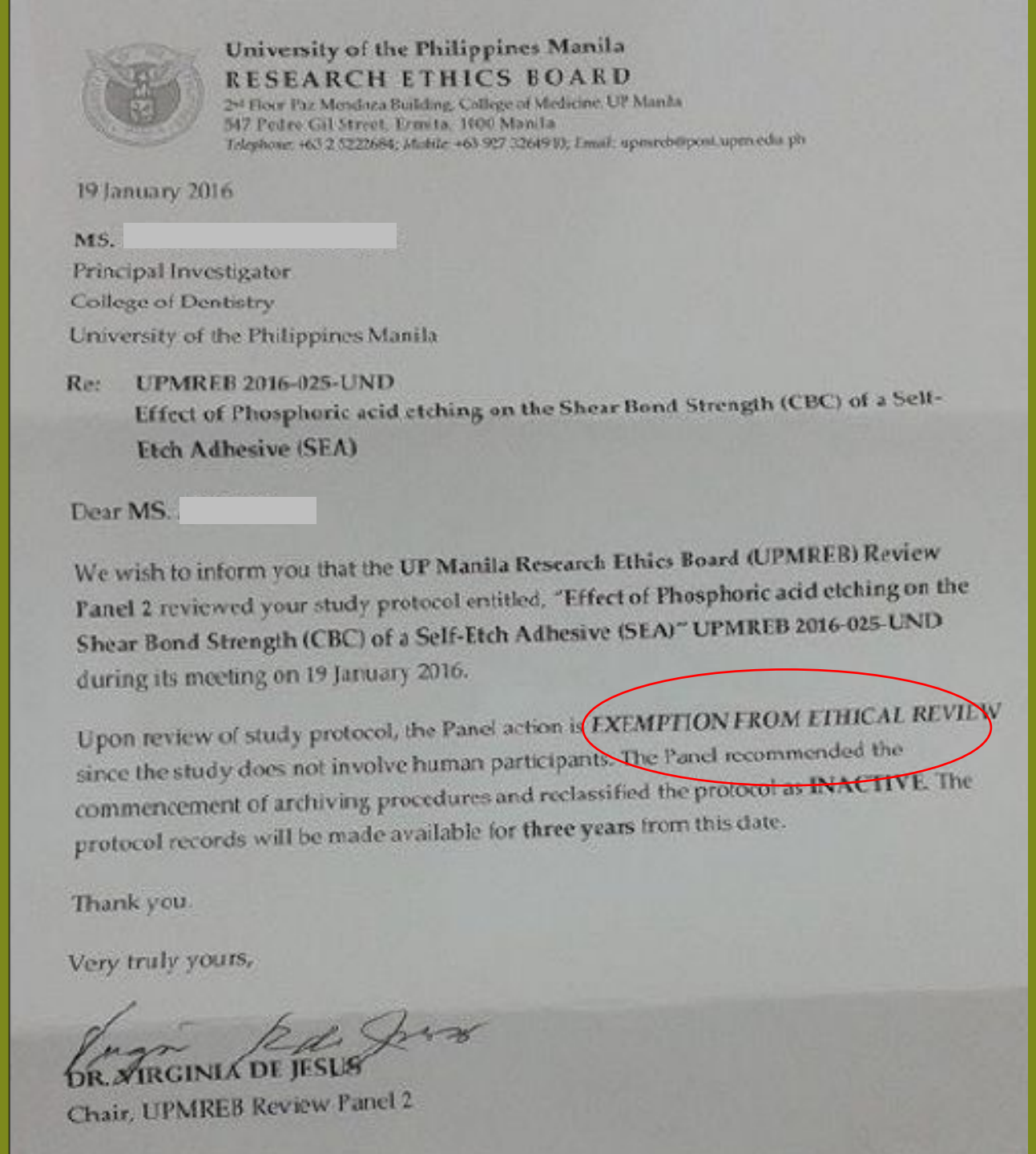
- letter issued to principal investigators to relay decisions on the ethical review of study protocol
- Decision letter may indicate:
  - **Exemption**
  - **Minor modifications**
  - **Major modifications**
  - **Disapproved**
  - **Pending**

University of the Philippines Manila Review Ethics Board (UPMREB)

Approval letter or Certificate of Approval

- letter issued to principal investigators to relay APPROVAL decision on the ethical review of study protocol

1. EXEMPTION



University of the Philippines Manila
RESEARCH ETHICS BOARD
2nd Floor Paz Mendoza Building, College of Medicine UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 5222684; Mobile +63 927 3264910; Email: upmreb@post.upm.edu.ph

19 January 2016

MS. [redacted]
Principal Investigator
College of Dentistry
University of the Philippines Manila

Re: **UPMREB 2016-025-UND**
Effect of Phosphoric acid etching on the Shear Bond Strength (CBC) of a Self-Etch Adhesive (SEA)

Dear **MS.** [redacted]

We wish to inform you that the **UP Manila Research Ethics Board (UPMREB) Review Panel 2** reviewed your study protocol entitled, "**Effect of Phosphoric acid etching on the Shear Bond Strength (CBC) of a Self-Etch Adhesive (SEA)" UPMREB 2016-025-UND** during its meeting on 19 January 2016.

Upon review of study protocol, the Panel action is ***EXEMPTION FROM ETHICAL REVIEW*** since the study does not involve human participants. The Panel recommended the commencement of archiving procedures and reclassified the protocol as **INACTIVE**. The protocol records will be made available for **three years** from this date.

Thank you.

Very truly yours,

DR. VIRGINIA DE JESUS
Chair, UPMREB Review Panel 2

2. MINOR MODIFICATION

- ✓ Protocol-related issues - go back to form 2(C)
- ✓ Ethical-related issues – review form 2(D)

University of the Philippines Manila
RESEARCH ETHICS BOARD
2nd Floor Paz Mendoza Building, College of Medicine, UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 5222684; *Mobile:* +63 927 3264910; *Email:* upmreb@post.upm.edu.ph

16 February 2016

[redacted]
Principal Investigator
College of Dentistry
University of the Philippines Manila

Re: **UPMREB 2016-088-01**
Dental Service Utilization Patterns of Senior Citizens 60 Years Old and Above in Multi-Branches of a Mall-Based Private Dental Facility in the Philippines

Dear [redacted]

We wish to inform you that the **UP Manila Research Ethics Board (UPMREB) Review Panel 2** reviewed your study protocol and is requesting further clarification. Your study has been assigned study protocol code UPMREB 2016-088-01, which should be used for all communication to the UPMREB Review Panel 2 related to this study.

As a result of the review, panel action is ***MINOR MODIFICATIONS***. Recommended revisions and/or clarifications are summarized below:

1. **Address protocol-related issues:**
   a. In the literature review, include results of Philippine National Dental surveys on 60 years old and above.
   b. Include in the literature review surveys done in the Philippines circa 2011 or earlier.
2. **Address ethical-related issues:**
   a. Provide terms of reference regarding authorship between Dentista Inc and the PI.
   b. Delineate the specific task of the Pi and the research assistant.
   c. Give specific details how coding will be done by the programmer and how data will be anonymized.

Please note that revisions requested by the **UPMREB Review Panel 2** should:

1. Be integrated into a revised STUDY PROTOCOL/PACKAGE and UPMREB FORM2(B)2012 APPLICATION FORM, and related documents in 4 (FOUR) printed

2. MINOR MODIFICATION

copies and one (1) electronic copy. Forms may be downloaded from the UPMREB website: **reb.upm.edu.ph**.

2. Be integrated in the UPMREB FORM 2(H)2012: REVIEW OF RESUBMITTED REVIEW FORM with the first column filled-out with recommendations and the second column with number outline corresponding the recommendations;

3. Be SUMMARIZED in a cover letter indicating in which page of the revised study protocol the respective revision may be found;

4. Modified part should be underlined and bold; and

5. Include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol.

Please note that resubmissions can only be accepted within 90 days from the date of this letter. Failure to respond within 90 days from the date of this letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the UPMREB **Review Panel 2** Secretariat at (02) 522 2684 or upmreb@post.upm.edu.ph.

The **UPMREB Review Panel 2** looks forward to your immediate response and action.

Very truly yours,

DR. VIRGINIA DE JESUS
Chair, UPMREB Review Panel 2

3. MAJOR MODIFICATION

- ✓ Protocol-related issues - go back to form 2(C)
- ✓ Ethical-related issues – review form 2(D)

University of the Philippines Manila
RESEARCH ETHICS BOARD
2nd Floor Paz Mendoza Building, College of Medicine, UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 5222684; Mobile: +63 927 3264910; Email: upmreb@post.upm.edu.ph

20 February 2016

[redacted]
Principal Investigator
College of Dentistry
University of the Philippines Manila

Re: UPMREB 2016-019-UND
Knowledge, Attitude and Practices of Pediatricians at a Level 3 Government Hospital on Dental Caries Prevention among Children

Dear [redacted]:

We wish to inform you that the **UP Manila Research Ethics Board (UPMREB) Review Panel 5** reviewed your study protocol and is requesting further clarification. Your study has been assigned study protocol code UPMREB 2016-019-UND, which should be used for all communication to the UPMREB Review Panel 5 related to this study.

As a result of the review, panel action is *MAJOR MODIFICATIONS*. Recommended revisions and/or clarifications are summarized below:

1. **Address protocol-related issues:**
   a. Revise objectives to show intention why demographic characteristics of the participants will be taken, if applicable.
   b. Specify in objectives if self-reported practice is to be asked of the participants.
   c. Anonymize name of the tertiary hospital in all parts of the proposal and other documents. Use black bar in document attachments where the hospital may be identified.
   d. Include local paediatrician practice and dental law guidelines in ROL. Example, look at June 2012 advisory to paediatricians, and other PPS policies and its effects on their practice.
   e. Add additional ROL from related research papers on oral health, referral practice to dentists, etc of residents and fellows of paediatrics in the tertiary hospital.
   f. Recommend using subheadings in ROL. This is to further check and add literature that ease analysis later of the collected data.
   g. Stated adequately for actual study, but in pilot test should need to revise for pilot test participants.
   h. Explicitly indicate in the statistical analysis section that a biostatistician will be employed for the study.
   i. Revise the inclusion to be more specific for criteria #1 and action of medicine and there is an overlap in #2 and #3. Include #4 will consent to participant.

3. MAJOR MODIFICATION

j. Revise data analysis plan for data encoding. Data encoding means in data management means how data is encoded before analysis NOT how collection tool is coded.
k. Revise participant criteria for pilot test to include paediatrician/s, primary care physician/s, pediatric dentist/s, dentist and even a parent.
l. Anonymize tertiary hospital in ALL parts of proposal.

2. **Address ethical-related issues:**
   a. Explicitly state if there are conflicts.
   b. State how codes and actual names of participants will be managed. How will the participants be identified by the field editor/researchers?
   c. Clarify "who" is the secretary and field editor and whether they are part of the study group.
   d. State how the paediatricians in the department will be informed about the study and how will they be asked to join the study. (Who is tasked to do this?)
   e. State qualification of this person. In addition, in the informed consent process suggest to use posters or info materials in the pediatric department to recruit the participants.
   f. Specify level of risk in proposal. There is a potential risk for residents and fellows, consider how they will submit and who to submit to. Suggest providing a envelope to be sealed etc.
   g. State if incentives or compensation will or will not be given specifically to the department secretary acting as data collector/field editor for the researchers. Is the gathering of this data part of their tasks? If not then some compensation or token of appreciation should be provided.
   h. Verify the consent of the tertiary hospital on the conduct of the study (not just the department of pedia). Check with the EHRO for details on research policies beyond that of the UPMREB.
   i. State if and how department secretary will be trained to do the research task (data collector and or field editor?) assigned to them.

3. **Other ethical-related issues:**
   a. Explicitly state that "research study" is being conducted.
   b. Anonymize name of study site.
   c. State the purpose of the research.
   d. Explicitly state benefit to pedia staff or patient community.
   e. State in ICF token or payment to be given.
   f. Explicitly state that researchers are doing undergraduate research study.
   g. Include full contact info of UPMREB.

DR. JOSEFINA TUAZON
UPMREB Panel 5 Chair
Address: 2/f Paz Mendoza
547 Pedro Gil St
Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph
Tel: +63 2 5264346

3. MAJOR MODIFICATION

Please note that revisions requested by the **UPMREB Review Panel 5** should:

1. Be integrated into a revised STUDY PROTOCOL/PACKAGE and UPMREB FORM2(B)2012 APPLICATION FORM, and related documents in four 4 printed copies and one (1) electronic copy. Forms may be downloaded from the UPMREB website: **reb.upm.edu.ph**.

2. Be SUMMARIZED in a cover letter indicating in which page of the revised study protocol the respective revision may be found;

3. Modified part should be underlined and bold; and

4. Include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol.

Please note that resubmissions can only be accepted within 90 days from the date of this letter. Failure to respond within 90 days from the date of this letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the UPMREB **Review Panel 5** Secretariat at (02) 522 2684 or upmreb@post.upm.edu.ph.

The **UPMREB Review Panel 5** looks forward to your immediate response and action.

Very truly yours,

DR. JOSEFINA TUAZON
Chair, UPMREB Review Panel 5

Sample Content of UPMREB Decision Letter

1. **Address Protocol related issues; (some comment examples are indicated below)**
    a. Include ROL of ….
    b. Explain sampling of participants …..
    c. State Data Analysis Plan
    d. Attach certificate of research ethics training of PI and team members and roles of research team members to specific tasks of the study.
2. **Address Ethical related issues:**
    a. State pertinent sections of DPA 2012 and its IRR 2016 that the study is in compliance with.
    b. State how participants will have access of results of the study.
3. **Address Informed Consent Form (ICF) related issues:**
    a. State duration of participation in the ICF.
    b. State if study is in compliance with DPA 2012 and IRR of 2016.

Sample Content of UPMREB Decision Letter

c. State how results of study will be accessible to participants.

d. State that UPMREB can be contacted for complaints and grievances on the conduct of the research with the following contact information:

Name of Panel Chair
Room 126 NIH Building, UP Manila
547Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 5264346; *Email*: upmreb@post.upm.edu.ph

e. Create ICF in English and Filipino.

After receiving the decision letter:

- Inform and send a copy to your research adviser and co-investigators
- Discuss the revisions to be made
- Revise the study protocol making sure revisions are made to the **protocol** and **ICF** and **ALL other documents**, as applicable

After receiving the decision letter:

- Make sure to respond to each recommendation
- Create a cover letter with the Summary of Revisions: recommendations, revisions made and paragraph and page number where it is found
- *Discuss and agree on revised protocol and ICFs and Form 2H with adviser and coinvestigators before submission*

Cover letter for Resubmission to REB

28 March 2016

UPMREB Review Panel 2
University of the Philippines Manila
Research Ethics Board
2nd Floor Paz Mendoza Building, College of Medicine, UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila

Dear Sir/Madam,

I, Kristine Rachelle R. Pacete-Estrera, DDM, Assistant Professor 1, of the University of the Philippines College of Dentistry, am resubmitting my requirements for Ethics Review for my study entitled **"Dental Service Utilization Patterns of Senior Citizens 60 years old and above in Multi-branches of a Mall-based Private Dental Facility in the Philippines."**

Attached herewith are the following documents:

Revised Study Protocol
Revised UPM REB Form 2(B) Registration and Application Form
UPM REB Form 2(H) Review of Resubmitted Protocol Form
CD (i.e. containing electronic copies of all the abovementioned documents)

The following are the recommended revisions stated in my action letter dated February 16 but received on February 28, 2016 via email:

1. In the literature review, include results of Philippine National Dental Surveys on 60 y/o and above (pp.9-10)
2. Include in the literature review surveys done in the Philippines circa 2011 or earlier. (pp.9-10)
3. Provide terms of reference regarding authorship between Dentista, Inc. and PI (p.19)
4. Delineate the specific task of the PI and the research assistant. (pp.20-21)
5. Give specific details how coding will be done by the programmer and how data will be anonymized. (p.13)

Should you have any questions or concerns, you may contact the proponent at (+63917)8255518.

Sincerely yours,

Kristine Rachelle R. Pacete-Estrera
Assistant Professor 1 - College of Dentistry
University of the Philippines Manila

Sample Resubmission Cover Letter

Letterhead

Date

_____
Chair, UPMREB Review Panel ___

Dear _____,

Thank you for your feedback on our study protocol. Please refer below for the summary of our responses to your comments.

Recommendations	Revisions made	Paragraph and page #
(see sample on next page)		

Respectfully yours,
Name of PI
Contact information

Summary of revisions (example)

Recommendations	Revisions	Paragraph and page #
1. Address Protocol-Related Issues		
a. Clarify if objective is to evaluate or to describe….	a. Study is descriptive only. Objective #5 "to evaluate" was deleted. Statement of purpose "to evaluate" in Significance and ICF was deleted.	a. Deleted from page5 para 2 and deleted from page 10 para1 and page 45 para3
3. Address ICF-Related Issues		
a. Write duration of participation in ICF.	a. Duration of participation of 20mins written in ICF and in revised protocol.	a. Added in ICF, page 46 and revised in protocol in page 20.

UPMREB Instructions on revisions

- Please note that revisions requested by the **UPMREB Review Panel #** should:

- Be integrated into a revised STUDY PROTOCOL/PACKAGE and UPMREB FORM2(B)2012 APPLICATION FORM, and related documents in FOUR (4) printed copies and one (1) electronic copy. Forms may be downloaded from the UPMREB website: **reb.upm.edu.ph**.

- Be integrated in the UPMREB FORM 2(H)2012: REVIEW OF RESUBMITTED REVIEW FORM with the first column filled-out with recommendations and the second column with number outline corresponding the recommendations.

UPMREB Instructions on revisions

- Be SUMMARIZED in a cover letter indicating in which page of the revised study protocol the respective revision may be found;

- Modified part should be **underlined and bold** in the research protocol;

- Include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol.

Form 2(H) for Resubmission to REB

Review of Resubmitted Study Protocol Form

UPMREB Code: UPMREB 2016-088-01	Date of Initial Submission: 27/Jan/2016
Study Protocol Title: Dental Service Utilization Patterns of Senior Citizens 60 Years Old and Above in Multi-Branches of a Mall-Based Private Dental Facility in the Philippines	
Total Participants: 5,000-7,000 patient records	✓ 2nd Review ☐ 3rd Review
Principal Investigator: Dr. Kristine Rachelle R. Pacete-Estrera	Tel.: (0917)8255518
Initial Review Date: 27/Jan/2016	Last Review Date:
Recommendations from last review: 1. In the literature review, include results of Philippine National Dental Surveys on 60 y/o and above (pp.9-10) 2. Include in the literature review surveys done in the Philippines circa 2011 or earlier. (pp.9-10) 3. Provide terms of reference regarding authorship between Dentista, Inc. and PI (p.19) 4. Delineate the specific task of the PI and the research assistant. (pp.20-21) 5. Give specific details how coding will be done by the programmer and how data will be anonymized. (p.13)	Were the recommendations met (Yes/No)? Explain 1. 2. 3. 4. 5.
RECOMMENDATION OF PRIMARY REVIEWER: ☐ APPROVE ☐ MINOR MODIFICATION ☐ MAJOR MODIFICATION ☐ DISAPPROVE ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE	**JUSTIFICATION FOR RECOMMENDED ACTION:**
PRIMARY REVIEWER Signature _____	
Date: <dd/mm/yyyy> Name <Title, Name, Surname>	

How often do you follow up after resubmission?

- ✓ Weekly?
- ✓ Monthly?

How do you do follow up after resubmission?

- ✓Personal visit
- ✓Calling
- ✓Email

**All methods of follow up may be documented / logged in Transaction Form

Some scenarios.....

1. Submission just before end of semester

2. Submission at the beginning of semester

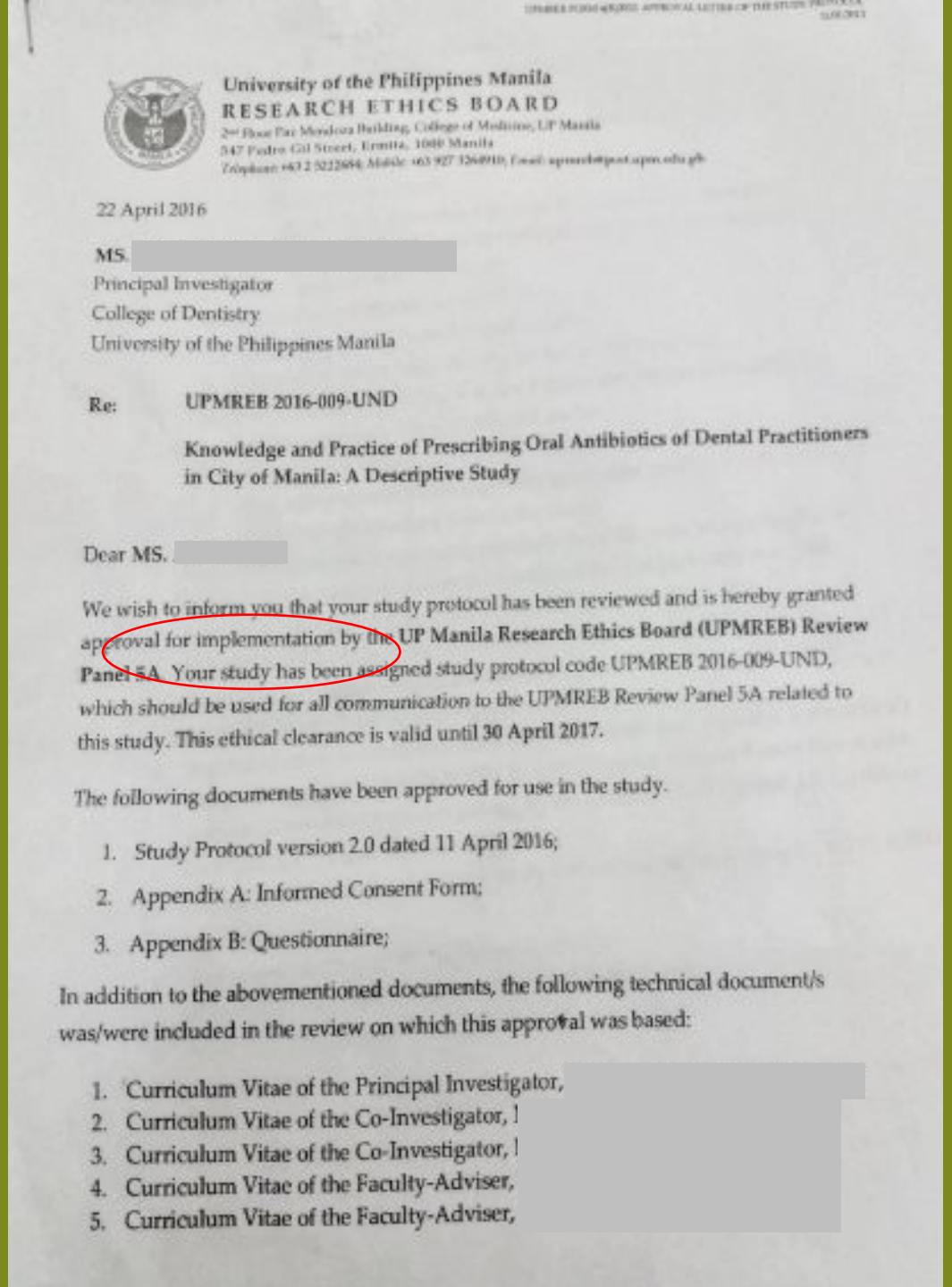
3. REB has reviewed but no signatory to release status letter

4. REB has reviewed but one reviewer has not given back comments

5. Change of study population or site (UPM REB Form 3(A))

6. Specific date for data collection already scheduled but no REB approval released yet

4. APPROVED



University of the Philippines Manila
RESEARCH ETHICS BOARD
2nd Floor Pat Mendoza Building, College of Medicine, UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 5222694; Mobile: +63 927 3268910; Email: upmreb@post.upm.edu.ph

22 April 2016

MS.
Principal Investigator
College of Dentistry
University of the Philippines Manila

Re: UPMREB 2016-009-UND

Knowledge and Practice of Prescribing Oral Antibiotics of Dental Practitioners in City of Manila: A Descriptive Study

Dear MS.

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the **UP Manila Research Ethics Board (UPMREB) Review Panel 5A**. Your study has been assigned study protocol code UPMREB 2016-009-UND, which should be used for all communication to the UPMREB Review Panel 5A related to this study. This ethical clearance is valid until **30 April 2017**.

The following documents have been approved for use in the study.

1. Study Protocol version 2.0 dated 11 April 2016;
2. Appendix A: Informed Consent Form;
3. Appendix B: Questionnaire;

In addition to the abovementioned documents, the following technical document/s was/were included in the review on which this approval was based:

1. Curriculum Vitae of the Principal Investigator,
2. Curriculum Vitae of the Co-Investigator,
3. Curriculum Vitae of the Co-Investigator,
4. Curriculum Vitae of the Faculty-Adviser,
5. Curriculum Vitae of the Faculty-Adviser,

Protocol APPROVAL

- Only after protocol approval should data collection, especially participant recruitment, be started
- Ethical approval expires after one (1) year; if for some reason you are unable to fulfill this, you need to accomplish Form 3(B) CRA

Continuing Review Application Form (3B)

- Ethical approval is granted for 1 year
- In case you are approaching expiry date of your ethical clearance, submit Form 3(B) at least 30 days prior to deadline


BE
POSITIVE,
PATIENT
AND
PERSISTENT
coolnsmart.com

References:

Rosanes, R. (2019, February). Lecture slides *on Responding to the UPMREB Decision Letter (Notice of Decision).* College of Dentistry, University of the Philippines Manila.

www.reb.upm.edu.ph