

SOP 3. Designation of an Independent Consultant

UPCHE REC SOP 03/03

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	(Adapted from UPMREB SOP and 2020 PHREB SOP Workbook)		
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3.1. Policy Statement

The UPCHE REC shall invite an Independent Consultant (IC) whose expertise is not present in the existing membership but needed in a study under review. The role of an IC is not to review but to clarify technical aspects of a protocol. The independent consultant need not be affiliated with the institution.

3.2. Objective

This activity aims to ensure that the appointment of IC conforms with recognized practice and complements the pool of expertise in the REC.

3.3. Scope

This SOP specifically contains details pertaining to the selection and designation of independent consultants in the review of research protocols of the REC. This SOP begins with the identification of the study that requires an IC and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.

3.4. **Designation of an Independent Consultant Workflow** (6 to 7 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Identification the study that requires an Independent Consultant (IC)	Chair, Primary Reviewer, Member Secretary	1
2	Invitation of the identified IC	Chair	2 to 3
3	Appointment of IC	Chair, Administrative Secretary	1
4	Receipt and filing of the signed COI disclosure and confidentiality agreement	Administrative Secretary	1
5	Inclusion in the list of ICs	Administrative Secretary	1

^{*}working days

3.5. Description of Procedure

3.5.1. Identification of the study that requires an Independent Consultant (IC):

- a. The Primary Reviewer, Member Secretary, or Chair identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of the REC.
- b. The Chair refers to the roster of specialists in the institution or in other institutions for the necessary expertise and selects the appropriate independent consultant.



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3.5.2. Invitation of the identified IC:

The Chair instructs the Administrative Secretary to prepare the letter of invitation to the identified IC which states the responsibilities of an Independent Consultant, as follows:

- **a.** Attend the UPCHE REC meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the UPCHE REC Administrative Secretary if unable to attend the meeting. S/He has no voting privilege during the meeting.
- **b.** Provide needed technical information for assigned protocols that concern his/her specialty and provide current knowledge about the subject of the study.
- c. Assess possible risks and benefits in the study based on his/her expertise.
- **d.** Return all protocol-related materials to the UPCHE REC Administrative Secretary after review.
- **e.** Submit an updated and signed CV and confidentiality and COI disclosure agreement annually.

The Administrative Secretary prepares a letter of invitation (Form 06) containing the terms of reference for signature of the Chair and sends this to the Independent Consultant. The letter of invitation contains a section for acceptance of the invitation.

3.5.3. Appointment of IC:

Upon receipt of the acceptance of the invitation, the Administrative Secretary sends the appointment letter, Form 2 [Confidentiality and Conflict of Interest Disclosure Agreement Form] and Form 3 [Curriculum Vitae] to the independent consultant.

3.5.4. Receipt and filing of the signed COI disclosure and confidentiality agreement:

The Secretariat receives the signed agreement forms and files this in the appropriate folder.

3.5.5. Inclusion in the pool of independent consultants:

The Administrative Secretary enters the name of the new independent consultants in the appropriate database containing name, expertise, institution and date of appointment.

3.6. Forms

The following forms are used in the implementation of this SOP:

- Form 02: Confidentiality and Conflict of Interest Disclosure Agreement Form
- Form 03: Curriculum Vitae
- Form 06: Invitation and Appointment Letter



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3.7. Document History

Version No.	Date	Authors	Main Change(s)
01		Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	First draft
02	04 December 2020	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.
02	30 August 2022	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Asst. Prof. Kristyn T. Caragay Mr. Edgar G. Belda Jr. Mary Anne Ramos-Tumanan, Ph.D. Assoc. Prof. Rowena Grace R. Sanchez Fredelyn G. Tolete	Revised the SOP right header box to include a simplified SOP code and added date of approval Section 4 Responsibilities: Included in Responsibilities the TOR for Independent Consultants as stated in the UP CHE REC Form 6
02	06 July 2023	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Added timeline (in working days) for each step in the Workflow Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement)
03	08 July 2024	See updated list of authors	Updated the list of authors to include all regular members following the change in membership of the UPCHE REC.