



Gullas College of *Medicine*
**RESEARCH ETHICS
COMMITTEE**



Ethos Universitas
HONORARY COMPANION

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SOP NO. 3 - APPOINTMENT OF INDEPENDENT CONSULTANTS

Section 1. Policy Statement.

Independent consultants whose expertise is not available among the current REC members but is needed in a study under review will be invited. Their role will be to review and clarify the technical aspects of the research proposal, not the ethical component of the research proposal.

Section 2. Objective of the Activity.

This SOP will ensure the appointment of independent consultants following institutional practices and policies. The purpose of independent consultant(s) in the REC is:

- a. To assure the quality of the research proposal.
- b. To ensure that the independent consultant's expertise is not available among REC members and his/her expertise is needed and;
- c. To help the REC identify mitigating measures to reduce the technical impact of the proposal on human participants.

Section 3. Scope.

Appointments of independent consultants shall begin with a review of the proposal by the REC to determine the need for such consultant/s. This is followed by the identification of independent consultants inside or outside GCM who are not REC members. The identified independent consultant is invited to review the research proposal. After he/she accepts the invitation, the name of the independent consultant shall be enlisted in the pool of consultants, and an appointment shall be made. This is the endpoint for the independent consultant appointment.

Section 4. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>	<i>TIMELINE</i>
Step 1: Identification of the study that requires an independent consultant	Primary Reviewer, Chairperson, Member Secretary	1 working day
Step 2: Identification of the independent consultant	Chairperson	2 working days
Step 3: Invitation of the independent consultant	Member Secretary	1 working day
Step 4: Receipt of the Appointment w Conforme /COI and Data privacy agreement of independent consultant	REC Member Secretary	3 working days
Step 5: Inclusion in the pool of independent consultants.	REC Member Secretary	1 working day
Step 6: Filing of appointment documents. See Form 4.7a (Filing Form Log) and ARTS (Form 1.9)	REC Administrative Secretary	2 working days
TOTAL		10 DAYS

Section 5. Description of Procedures

Step 1: Identification of the study that requires an independent consultant.

During the protocol review workflow, any specialized protocol requiring niche technical, clinical, or socio-cultural expertise that is not currently represented within the active Research Ethics Committee (REC) general membership must be flagged. The Primary Reviewer, Committee

Chairperson, or REC Member Secretary possesses the authority to identify these specific protocols. Once a gap in internal expertise is declared, the REC Member Secretary shall explicitly document the exact nature of the scientific, ethical, or technical competency required to properly evaluate the proposal.

Step 2: Identification of the independent technical consultant.

The REC Member Secretary shall formally brief the Chairperson regarding the specific domain expertise needed for the protocol under review. Upon notification, the Chairperson will conduct a comprehensive audit of the internal institutional roster, including active members and alternate specialists across the Gullas College of Medicine (GCM) and Vicente Gullas Memorial Hospital (VGMH).

If a qualified specialist cannot be sourced internally, the search will expand to external affiliate institutions. Once an appropriate expert is identified who can provide the necessary clarity and objective review, the Chairperson will officially select the candidate and instruct the REC Member Secretary to initiate the formal invitation protocol.

Step 3: Invitation of the independent consultant.

Upon receiving authorization from the Chairperson, the REC Member Secretary is responsible for compiling the formal invitation packet. This packet must include:

- **The Formal Letter of Invitation (Form 3.1):** Outlining the scope of the protocol, the specific feedback required, and the expected timelines.
- **The Conforme Form (Form 1.2):** Serving as the candidate's initial mechanism for formal acceptance or refusal.

The Member Secretary shall route the finalized Invitation Letter to the Chairperson for signature before dispatching the complete packet to the prospective consultant.

Step 4: Receipt of the Appointment w Conformance /COI and Data privacy agreement of independent consultant.

The invited expert must formally communicate their willingness to serve by returning an executed copy of the Conformance (Form 1.2). Upon receipt of the affirmative Conformance, the Member Secretary shall immediately prepare the official **Letter of Appointment (Form 3.2)**, which must be signed by the REC Chairperson and transmitted back to the consultant. To protect the integrity of the research and ensure regulatory compliance, the onboarding consultant must

review, execute, and return the following regulatory documents prior to accessing any research protocols:

- Conflict-of-Interest (COI) Disclosure Statement (Form 1.5)
- Data Privacy Agreement (DPA) (Form 1.6)
- Comprehensive Curriculum Vitae (CV) via the Institutional Template (Form 1.7)
- Confidentiality and Non-Disclosure Agreement (NDA) (Form 1.8)

Step 5: Inclusion in the pool of consultants.

Once all signed onboarding agreements are successfully verified, the REC Member Secretary shall officially induct the specialist into the committee's active consultant registry. The Member Secretary will encode the consultant's complete professional profile, contact information, and specific areas of technical expertise into the digital **Administrative Research Tracking System (Form 1.9 - ARTS)**. This updates the roster in real time, making the consultant searchable for future protocol distributions.

Step 6: Filing of appointment documents. (See SOP 23 on Managing Active Files).

To ensure absolute compliance with institutional audits and record-keeping regulations, all physical and digital records generated during this process must be systematically archived in accordance with **SOP 23: Management of Active Files**:

- **Physical Records:** The Administrative Secretary will gather the signed Appointment Letters, Conformes, COIs, DPAs, and CVs, and file them securely in the designated REC active storage repository.
- **Document Log Control:** The Administrative Secretary will update **Form 4.7A (Filing Form Log)** to track the physical file placement and perform corresponding system updates on the primary tracking platform (**Form 23.4 - ARTS**) to maintain cross-referenced accuracy. Each independent consultant will have a separate and independent folder.

Roster of Founding Independent Consultants (N = 13)

The following subject-matter experts have been formally vetted, designated, and integrated into the institutional pool of Independent Consultants (IC). They serve as

external, non-voting scientific reviewers when specialized protocol evaluations are triggered.

INDEPENDENT CONSULTANTS (N = 11)				
Albim Cabatingan	Management, PhD BA, DPA	UV	IC	Scientist
Ronald Catacte	Biomedical Research, MAN, PhD ongoing, Nurse	SWU	IC	Scientist
Maricar Canonigo	Biomedical Research, MAN, PhD ongoing, Nurse	SWU	IC	Scientist
Aljoriz Dublin	Education, MBA	UV	IC	Scientist
Rosemarie Camille Cunanan	Pharmacy, MPA, DPA	Non-GCM	IC	Scientist
Julius Mario	Medical Technology, PhD Med Tech	SWU	IC	Scientist
Rosie Mendoza	English, MA Eng, PhD Edu	UV	IC	Scientist
Queen Heneylour Relatorres	Criminal Justice, MA Crim Justice	UV	IC	Scientist
Niño Ismael Pastor	Epidemiology, Medical Education DRDM	GCM	IC	Scientist
Mara Bernadette Redula	Gen Medicine	GCM	IC	Scientist
Rochelle Go	Pharmacist	Velez Gen Hosp	IC	Scientist
Joanne Camello	Gen Pediatrics	CIM, VGH	IC	Scientist

Section 6. Forms

Form 3.1 – Letter of Invitation for a Technical Expert
 Form 3.2 – Appointment letter independent consultant
 Form 1.2 - Conforme
 Form 1.8 – Confidentiality Agreement
 Form 1.5 - Conflict of Interest Declaration Form
 Form 1.6 – Data privacy agreement
 Form 21.2 – Active File Mgt
 Form 1.9 - ARTS

Section 7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	10.6.23	CHRI Director	First draft
2	9.26.24	Faith Yee	Workflow, form labels
3	6.4.26	Nino Ismael Pastor	Form labels, few content

Section 8. References

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