



Review & approval for ethical conduct of research involving human participants

I. SERVICE: Application for Review of research protocol

Schedule of Availability of Service		
Days	:	Monday – Friday
Hours	:	8:00 am – 5:00 pm
Who May Avail of the Service	:	Medical and Ancillary Department staff Nursing Service staff Dietary Department staff
 Documentary Requirements Review checklist form Registration & application fo Study protocol assessment f Research protocols Structured summary Informed consent form (as a Informed consent assessme Data collection form Curriculum vitae of principal Hard and Electronic copy or 	rm form pplicable nt form investiga	e) ator & team members

Processing Period

: Within 48 Hours

How to avail of the Service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES	FORM
1	Submits documentary requirements	Receives study documents for initial review & documentation of completeness of submission	Within 48 hours upon receipt of complete study documents	Research proponent QCGH IERB Secretariat		Documentary requirements stated above, Document received form
2		Enters data into the logbook & assigns QCGH IERB protocol number	Within 24 hours after documentation of completeness of submission	Secretariat Vice Chair	No fees	Submissions log





3	Determines type of action/type of review a. Exemption from review b. Expedited review c. Full review	Within 48 hours upon receipt of the documents from the Secretariat	Chair Secretariat		Registration and application form and Study Protocol Assessment Form	
4	Prepares protocol folder	N/A	Secretariat		Protocol folder	
5	Entry into the database	N/A	Secretariat		N/A	
END of TRANSACTION						

II. SERVICE: Expedited Review of research protocol

:

Schedule of Availability of Service	
Days	:
Hours	:

Monday – Friday
8:00 am – 5:00 pm
Medical and Ancillary Department staff
Nursing Service staff
Dietary Department staff

Documentary Requirements :

Research protocols

Who May Avail of the Service

- Informed consent form
- Study protocol assessment form
- Informed consent assessment form
- Curriculum vitae of research proponent & team members

Processing Period : How to avail of the Service

Within 16 Days





STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES	FORM
1		Assigns reviewers or independent consultant	Within 24 hours upon determination of the type of review	Chair		Study Protocol Assessment Form and Informed Consent Assessment Form
2		Notifies reviewer or independent consultant	Within 48 hours upon assignment of primary reviewers	Secretariat	No fees	NOTICE OF REVIEW
3		Responds to notice of review	Within 48 hours from date of receipt of notice	Primary Reviewers		NOTICE OF REVIEW
4		Provides study documents & evaluation forms to reviewers	Within 24 hours upon confirmation of the availability of the primary reviewer	Secretariat	No fees No fees	Study protocol, Informed consent form (as applicable), Study Protocol Assessment Form, and Informed Consent Assessment Form (as applicable)
5		Accomplishes & submits evaluation forms	Within 7 calendar days from receipt of complete documents	Primary Reviewers		Study Protocol Assessment Form, and Informed Consent Assessment Form (as applicable)
6		Consolidation and Finalization of the review results	Within 1 week upon receipt of assessment forms from the primary reviewers	Chair	No fees	Study Protocol Assessment Form, and Informed Consent Assessment Form (as applicable), and Certificate of Approval
7		Communicates review results to the researcher	Within 1 week upon finalization of review results	Chair Secretariat		Certificate of Approval, Letter template for modification, or Review of Resubmitted Study Protocol Form
8		Files documents in the protocol file		Secretariat		Protocol- related documents
9		Inclusion of the review in the agenda of the next IERB meeting		Chair Secretariat		Notice of meeting & agenda
			END of TRANSACTION			





III. SERVICE: Full Review of research protocol

Schedule of Availability of Service		
Days	:	Monday – Friday
Hours	:	8:00 am – 5:00 pm
Who May Avail of the Service	:	Medical and Ancillary Department staff
		Nursing Service staff
		Dietary Department staff
Be seen to Be see the second		

Documentary Requirements :

- Research protocols
- Informed consent form
- Study protocol assessment form
- Informed consent assessment form
- Curriculum vitae of research proponent & team members

:

Processing Period How to avail of the Service 16 to 30 days

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES	FORM
1		Assigns reviewers or independent consultant	Within 24 hours upon determination of the type of review	Chair	No fees	NOTICE OF REVIEW
2		Notifies reviewer or independent consultant	Within 48 hours after getting assignment	Secretariat		NOTICE OF REVIEW
3		Responds to notice of review	Within 48 hours upon receipt of notice of review	Reviewer		N/A
4		Reviews protocol & informed consent form	3 days before the full board review meeting	Primary reviewer		Study Protocol Assessment Form and Informed Consent Assessment Form





5	related	les protocol & protocol- d documents to the rest of the ittee members	At least 3 days before the full board meeting	Secretariat	No fees	Executive summary of study protocol
6		nts review findings & mendations during committee	At least 3 days before the full board meeting	Primary reviewer		Study Protocol Assessment Form and Informed Consent Assessment Form
7	Discuss	sses technical & ethical issues	N/A	Chair IERB members		Study Protocol Assessment Form and Informed Consent Assessment Form
8	Summa	arizes & issues resolutions	N/A	Chair		N/A
9	Review	w board action committee action	N/A	Chair IERB members	1	N/A
10	Docum action	nents committee deliberation &	N/A	Secretariat		Minutes of Meeting
11		nunicates committee action to searcher	Within 1 week of the signed finalized results of the review	Chair Secretariat		Certificate of Approval, Notice of Panel Action to Study Protocol, and Review of Resubmitted Study Protocol Form
12		protocol-related documents & es protocol database	N/A	Secretariat		N/A
			END of TRANSACTION			





IV. SERVICE: Resubmission of research protocol

Schedule of Availability of Service

Days	:	Mondays – Friday
Hours	:	8:00 am – 5:00 pm
Who May Avail of the Service	:	Medical and Ancillary Department staff
		Nursing Service staff
		Dietary Department staff

Documentary Requirements :

- Review of resubmitted study protocol form
- resubmitted study documents
- Document received form
- Submissions log
- Letter template for modification form or
- Notice of panel action to study protocol submissions form

Processing Period : Within 13 days How to avail of the Service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES	FORM
1	Research proponent	Receives research protocol & other study documents	Within 48 hours upon receipt of complete study documents	Secretariat		Review of Resubmitted Study Protocol Form and Document received form
2		Coding of resubmitted protocol documents	Within 24 hours upon confirmation of complete study documents	Secretariat	No fees	Submissions log
3		Notification of the Chair and Reviewers	Within 48 hours upon receipt of complete and revised study documents	Secretariat		Letter template for modification form or Notice





						of Panel Action to Study Protocol Submissions form	
4		Review of the resubmitted protocol	Within 4 weeks for expedited review, within 5 weeks for full review	Primary Reviewers		Study protocol and Review of Resubmitted Study Protocol Form	
5		Communicates decision	Within 1 week after finalization of review	Chair Secretariat		Certificate of Approval	
6		Files documents in the protocol file & updates database	N/A	Secretariat		N/A	
	END of TRANSACTION						