

CITIZEN'S CHARTER

QCGH IERB (Institutional Ethics Review Board)

CORE PROCESS: Review 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: 8:00am – 5:00pm

Who may avail of the service:

Medical and Ancillary Department staff

Nursing Service staff

Dietary Department staff

Documentary requirements

- Registration & application form
- Research protocols
- Informed consent form (as applicable)
- Review checklist form
- Study protocol assessment form
- Informed consent assessment form
- Curriculum vitae of principal investigator & team members
- Hard and Electronic copy of the above documents

Processing period

Within 48 hours

How to avail of the service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION	PERSON RESPONSIBLE	FEE S	FORMS
1	Submits documentary requirements	Receives study documents for initial review & documentation of completeness of submission	Within 48 hours upon receipt of complete study documents	Investigator/ Researcher QCGH IERB Secretariat	No fees	Documentary requirements stated above
2		Enters data into the logbook & assigns QCGH IERB protocol number	Within 24 hours after documentation of completeness of submission	Secretariat Vice Chair		QCGH IERB FORM 6F 2022: 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						

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II. SERVICE: Expedited Review of research protocol

Schedule of availability of service

Days: Monday – Friday

Hours: 8:00am – 5:00pm

Who may avail of the service:

Medical and Ancillary Department staff

Nursing Service staff

Dietary Department staff

Documentary requirements

- Research protocols
- Informed consent form
- Study protocol assessment form
- Informed consent assessment form
- Curriculum vitae of principal investigator & team members

Processing period

Within 16 days

How to avail of service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION	PERSON RESPONSIBLE	FEE S	FORMS
1		Assigns reviewers or independent consultant	Within 24 hours upon determination of the type of review	Chair	No fees	Study Protocol Assessment Form and Informed Consent Assessment Form
2		Notifies reviewer or independent consultant	Within 48 hours upon assignment of primary reviewers	Secretariat		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		Study protocol, Informed consent form (as applicable), STUDY PROTOCOL ASSESSMENT FORM, and INFORMED CONSENT ASSESSME

						NT 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		N/A
9		Inclusion of the review in the agenda of the next IERB meeting		Chair Secretariat		N/A
END OF TRANSACTION						

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III. SERVICE: Full Review of research protocol

Schedule of availability of service

Days: Monday – Friday

Hours: 8:00am – 5:00pm

Who may avail of the service:

Medical and Ancillary Department staff

Nursing Service staff

Dietary Department staff

Documentary requirements

- Research protocols
- Informed consent form
- Study protocol assessment form
- Informed consent assessment form
- Curriculum vitae of principal investigator & team members

Processing period

16 to 30 days

How to avail of service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION	PERSON RESPONSIBLE	FEE S	FORMS
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		Provides protocol & protocol-related documents to the rest of the	At least 3 days before the full board meeting	Secretariat		Executive summary of study protocol

		committee members					
6		Presents review findings & recommendations during committee meeting	At least 3 days before the full board meeting	Primary reviewer	No fees	Study Protocol Assessment Form and Informed Consent Assessment Form	
7		Discusses technical & ethical issues	N/A	Chair IERB members		Study Protocol Assessment Form and Informed Consent Assessment Form	
8		Summarizes & issues resolutions	N/A	Chair		N/A	
9		Review board action committee action	N/A	Chair IERB members		N/A	
10		Documents committee deliberation & action	N/A	Secretariat		Minutes of Meeting	
11		Communicates committee action to the researcher	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		Files protocol-related documents & updates protocol database	N/A	Secretariat		N/A	
END OF TRANSACTION							

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IV. SERVICE: Resubmission of research protocol

Schedule of availability of service

Days: Monday – Friday

Hours: 8:00am – 5:00pm

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 service

STEP	APPLICANT / CLIENT	SERVICE PROCESS	DURATION	PERSON RESPONSIBLE	FEES	FORMS
1	Investigator/ Researcher	Receives research protocol & other study documents	Within 48 hours upon receipt of complete study documents	Secretariat	No fees	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		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	Primary Reviewers		Study protocol and Review of Resubmitted

			weeks for full review			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						