



# **RESEARCH ETHICS REVIEW COMMITTEE**

**Academic Services/Academic-Related Services**



## 1. APPLICATION FOR ETHICS REVIEW

This applies to initial study protocol submissions by faculty, staff, and students of Tarlac State University received by the TSURERC. This process begins with the receipt of study documents for initial review, determination of completeness of submission, and ends with the determination of type of review or action.

<b>Office or Division:</b>	Research Ethics Review Committee			
<b>Classification:</b>	Simple (up to 3 days) Complex (beyond 3 days to 7 days) Highly Technical (7 days to 20 days)			
<b>Type of Transaction:</b>	G2C - Government to Citizen G2B – Government to Business Entity/ies G2G - Government to Government			
<b>Who may avail:</b>	TSU Faculty and Student			
<b>CHECKLIST OF REQUIREMENTS</b>		<b>WHERE TO SECURE</b>		
<ul style="list-style-type: none"> <li>- <b>Application Form</b> (TSU-ERC-SF-07)</li> <li>- <b>Cover Letter</b> (Request Letter to the Chairperson)</li> <li>- <b>Certificate of Endorsement Letter</b> (TSU-ERC-SF-012)</li> <li>- <b>Research Protocol</b> (the protocol must include the title, objectives of the study, significance of the study, literature review, methodology and procedures, description of the study population, exclusion/inclusion criteria, data analysis plan, and <b>ethical considerations</b>)</li> <li>- <b>Informed Consent Document</b> (TSU-ERC-SF-42) English and Filipino version</li> <li>- <b>Informed Assent Form</b> (TSU-ERC-SF-48) English and Filipino version <b>for studies involving minors</b> and relevant populations deemed incompetent to sign an informed consent form.</li> <li>- <b>Study Tools</b> (These include survey questionnaires, interview guide, case report form, posters/advertisements for recruitment, etc.)</li> <li>- <b>Curriculum Vitae of the Researcher/s</b></li> <li>- Adviser's Curriculum Vitae (for students)</li> </ul>		Research Ethics Review Committee/ Downloadable at the TSU Website		
<b>CLIENT STEPS</b>	<b>AGENCY ACTIONS</b>	<b>FEES TO BE PAID</b>	<b>PROCESSING TIME</b>	<b>PERSON RESPONSIBLE</b>
1. Receipt of study documents for initial review and determination of completeness of submission	1. The principal Investigator submits research proposal to the TSURERC Secretariat for review and approval of Initial Review Application	None	10-15 minutes	<ul style="list-style-type: none"> <li>- Researchers (Faculty/ Student)</li> <li>- Secretariat</li> </ul>
	2. The TSURERC Secretariat shall inform the Principal Investigator on the completeness of the submitted documents.	None		<ul style="list-style-type: none"> <li>- Secretariat</li> </ul>



	3. The TSURERC Secretariat will stamp, sign and date of receipt on the cover letter confirming receipt of the documents. A photocopy of the completed document shall be given to the applicants for their records.	None		- Secretariat
	4. Incomplete or incorrect submissions will not be accepted and will be returned.	None		- Secretariat
	5. The TSURERC Secretariat ensures that all required forms and materials are contained within the submitted package.	None		- Secretariat
	6. Checking is done as per checklist for submissions for initial review.	None		- Secretariat
2. Assessment and Categorization of the Study Protocol Type of Review by the Chair	1. Expedited	None	10-20 minutes	- Chairperson
	2. Full Review			
	3. Exemption from Review			
3. Review of Protocols	Review the Protocol by the Primary Reviewer.	None	Expedited -5 Days	- Primary Reviewer
			Full Board -14 Days	- All members
			Exempted -1 Day	- Chairperson
4. Action on the reviewed protocol	Draft the ethical clearance whether the study is full board/ expedited/ exemption from the review protocol based on returned reviews and duly signed by the Chairperson.	None	5 minutes	- Chairperson - Secretariat
<b>TOTAL:</b>			5 Days, 45 minutes – Expedited Review 20 Days, 45 minutes – Full Board Review 1 Day, 45 minutes – Exempted from review	



## 2. PROCESS ON THE RESUBMITTED PROTOCOLS

This process only applies to resubmissions of protocol by faculty, staff, and students of Tarlac State University received by the TSURERC. The process begins with the receipt of study documents for resubmission review, determination of completeness, and ends with the determination of type of review or action.

<b>Office or Division:</b>	<b>RESEARCH ETHICS REVIEW COMMITTEE</b>			
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<b>Type of Transaction:</b>	G2C - Government to Citizen G2B – Government to Business Entity/ies G2G - Government to Government			
<b>Who may avail:</b>	TSU Faculty and Student			
<b>CHECKLIST OF REQUIREMENTS</b>		<b>WHERE TO SECURE</b>		
<ul style="list-style-type: none"> <li>- Application Form (TSU-ERC-SF-07)</li> <li>- Revised Research Protocol</li> <li>- Revised Informed Consent Document (TSU-ERC-SF-42) English and Filipino version</li> <li>- Revised Informed Assent Form (TSU-ERC-SF-48) English and Filipino version <i>*if applicable</i></li> <li>- Review of Resubmitted Protocol (TSU-ERC-SF-40)</li> </ul>		RESEARCH ETHICS REVIEW COMMITTEE/ Downloadable at the TSU Website		
<b>CLIENT STEPS</b>	<b>AGENCY ACTIONS</b>	<b>FEES TO BE PAID</b>	<b>PROCESSING TIME</b>	<b>PERSON RESPONSIBLE</b>
1. Resubmission of Revised Protocols	1. The principal Investigator shall resubmit research proposal to the TSURERC Secretariat.	None	10 – 15 minutes	Secretariat
	2. The TSURERC Secretariat shall inform the Principal Investigator on the completeness of the submitted documents			
	3. Incomplete or incorrect submissions will not be accepted and will be returned.			



	4. The TSURERC Secretariat ensures that all required forms and materials are contained within the submitted package.			
	5. Checking is done as per checklist for submissions for initial review.			
2. Review of the Resubmitted Revised Protocols	Review the Protocol by the Primary Reviewer.	None	Expedited - 7 Days Full Board - 14 Days	- Primary Reviewer/s - All members
3. Issuance of Ethical Clearance	Draft the Ethical Clearance forwarded from full board/ expedited protocol based on returned reviews and duly signed by the Chairperson.	None	5 minutes	- Chairperson - Secretariat
<b>TOTAL:</b>		7 Days, 20 minutes – Expedited Review 14 Days, 20 minutes – Full Board Review		



### 3. PROCESS ON THE FINAL REVIEW OF PROTOCOL

The review of final report ensures continuous protection of participants and compliance with initially approved protocol.

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<b>Type of Transaction:</b>	G2C - Government to Citizen G2B – Government to Business Entity/ies G2G - Government to Government			
<b>Who may avail:</b>	TSU Faculty and Student			
<b>CHECKLIST OF REQUIREMENTS</b>		<b>WHERE TO SECURE</b>		
<ul style="list-style-type: none"> <li>- Application Form (TSU-ERC-SF-07)</li> <li>- Final Report Form (TSU-ERC-SF-30)</li> <li>- Completed Research Study</li> <li>- Final Manuscript (for students)</li> <li>- Signed Informed Consent Document English and Filipino version</li> <li>- Signed Informed Assent English and Filipino version</li> </ul>		RESEARCH WRHICS REVIEW COMMITTEE		
<b>CLIENT STEPS</b>	<b>AGENCY ACTIONS</b>	<b>FEES TO BE PAID</b>	<b>PROCESSING TIME</b>	<b>PERSON RESPONSIBLE</b>
1. Submission of Final Report	1. The principal Investigator shall submit a final report with attached final research paper and other documents	None	10 – 15 minutes	Secretariat
	2. The TSURERC Secretariat shall inform the Principal Investigator whether the documents are complete or incomplete.			
	3. The TSURERC Secretariat will stamp, sign and date of receipt of the final report.			
	4. Incomplete or incorrect submissions will not be accepted and will be returned.			



	5. The TSURERC Secretariat ensures that all required forms and materials are contained within the submitted package. Checking is done as per checklist for submissions for initial review.			
2. Review of the Final Report	Review the Protocol by the Primary Reviewer.	None	7 Days	Primary Reviewer/s
Step 3 Issuance of Final Report Approval	Draft the Final Report Approval letter forwarded from full board/ expedited review based on returned reviews and duly signed by the Chairperson.	None	5 minutes	<ul style="list-style-type: none"> <li>- Chairperson</li> <li>- Secretariat</li> </ul>
<b>TOTAL:</b>		7 Days, 20 minutes		