

**Info about approvals filing**  
**IRB of the Public Health Centre of the Ministry of Health of Ukraine**

<b>STAGE</b>	<b>STAGES</b>	<b>REQUIRED DOCUMENTS</b>	<b>TERMS</b>	<b>TIME FOR EXPERTISE</b>	<b>EXPECTED RESULTS</b>
<b>Planning</b>	<b>APPLICATION FOR A FULL REVIEW</b>	<ol style="list-style-type: none"> <li>1. Application form for a full review or an application form for exclusion</li> <li>2. Study protocol</li> <li>3. Study instrument</li> <li>4. CV of the leading researcher</li> <li>5. Form of informed consent</li> <li>6. Confidentiality form for the researcher</li> <li>7. Other relevant documents</li> </ol>	Before the start of the study	Up to 15 working days	<p>Approved with no comments → realization of the study</p> <p>Approved after minor changes → application for a follow-up review</p> <p>Subject to re-submission → application for a follow-up review</p> <p>Not approved → suspension or closure of the study</p>
	<b>APPLICATION FOR EXCLUSION</b>				<p>Approved → realization of the study</p> <p>Not approved → full review</p>
	<b>APPLICATION FOR A FOLLOW-UP REVIEW</b>	<ol style="list-style-type: none"> <li>1. Application form for a follow-up review</li> <li>2. Study protocol</li> <li>3. Other documents that were updated/changed</li> </ol>	Not later than 5 days after receiving a letter from the IRB	Up to 10 working days	<p>Approved with no comments → realization of the study</p> <p>Approved after minor changes → application for a follow-up review</p> <p>Subject to re-submission → application for a follow-up review</p> <p>Not approved → suspension or closure of the study</p>
<b>Realization</b>	<b>APPLICATION FOR A ROUTINE REVIEW</b>	<ol style="list-style-type: none"> <li>1. Application form for a routine review</li> <li>2. Study protocol</li> <li>3. Study instrument</li> <li>4. Form of informed consent</li> <li>5. Confidentiality form for the researcher</li> <li>6. Other relevant documents</li> </ol>	<p>Every 12 month after the has been approved</p> <p>At the request of the IRB at any stage of the study</p>	Up to 10 working days	<p>Approved → realization of the study</p> <p>Not approved → suspension or closure of the study</p>
	<b>APPLICATION DUE TO THE CHANGES</b>	<ol style="list-style-type: none"> <li>1. Application form due to changes</li> <li>2. Updated study protocol</li> <li>3. Other documents that were updated/changed</li> </ol>	Not later than 15 days of the planned changes	Up to 5 working days	<p>Approved → continuation of the research with changes</p> <p>Approved after minor changes → application for a follow-up review</p> <p>Subject to re-submission → application for a follow-up review</p> <p>Not approved → suspension or closure of the study</p>
	<b>REPORTING UNFORSEEN EVENTS</b>	<ol style="list-style-type: none"> <li>1. Form for reporting unforeseen events</li> <li>2. Other relevant documents that include information on the case of unforeseen circumstances</li> </ol>	No later than 3 days after the occurrence of an unforeseen circumstance or its detection	Up to 5 working days	<p>Approved → continuation of the research with or without changes</p> <p>Not approved → suspension or closure of the study</p>
<b>Final stage</b>	<b>APPLICATION FOR THE FINAL REVIEW</b>	<ol style="list-style-type: none"> <li>1. Application form for the final review</li> <li>2. Study protocol</li> <li>3. Study instrument</li> <li>4. Form of informed consent</li> <li>5. Confidentiality form for the researcher</li> <li>6. Report on the results of the study (if available)</li> <li>7. Other relevant documents</li> </ol>	No later than 3 days after the completion of data processing and/or finalization of the research report	Up to 15 working days	<p>Approved → finalize research</p> <p>Not approved → finalize research</p>