

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

Stage	Steps	Required documents	Terms	Time for expertise	Expected results
Planning	<b>Application for a full review</b>	1. Application form for a full review or an application form for exclusion 2. Study protocol 3. Study instrument	Before the start of the study	Up to 15 working days	Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
	<b>Application for exclusion</b>	4. CV of the leading researcher 5. Form of informed consent 6. Confidentiality form for the researcher 7. Other relevant documents			Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
	<b>Application for a follow-up review</b>	1. Application form for a follow-up review 2. Study protocol 3. Other documents that were updated/changed	Not later than 5 days after receiving a letter from the IRB	Up to 10 working days	Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
Realization	<b>Application for a routine review</b>	1. Application form for a routine review 2. Study protocol 3. Study instrument 4. Form of informed consent 5. Confidentiality form for the researcher 6. Other relevant documents	Every 12 month after the has been approved or At the request of the IRB at any stage of the study	Up to 10 working days	Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
	<b>Application due to the changes</b>	1. Application form due to changes 2. Updated study protocol 3. Other documents that were updated/changed	Not later than 15 days of the planned changes	Up to 5 working days	Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
	<b>Reporting unforeseen events</b>	1. Form for reporting unforeseen events 2. Other relevant documents that include information on the case of unforeseen circumstances	No later than 3 days after the occurrence of an unforeseen circumstance or its detection	Up to 5 working days	Approved with no comments→ realization of the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)
Final stage	<b>Application for the final review</b>	1. Application form for the final review 2. Study protocol 3. Study instrument 4. Form of informed consent 5. Confidentiality form for the researcher 6. Report on the results of the study (if available)	No later than 3 days after the completion of data processing and/or finalization of the research report	Up to 15 working days	Approved with no comments→ finalize the study Approved after minor changes → application for a follow-up review (minor changes) Subject to re-submission → application for a follow-up review (significant changes)

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		7. Other relevant documents			
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