IRB FEE SCHEDULE

Effective January 1, 2025 – December 31, 2025

2025 IRB Fee Schedule

Review Services	Fees	Unit
Initial Review [Initial Review includes product information and first informed consent form (ICF)]		
Multi-Site Initial Review of Protocol	**$1,755**	
Investigator Initial Review	**$1,345**	Per site
Single Site Initial Review of Protocol with Investigator Review	**$3,100**	
Additional Informed Consent (submitted at time of Initial Review)	**$460**	Per ICF
Continuing Review		
Multi-Site Continuing Review of Protocol	**$1,755**	
Investigator Continuing Review	**$1,345**	Per site
Single Site Continuing Review of Protocol and Investigator	**$3,100**	
Close Out of Research		
Multi-Site Protocol Closeout	**$410**	
Multi-Site Investigator Closeout	**$345**	Per site
Single Site Protocol and Investigator Closeout	**$525**	
Research Materials ("Recruitment or Subject-Facing Materials") Initial submissions or revised ads, diaries, appendices submitted separately from protocol, questionnaires, dosing cards, attestations related to the e-consent process/content, etc. Submissions with multiple formats/item types will be assessed and billed accordingly as individual items.	**$430**	Per item
Product Information Investigator brochures, device manuals or other product information submitted after initial protocol review	**$495**	Per document
Notification of Approval for Research Materials or Product Information to Sites	**$90**	Per site, per submission
Translation Services		
ICF Translations Acknowledgement	**$315**	Per site, per item
Research Materials Translations Acknowledgement	**$315**	Per item
Release of Translated Research Materials to Sites	**$90**	Per site, per submission
Third-Party Translation Costs (when request is to utilize Advarra's vendor)	**Custom Pricing**	(Based on language and word count)
Full or Partial Waiver of Privacy Authorization/HIPAA (upon request)	**$610**	Per request, per site
Protocol Amendments without ICF Changes (examples include amendments, administrative change/protocol clarification letters)	**$610**	Per site, per item
Protocol Amendments with ICF Changes (examples include amendments, administrative change/protocol clarification letters)	**$810**	Per site, per item
New/Revised Informed Consent (submitted after initial review)	**$810**	Per site, per item
Administrative Changes not requiring IRB Review or Site-Specific ICF (to incorporate institutional, state, local or provincial requirements)	**$460**	Per site, per consent
Change in Investigator at Approved Site	**$1,345**	Per site
Site Location Change or Sub-Investigator Review	**$460**	Per site, per location

Review Services	Fees	Unit
Safety Report Acknowledgement and Distribution	$95	Per report, per protocol, per site
Reportable Events	$380	Per item
Emergency Use of an Investigational Test Article	$1,210	Per protocol
Additional Review Services [Fees apply at Initial and Continuing Reviews (as applicable)]	**Fees**	**Unit**
Non-Human Subject, Humanitarian Use Device (HUD) or Exempt from IRB Review Determination	$1,345	Per protocol
IRB Review of Draft Materials (Advisory Review)	$790	Per protocol
Single-Site Expanded Access/Compassionate Use	$2,890	Per protocol
Multi-Site Expanded Access/Compassionate Use (Protocol Review)	$1,500	Per protocol
Multi-Site Expanded Access/Compassionate Use (Site Review)	$1,345	Per site
Generic, Non-Study-Specific Recruiting/Subject-Facing Materials	$640	Per item
Generic, Non-Study-Specific Informed Consents with screening protocol	$640	Per item
Timeline Changes	**Fees**	**Unit**
Rush Processing (applies to rush processing of documents only, not IRB review time)	$460	Per item, per site (surcharge)
Withdrawal of Submission Prior to IRB Review	$180	Per item
Re-open Protocol or Site for Single Item Processing	$475	Per protocol or site
Ongoing Review Late Report (applies if ongoing review or terminations not received within 2 weeks prior to expiration)	$315	Per protocol and or site
Ancillary Support Services	**Fees**	**Unit**
Request for Advarra to Incorporate Protocol Changes into IRB Approved Consent Form	$1,025	Per item
Draft ICF Preparation		
Main ICF (Phase I Healthy Drug Studies)	$1,100	Per item
Main ICF (Therapeutic Phase I Drug Studies/Healthy Phase II Drug Studies)	$1,500	Per item
Main ICF (Phase II, III and IV Drug Studies)	$3,000	Per item
Main ICF (Investigator-Initiated/Social/Behavioral Studies, All Device Studies)	$3,000	Per item
Ancillary Documents (Sub-Study, Assent, Pregnant Partner, etc.)	$600	Per item
Site Identification Services – SiteIQ ™	**Contact Commercial Team**	
Consulting Services (GxP Services; Research Compliance & Site Operations)	**Contact Commercial Team**	
Institutional Biosafety Committee Review Services (IBC)	**Contact Commercial Team**	
Data Monitoring Committee Services	**Contact Commercial Team**	
Endpoint Adjudication Committee Services	**Contact Commercial Team**	

Advarra reserves the right to revise the fee schedule billing methodology, services and fees on a periodic basis

For fee inquiries and estimates, please visit www.advarra.com/gaq

Requirements to upload invoice into a client-specific portal may incur additional fees