

Review Services	Fees	Unit
Initial Review [Initial Review includes product information and first informed consent form (ICF)]		
Multi-Site Initial Review of Protocol	\$1,670	
Investigator Initial Review	\$1,280	per site
Single Site Initial Review of Protocol <u>with</u> Investigator Review	\$2,950	
Additional Informed Consent (submitted at time of Initial Review)	\$440	per ICF
Continuing Review		
Multi-Site Continuing Review of Protocol	\$1,670	
Investigator Continuing Review	\$1,280	per site
Single Site Continuing Review of Protocol and Investigator	\$2,950	
Close Out of Research		
Multi-Site Protocol Closeout	\$390	
Multi-Site Investigator Closeout	\$330	per site
Single Site Protocol and Investigator Closeout	\$500	
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.	\$410	per item
Product Information Investigator brochures, device manuals or other product information submitted after initial protocol review	\$470	per document
Notification of Approval for Research Materials or Product Information to Sites	\$85	per site, per submission
Translation Services		
ICF Translations Acknowledgement	\$300	per site, per item
Research Materials Translations Acknowledgement	\$300	per item
Release of Translated Research Materials to Sites	\$85	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)	\$580	per request, per site
Protocol Amendments without ICF Changes (examples include amendments, administrative change/protocol clarification letters)	\$580	per site, per item
Protocol Amendments with ICF Changes (examples include amendments, administrative change/protocol clarification letters)	\$770	per site, per item
New/Revised Informed Consent (submitted after initial review)	\$770	per site, per item
Administrative Changes not requiring IRB Review or Site-Specific ICF (to incorporate institutional, state, local or provincial requirements)	\$440	per site, per consent
Change in Investigator at Approved Site	\$1,280	per site
Site Location Change or Sub-Investigator Review	\$440	per site, per location
Safety Report Acknowledgement and Distribution	\$90	per report, per protocol, per site
Reportable Events	\$360	per item
Emergency Use of an Investigational Test Article	\$1,150	per protocol

Additional Review Services [Fees apply at Initial and Continuing Reviews (as applicable)]		Fees	Unit
Non-Human Subject or Exempt from IRB Review Determination		\$1,280	per protocol
IRB Review of Draft Materials (Advisory Review)		\$750	per protocol
Single-Site Expanded Access/Compassionate Use		\$2,750	per protocol
Multi-Site Expanded Access/Compassionate Use (Protocol Review)		\$1,430	per protocol
Multi-Site Expanded Access/Compassionate Use (Site Review)		\$1,280	per site
Generic, Non-Study-Specific Recruiting/Subject-Facing Materials		\$610	per item
Generic, Non-Study-Specific Informed Consents with screening protocol		\$610	per item
Timeline Changes		Fees	Unit
Rush Processing (applies to rush processing of documents only, not IRB review time)		\$440	per item, per site (surcharge)
Withdrawal of Submission Prior to IRB Review		\$170	per item
Re-open Protocol or Site for Single Item Processing		\$450	per protocol or site
Ongoing Review Late Report (applies if ongoing review or terminations not received within 2 weeks prior to expiration)		\$300	per protocol and or site
Ancillary Support Services		Fees	Unit
Request for Advarra to Incorporate Protocol Changes into IRB Approved Consent Form		\$975	per item
Draft ICF Preparation			
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.)		\$450	per item
Site Identification Services – SiteIQ™		Contact Commercial Team	
Consulting Services (Clinical, Quality, Regulatory, and Institutional Research Centers of Excellence)		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