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IRB Fee Schedule

Effective January 1, 2023

Review Services	Fees	Unit
Initial Review [Initial Review includes product information and first informed consent form (ICF)]		
Multi-Site Initial Review of Protocol	$1,515	
Investigator Initial Review	$1,155	per site
Single Site Initial Review of Protocol with Investigator Review	$2,680	
Additional Informed Consent (submitted at time of Initial Review)	$395	per ICF per site
Continuing Review		
Multi-Site Continuing Review of Protocol	$1,515	
Investigator Continuing Review	$1,155	per site
Single Site Continuing Review of Protocol and Investigator	$2,680	
Close Out of Research		
Multi-Site Protocol Closeout	$350	
Multi-Site Investigator Closeout	$295	per site
Single Site Protocol and Investigator Closeout	$450	
Recruitment or Subject-Facing Materials ("Research Materials") Initial submissions or revised ads, diaries, appendices submitted separately from protocol, questionnaires, dosing cards, attestations related to e-consent process/content, etc.	$365	per item
Product Information Investigator brochures, device manuals or other product information submitted after initial review	$425	per document
Notification of Approval for Research Materials or Product Information to Sites	$70	per site per submission
Translation Services		
ICF Translations Acknowledgement	$265	per site per item
Research Materials Translations Acknowledgement	$265	per item
Release of Translated Research Materials to Sites	$80	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)	$525	per request per site
Protocol Amendments without ICF Changes (to include administrative change and protocol clarification letters)	$525	per site per item per protocol
Protocol Amendments with ICF Changes (to include administrative change and protocol clarification letters)	$695	per site per item per protocol
New/Revised Informed Consent (submitted after initial review)	$695	per site per item per protocol
Customization of Site ICF (to incorporate state, local or provincial requirements)	$325	surcharge per site per consent
Administrative Changes to Previously Approved Materials not requiring IRB review	$395	per site per item
Review of E-Consent in customer's platform	$350	per site per item
Change in Investigator at Approved Site	$1,155	per site
Sub-Investigator Review or Site Location Change	$395	per site per location
Safety Report Acknowledgement and Distribution	$80	per report per protocol per site
Reportable Events	$325	per item

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Additional Review Services (Fees apply at Initial and Continuing Reviews (as applicable)	Fees	Unit
Non-Human Subject or Exempt from IRB Review Determination	$1,155	per protocol
IRB Review of Draft Materials (Advisory Review)	$675	per protocol
Single-Site Expanded Access/Compassionate Use	$2,500	per protocol
Multi-Site Expanded Access/Compassionate Use (Protocol Review)	$1,295	per protocol
Multi-Site Expanded Access/Compassionate Use (Site Review)	$895	per site
Single Site Exempt from Informed Consent (EFIC) Protocol and Investigator	$3,295	per protocol
Generic, Non-Study-Specific Recruiting/Subject-Facing Materials	$550	per item
Generic, Non-Study-Specific Informed Consents	$550	per item
Unplanned Emergency Research	$1,045	per protocol
Timeline Changes	**Fees**	**Unit**
Rush Processing	$395	per item per site (surcharge)
Withdrawal of Submission Prior to IRB Review	$150	per item
Ongoing Review Late Report (applies if ongoing review or terminations not received within 2 weeks prior to expiration)	$265	per protocol or site
Ancillary Support Services	**Fees**	**Unit**
Draft ICF Preparation		
Main ICF (Healthy Phase I Drug Studies), assumes up to 8 hours of effort	$900	per item
Main ICF (Therapeutic Phase I Drug Studies/Healthy Phase II Drug Studies), assumes up to 16 hours of effort	$1,500	per item
Main ICF (Phase III/IV Drug Studies), assumes up to 40 hours of effort	$3,000	per item
Main ICF (Investigator-Initiated/Social/Behavioral Studies, All Device Studies), assumes up to 40 hours of effort	$3,000	per item
Ancillary Documents (Sub-Study, Assent, Pregnant Partner, etc.)	$450	per item
Site Identification Services – SiteIQ ™	Contact Business Development	
Consulting Services (Clinical, Quality, Regulatory, and Institutional Research Centers of Excellence)	Contact Business Development	
Institutional Biosafety Committee Review Services (IBC)	Contact Business Development	
Data Monitoring Committee Services	Contact Business Development	
Endpoint Adjudication Committee Services	Contact Business Development	

Advarra reserves the right to revise the fee schedule billing methodology, services and fees on a periodic basis
For free inquiries and estimates, please contact: businessdevelopment@advarra.com
Requirements to upload invoice into a client-specific portal may incur additional fees