# CLINICAL RESEARCH ADMINISTRATIVE FEE SCHEDULE

*This template should be customized with your institution's specific costs, policies, and procedures. Consult with sponsored research, finance, and legal counsel before finalizing.*

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## OVERVIEW

This fee schedule outlines the actual cost of conducting clinical research at our institution. Each fee reflects actual expenses incurred to ensure site sustainability, regulatory compliance, fair compensation for skilled personnel, and transparency with sponsors. Sites that fail to capture these costs adequately often operate at a loss, experience staff burnout, compromise data quality, and eventually exit the research business. These fees represent the essential "behind-the-scenes" work required for successful clinical trial conduct and are supported by detailed cost worksheets available upon request.

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## OVERHEAD & INDIRECT COSTS

### Institutional F&A Rate: [XX]% of Total Direct Costs*

This federally negotiated rate covers facilities (research space, utilities, maintenance, security, insurance), administrative infrastructure (IT systems, legal counsel, HR support, finance systems, compliance programs), and shared research resources (biosafety, informatics, quality assurance).

### Departmental Administrative Fee: $_____ per study

This direct cost covers dedicated research administrative personnel who support your specific study, separate from institutional overhead. It funds financial management (budget development, invoicing, payment tracking, audit support), research billing compliance (coverage analysis, charge capture, False Claims Act compliance), grant and contract administration (CTA negotiation, vendor management, regulatory filing), and pooled support services (nursing coverage, administrative staff, document preparation). Without this fee, these complex tasks fall to Principal Investigators and coordinators, taking time away from patient care and protocol compliance.

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# START-UP COSTS & FEES

## Why Start-Up Fees Are Non-Refundable

Start-up activities occur before the first patient enrolls and represent real costs whether the study succeeds, is cancelled, fails IRB approval, or is placed on hold. Sites typically invest 200-400 hours of professional time before the first subject consents. These fees may be adjusted by mutual agreement if cancelled early, but sites expect sponsors to honor all fixed costs for activities undertaken in good faith.

## Non-Refundable Administrative Start-Up Fee*

| Tier | Study Type | Fee | Est. Hours |
|---|---|---|---|
| **Tier 1** | Phase I-III interventional, investigational drug/device, inpatient studies, category A/B device studies | $_____ | 250-350 |
| **Tier 2** | Observational with biospecimen, post-market device, registries | $_____ | 150-200 |
| **Tier 3** | Registry studies, chart reviews, secondary data analysis | $_____ | 80-120 |

This comprehensive fee covers protocol and feasibility review, regulatory document preparation (FDA 1572, financial disclosure, CV verification, lab certifications), IRB submission package preparation, budget and contract negotiation, study team assembly and training, systems infrastructure setup (CTMS, EDC, EMR, pharmacy, lab), vendor coordination, site initiation visit preparation, and quality assurance activities. The fee may be bundled or itemized based on sponsor preference.

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## Coverage Analysis (Billing Grid): $_____

A coverage analysis determines which procedures are routine care (billable to insurance), research (billable to sponsor), or both. The process includes line-by-line protocol review, standards of care research using NCDs/LCDs/clinical guidelines, comprehensive billing grid creation with detailed justifications, and system implementation with staff training. Without this analysis, sites risk federal investigations, patient complaints, and sponsor disputes.

## IRB Initial Submission Preparation: $_____

This fee compensates site staff time to prepare the IRB submission package, separate from the IRB's review fee. Activities include completing the IRB application, writing protocol synopsis and risk-benefit analysis, customizing informed consent forms for local population and literacy level, preparing HIPAA authorizations and recruitment materials, coordinating multi-department signatures, and managing IRB contingency responses. May be bundled into Administrative Start-Up Fee.

## Pharmacy Set-Up: $_____ to $_____ (based on complexity)

Investigational product management requires licensed pharmacists with specialized training, secure 24/7 monitored storage, complex accountability systems, and multiple system integrations. This fee covers infrastructure setup (dedicated storage, temperature monitoring, security access, environmental controls), systems configuration (pharmacy management system, IVRS/IWRS integration, EMR order sets), regulatory documentation (accountability logs, temperature logs, procedures), and staff training on handling, blinding, randomization, and dosing procedures.

## Laboratory Set-Up: $_____

This fee configures lab systems to handle protocol-specific specimens correctly and prevent processing errors. Activities include laboratory information system configuration (custom test panels, specimen types, processing protocols), collection kit management (inventory, tracking, expiration monitoring), special processing procedures documentation (timing, temperature, centrifugation, aliquoting), staff training (phlebotomists, technicians), and quality control validation.

## Clinical Engineering/Equipment: $_____

For studies with sponsor-provided equipment, this fee covers equipment receipt and inspection, safety and electrical verification, calibration verification, asset tracking, setup and installation, integration with existing systems, staff training, and inspection documentation. Annual maintenance fee of $_____ covers ongoing inspections and required testing.

## Radiology/Imaging Protocol Setup: $_____

This fee covers imaging protocol review, scanner parameter programming, phantom scan coordination, core lab connectivity testing, image transfer procedures, quality assurance, and staff training. Protocol harmonization across multiple scanners may be required.

## Third-Party Vendor Integration: $_____ per vendor

Each sponsor-required vendor (ePRO/eDiary, IVRS/IWRS, central labs, imaging cores, recruitment platforms, payment systems) requires account setup, technical integration and connectivity testing, staff training on protocol-specific workflows, and end-to-end quality assurance testing. Sites typically integrate 3-8 vendors per complex protocol.

## Mock Subject Run-Through: $_____

This quality assurance activity tests all systems and workflows with a simulated subject before enrolling actual patients. The mock run identifies problems in procedures, documentation, systems integration, and workflow, prevents protocol deviations with real subjects, validates time estimates for scheduling, and identifies training gaps. This proactive testing improves subject experience and reduces staff confusion.

### Protocol-Required Test/Phantom Scans: $_____ per scan

Imaging studies requiring calibration use specialized phantom equipment or volunteer scans per protocol specifications. Costs include scanner time, technical staff, image acquisition, core lab transfer, and radiologist interpretation (professional fees).

### Clinical Research Unit Setup: $_____

One-time fee for dedicated research space covering room assignment and scheduling system, equipment placement, supply stocking, emergency equipment verification, specialized equipment setup, scheduling templates, and staff access management. Ongoing utilization fee of $_____ per hour may apply.

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# IRB & ETHICS REVIEW FEES

### Direct IRB Fees (Pass-Through) *

| Review Type | Fee |
|---|---|
| Initial Review (Full Board) * | $_____ |
| Continuing Review (Annual)* | $_____ |
| Amendment - Substantial* | $_____ |
| Amendment - Minor | $_____ |
| Study Closure* | $_____ |

*These fees are charged by the IRB institution and represent direct pass-through costs, typically exempt from institutional F&A.*

### IRB Preparation Fees (Site Staff Time)

**Continuing Review Preparation: $_____** - Annual preparation includes enrollment statistics compilation, adverse event summaries, protocol deviation trending, progress report narrative, updated investigator brochure and certifications, staff roster updates, and IRB application completion with document uploads.

**Protocol Amendment Preparation: $_____ to $_____** (tiered by complexity) - Minor amendments ($**) cover administrative changes requiring 10-15 hours. Moderate amendments ($**) involve visit changes and procedure additions requiring 15-25 hours including consent revisions and system updates. Major amendments ($_____) address significant protocol changes requiring 25-40+ hours including comprehensive retraining, system reconfiguration, and possible subject reconsenting.

**SAE Report Preparation: $_____** - SAE reports require immediate attention with complete medical record review, timeline construction, causality and severity assessment, clinical narrative preparation, sponsor and IRB notification coordination, and comprehensive documentation. This disrupts planned workflow and requires priority response within regulatory timelines.

**IND Safety Report Processing: $_____** - For safety reports not meeting IRB reporting thresholds, this fee covers PI review, criteria assessment, signature acknowledgment, and regulatory filing. Large trials may generate hundreds annually.

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# ONGOING STUDY FEES

## Pharmacy Services

**Monthly Drug Storage: $_____** - Covers 24/7 climate-controlled secure storage, continuous temperature monitoring with automated alarms, backup power systems, physical inventory counts, expiration monitoring, and compliance documentation.

**Dispensing Fees** - Simple ($)**: pre-packaged medications with basic documentation. Moderate ($)**: dose calculations, kit preparation, IVRS interaction. Complex ($_____+): compounding, reconstitution, multiple-step preparation, stability calculations.

**Monitoring Visit Support: $_____** - Pharmacist time for accountability record review, temperature log review, dispensing documentation, and query resolution during monitoring visits.

**Amendment Management: $_____** - Pharmacy system changes, procedure redesign, and staff retraining required when protocol amendments affect investigational product management.

## Laboratory Services

**Specimen Processing: $_____** (standard) or $_____** (complex with special handling) - Per specimen costs for protocol-specific processing beyond standard clinical lab work.

**Lab Kit Management: $_____** per month - Inventory tracking, expiration monitoring, par level maintenance, and reorder coordination.

## Administrative Maintenance

**Annual Maintenance Fee: $_____** (Years 2+) - Ongoing oversight including quarterly financial reviews, regulatory binder maintenance, staff training updates, licensure tracking, quality audits, metrics monitoring, and vendor management. Essential for multi-year study integrity.

# MONITORING & AUDIT SUPPORT

## Monitoring Visit Support: $_____ per day or $_____ per half-day

During monitoring visits, coordinators must stop all other activities to provide dedicated support. This fee covers pre-visit preparation (source document organization, query resolution, regulatory binder review), during-visit support (full coordinator availability, medical record navigation, real-time query resolution, PI consultation), and post-visit follow-up (action item completion, corrections). Coordinators cannot perform revenue-generating activities like subject visits or enrollment during monitoring, making this fee essential for opportunity cost recovery.

## Remote Monitoring: $_____ per session

Remote monitoring is not cheaper for sites and often requires more work. Activities include scanning 50-200 pages of source documents per subject, PHI redaction per HIPAA, file upload and organization, live session support with screen-sharing, and follow-up document requests. Technology challenges and additional time for document preparation justify this fee.

## Unscheduled Monitoring Inquiry: $_____ per hour

Ad hoc requests between scheduled visits disrupt planned workflow and fragment coordinator time. This fee covers single-subject clarifications, urgent document requests, and individual query resolution, encouraging monitors to consolidate questions for scheduled visits while ensuring compensation for genuinely urgent issues.

## Sponsor Audit: $_____ per day

Sponsor audits involve greater scope than monitoring, require multiple staff simultaneously, carry higher stakes for site reputation, and need extensive preparation. This includes complete regulatory binder review, 100% pharmacy accountability verification, mock audit/self-inspection, deficiency correction, availability of PI/coordinator/pharmacist/lab staff during audit, CAPA plan development, and formal response letter preparation.

## FDA/Regulatory Audit: $_____ per day

FDA inspections can impact the site's ability to conduct future research and the investigator's ability to serve as PI. This highest-stakes audit requires legal counsel involvement, institutional compliance officer participation, executive leadership coordination, formal written responses (often 10-20 pages), Form FDA 483 response if issued, and corrective action implementation with follow-up preparation.

### Change of Monitor: $_____

New monitors require site orientation (facility tour, medical record system training, filing system explanation, key personnel introductions) and study-specific orientation (historical issue review, subject-specific nuances, site conventions). New monitors typically require more time for initial visits, ask previously answered questions, and need more guidance, creating inefficiency the site bears.

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## AMENDMENT & SUBJECT SERVICES

### Subject Reconsenting: $_____ per subject

Required when new safety information, procedure additions, or risk profile changes affect informed consent. Activities include subject contact and scheduling (may require special visit), line-by-line explanation of changes, question answering, re-signing and witnessing, and documentation in medical record and EDC. Fee applies to the effort regardless of whether subject continues participation.

### Contract/Budget Amendment: $_____

When protocol changes require budget modifications, this covers budget impact analysis, new procedure costing, visit schedule recalculation, budget justification, sponsor negotiation, contract amendment drafting, and signature routing.

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## SUBJECT-RELATED COSTS

### Pre-Screening/Chart Review: $_____ per hour

Electronic health record searches using eligibility criteria, preliminary chart review, provider consultation, and screening log maintenance. Effective pre-screening reduces screen failure rates, improves enrollment efficiency, and reduces patient burden by avoiding screening of clearly ineligible subjects.

### Recruitment Activities (Staff Time): $_____ per hour (capped at $_____)

Community outreach, patient advocacy presentations, provider education, recruitment material creation, tracking systems, and metrics monitoring. Cap amount requires pre-approval for additional recruitment spending.

### Recruitment Vendor Costs: Pass-through + [___] % admin fee

For advertising agencies, media placement, graphic design, call centers, and patient databases. Admin fee covers vendor vetting, contract negotiation, performance monitoring, invoice processing, and issue resolution.

### Unscheduled Subject Visit: Per procedure rates

For adverse event assessment, protocol-required safety follow-up, equipment issues, or retention efforts, bill using the same procedure rates as scheduled visits since work is equivalent.

### Subject Transportation: Pass-through + [___] % admin fee

Rideshare, taxi, medical transportation, or mileage reimbursement. Admin fee covers vendor contracting, subject education, expense approval, and reimbursement processing.

### Translation & Interpretation: Pass-through + admin fee

Admin fee covers certified translator vetting, quality verification, scheduling, and document management.

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# CLOSE-OUT COSTS

### Administrative Close-Out: $_____

Final study wind-down including final visit verification, outstanding query resolution, database lock preparation, financial reconciliation and final invoicing, regulatory close-out (IRB notification, final logs, essential document verification), data transfer to sponsor, and lessons learned documentation.

### IRB Close-Out Preparation: $_____

Final report to IRB including enrollment summary with demographics, adverse event summary with causality assessments, protocol deviation summary, study outcomes if unblinded, IRB form completion, and PI signature coordination. May be bundled into Administrative Close-Out Fee.

### Pharmacy Close-Out: $_____

Final drug accountability (complete reconciliation, discrepancy investigation, final report), drug disposition coordination (return packaging and shipping or destruction with certificates), system deactivation, and comprehensive documentation archiving.

### Record Packaging: $_____

Preparation for long-term storage including final quality check (all consents signed, all source documents complete, remove duplicates), organization by subject with table of contents, digitization if required (scanning, OCR, quality check), and secure packaging with clear labeling.

### Long-Term Record Storage: $_____ per year

Annual costs for secure climate-controlled storage (on-site or third-party facility), inventory verification, environmental protection (fire suppression, humidity control), and retrieval capability maintenance. Retention period typically 2-25 years per FDA/ICH/institutional requirements. CTA should specify that site retains records for required period, then provides sponsor 30-day notice before destruction with option for sponsor to request transfer at sponsor's expense.

### Post-Close-Out Record Retrieval: $_____

When sponsor requests archived documents after close-out for inspection, publication, or queries. Covers records location, retrieval from storage, document review, copying/scanning, shipping coordination, and return to storage.

### Records Destruction & E-Waste Recycling: $_____

After retention period expires, coordination with certified destruction vendor, witnessed destruction if required, certificates of destruction for paper and electronic media, and documentation. Includes proper e-waste recycling with data destruction certification.

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## SPECIAL CIRCUMSTANCES

### Unexpected Cost Allotment: $_____

Pre-approved budget allowance for unforeseen expenses (unanticipated safety procedures, equipment failure, vendor price increases, emergency supplies, COVID-related costs) that don't require full contract renegotiation. Requires prior written sponsor approval with justification.

### Cancelled Protocol Fee: $_____

When study is cancelled before enrollment, covers costs already incurred (protocol review, budget development, contract negotiation, IRB preparation, partial system setup, staff training, non-refundable vendor fees). Typically calculated as percentage of start-up fees based on cancellation stage.

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# INVOICING & PAYMENT TERMS

**Invoice Requirements:** Must include PI name, sponsor protocol number, agreement-specific IPN/project number (provided upon execution), detailed line-item breakdown, and supporting documentation for pass-through costs.

**Payment Terms:**

- Start-Up Fees: Due within [30] days of invoice
- Per-Subject Visits: Invoiced [monthly/quarterly], due within [30-60] days
- Monthly Fees: Invoiced in arrears, due within [30] days
- Pass-Through Costs: Due within [30] days with copy of third-party invoice
- Close-Out Fees: Due within [30-60] days, NOT subject to holdback

**Inflation Adjustment:** For multi-year studies, all fees increase [___] % annually OR adjust per published index (CPI, Medical Care CPI, Employment Cost Index) to maintain purchasing power.

**Late Payment:** [___] % per month on balances over [60/90] days past due. Accounts over [90/120] days may result in enrollment suspension per CTA terms.

**Disputed Charges:** Sponsor must notify in writing within [30] days. Undisputed portions paid per normal terms while parties negotiate in good faith with site providing supporting documentation.

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# PERSONNEL HOURLY RATES (For Reference)

*Fully loaded rates include base salary + benefits + overhead + reasonable margin*

| Role | Rate |
|---|---|
| Principal Investigator | $_____ |
| Sub-Investigator | $_____ |
| Research Coordinator (Senior) | $_____ |
| Research Coordinator | $_____ |
| Research Nurse | $_____ |
| Regulatory Specialist | $_____ |
| Pharmacist | $_____ |
| Lab Technologist | $_____ |
| Phlebotomist | $_____ |
| Research Administrator | $_____ |

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