

MCC-CRO Fee Structure for Industry Sponsored Trials Effective 7/1/15

Start-Up Costs Including 27.4% F&A)

Item	Frequency	Total with F&A
IRB Initial Submission	One Time - Nonrefundable	2,000.00
Study Start Up	One Time - Nonrefundable	13,500.00
Pharmacy Start Up	One Time - Nonrefundable	1,911.00

Ongoing Costs Including 27.4% F&A)

Item	Frequency	Total with F&A
Pharmacy Maintenance Fee _IDS Staff Time: \$50 per patient charged as patients enrolled) -	Each	63.70
IRB Annual Continuation Review Prep	Each	765.00
Revisions/Amendments: to Protocol, IB, ICF, contract, etc.	Each	765.00
Outside Safety Reports	Each	77.00
Archiving/document Storage	Annually	471.00
Monitoring Visit	Each Day	506.00
SAEs (For each SAE Occurrence)	Each	759.00
Dry Ice (as required to ship specific laboratory samples.)	Each	14.00
Study Close Out Review	One Time	637.00
Pharmacy Close Out fee	One Time	637.00

Study Coordinator Hourly Rate

(Note: Hourly Rate Does Not Include 27.4% F&A.

Number of hours per patient dependent upon review of protocol)

Study Coordinator	Hourly Rate
Clinical Research Associate (CRA)	\$51.50
Research Nurse	\$75.00

Costs for Medical Tests and Procedures

Costs for medical tests and procedures considered (Research) Above Standard of Care will be provided after a review of the Study Calendar with the PI

MCC-CRO Fee Structure for IITs (Industry Funding) Effective 7/1/15

Start-Up Costs Including 27.4% F&A)

Item	Frequency	Total with F&A
IRB Initial Submission	One Time - Nonrefundable	2,000.00
Study Start Up	One Time - Nonrefundable	9,555.00
Pharmacy Start Up	One Time - Nonrefundable	Contact Seth Larkin for project specific budget
Oncore	One Time - Nonrefundable	Contact Eric Durbin for project specific budget
Biostatistician		See Generic Biostatistician Shared Resource Facility (BSRF Budget)

Ongoing Costs Including 27.4% F&A)

Item	Frequency	Total with F&A
Pharmacy Maintenance Fee (IDS Staff Time: \$50 per patient charged as patients enrolled)	Each	Contact Seth Larkin for project specific budget
IRB Annual Continuation Review Prep	Each	765.00
Revisions/Amendments: to Protocol, IB, ICF, contract, etc.	Each	765.00
Monitoring Visit	Each Day	77.00
Archiving/document Storage (If applicable)	Annually	471.00
Monitoring Visit (If applicable)	Each Day	506.00
SAEs (For each SAE Occurrence) (If SAEs are required to be sent to sponsor, a fee of \$759 for each SAE will be required from sponsor)	Each	759.00
Dry Ice (as required to ship specific laboratory samples.)	Each	14.00
Pharmacy Close Out fee	Each	Contact Seth Larkin for project specific budget
Study Close Out Review (If applicable)	One Time	637.00

Study Coordinator Hourly Rate

(Note: Hourly Rate Does Not Include 27.4% F&A.

Number of hours per patient dependent upon review of protocol)

Study Coordinator	Hourly Rate
Clinical Research Associate (CRA)	\$51.50
Clinical Research Associate (Regulatory)	\$51.50
Research Nurse	\$75.00

Costs for Medical Tests and Procedures

Costs for medical tests and procedures considered (Research) Above Standard of Care
will be provided after a review of the Study Calendar with the PI

Generic Biostatistics Shared Resource Facility (BSRF) Budget for support of IITs

(THIS IS A GUIDE AND WILL NEED TO BE VERIFIED ON A CASE BY CASE BASIS)

October 16, 2013

PHASE I Trials

- Assume maximum of about 30 patients for dose-finding studies
- Assume model-based or modifications of 3+3 design will be utilized which entails a bit more real-time monitoring.
- 10% FTE for faculty biostatistician, 15% staff biostatistician
(TOTAL ~ 20K per year. Assuming about a 2 year study duration).
- NOTE: This is a generic estimate and final cost will be determined on a protocol by protocol basis in consultation with assigned faculty biostatistician

PHASE II Trials

- For single arm Phase II trials, assume maximum of about 40-50 patients
- Assume some kind of two-stage designs or interim monitoring for feasibility, etc might be included in protocol plan.
- Might entail correlative/several biomarker evaluations
- 10% FTE for faculty biostatistician, 20% staff biostatistician
(TOTAL ~ 22K per year. Assuming about a 2 year study duration).
- NOTE: This is a generic estimate and final cost will be determined on a protocol by protocol basis in consultation with assigned faculty biostatistician
- For randomized Phase II trials, with about a maximum of about 100 patients
- Will entail randomization, perhaps some interim analysis for efficacy
- Might entail correlative/several biomarker evaluations
- 15% FTE for faculty biostatistician, 25% staff biostatistician
(TOTAL ~ 30K per year. Assuming about a 2 year study duration).

NOTE: This is a generic estimate and final cost will be determined on a protocol by protocol basis in consultation with assigned faculty biostatistician

**MCC-CRO Fee Structure for IITs (Non-Industry Funding)
Effective 7/1/15**

**Start-Up Costs (Does not Include F&A- F&A to be added
dependent upon funding source)**

Item	Frequency	Total without F&A
IRB Initial Submission	One Time - Nonrefundable	Waived
Study Start Up	One Time - Nonrefundable	Waived
Pharmacy Start Up	One Time - Nonrefundable	Waived
Oncore		Contact Eric Durbin for project specific budget
Biostatistician		See Generic Biostatistician Shared Resource Facility (BSRF Budget)

**Ongoing Costs (Does not Include F&A- F&A to be added
dependent upon funding source)**

Item	Frequency	Total without F&A
Pharmacy Maintenance Fee (IDS Staff Time: \$50 per patient charged as patients enrolled)	Each	Waived
IRB Annual Continuation Review Prep	Each	Waived
Revisions/Amendments: to Protocol, IB, ICF, contract, etc.	Each	Waived
Monitoring Visit	Each Day	Waived
Archiving/document Storage (If applicable)	Annually	Waived
Monitoring Visit (If applicable)	Each Day	Waived
SAEs (For each SAE Occurrence)	Each	Waived
Pharmacy Close Out fee	Each	Waived
Study Close Out Review (If applicable)	One Time	Waived

Study Coordinator Hourly Rate

(Note: Hourly Rate Does Not F&A.

Number of hours per patient dependent upon review of protocol)

Study Coordinator	Hourly Rate
Clinical Research Associate (CRA)	\$51.50
Clinical Research Associate (Regulatory)	\$51.50
Research Nurse	\$75.00

Costs for Medical Tests and Procedures

**Costs for medical tests and procedures considered (Research) Above Standard of Care
will be provided after a review of the Study Calendar with the PI**