

## Binder Log / Flow Sheet

INVESTIGATOR: \_\_\_\_\_ EXT. #: \_\_\_\_\_ DEPT: \_\_\_\_\_

STUDY COORDINATOR: \_\_\_\_\_ EXT. #: \_\_\_\_\_

PROCOTOL TITLE: \_\_\_\_\_

SPONSOR: \_\_\_\_\_ SPONSOR REP: \_\_\_\_\_

FAX#: \_\_\_\_\_

PROTOCOL#: \_\_\_\_\_ PHONE#: \_\_\_\_\_

CRO/SMO: \_\_\_\_\_ CRO/SMO REP: \_\_\_\_\_

PHONE#: \_\_\_\_\_ FAX#: \_\_\_\_\_

DOCUMENTS	SENT	RECEIVED/APPROVED	COMMENTS
Curriculum Vitae – Investigator			
-Co/Sub Investigator			
Medical License/DEA #			
1572			
Financial Disclosure Form			
Protocol/Investigator Agreement/Signature Page			
Lab Certification/-Lab Normal Ranges			
IRB Membership Roster			
Consent Form (draft) – PI			
Consent Form (draft) – Sponsor			
IRB Application			
IBC, RDRC, or Radiation Safety Submission			
Provisos – PI			
Provisos – Sponsor			
Provisos to IRB			
IRB - Report of Action			
CenterWatch Website listing			
Other Website listings _____			
Confidentiality Agreement			
Contract/Agreement/Indemnification			
Budget			
Discount - Lab Radiology Cardiology Pharmacy			
Study Billing #			
Biosafety Report Form			
Documents to PI/Study Coordinator			
Checklist - Research Office			

DATABASE INFORMATION

INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
 PRODUCT: \_\_\_\_\_

LOG		BINDER QA	
PI Degree		Doc's Sent to Sponsor	/ /
Dept/Division		Letter to Initiate	/ /
Sponsor		Draft Contract to Cont Officer	/ /
CRO		Final Contract Received	/ /
Study Type		Draft Budget to PI	/ /
Disease		Draft Budget from PI	/ /
Indication		Draft Budget to Sponsor	/ /
Trial Status		Fixed Budget	Yes / No
Was Trial Initiated	Yes / No	Budget Accepted	/ /
1 <sup>st</sup> Subject Enrolled		Discount Applied	/ /
		Docs to Coordinator	/ /
Contracted \$'s Tracking		Recruitment Tracking	
Total Contracted Dollars	\$	Sent to PI	/ /
IRB Fee	\$	PI Respond to RI	/ /
IRB Invoice Required	Yes / No	PI Replied to Sponsor	/ /
IRB Fee Received	/ /	CDA Received	/ /
Sponsor Executed Agreement	/ /	CDA to Contracts Officer	/ /
Institute Executed Agreement	/ /	CDA to PI	/ /
Full Execution	/ /	CDA Signed by PI	/ /
Phase #		CDA to Sponsor	/ /
Number Subjects Contracted		Protocol Received by	/ /
Actual Dollars Received	\$	Site Evaluation Date	/ /
Total Number Subjects Enrolled		Sponsor Acceptance	Yes / No
RI Number		PI Acceptance	Yes / No
Study Billing number			
IRB Closure	/ /	Turn Around QA	
Reason For Closure		Draft CF to PI	/ /
Closure by Whom		Draft CF from PI	/ /
Reconciliation Sent	/ /	Draft CF to Sponsor	/ /
Reconciliation Amt Requested	\$	Draft CF from Sponsor	/ /
Reconciliation Recvd Sponsor	/ /	Submission to IRB	/ /
Reconciliation Amt Recvd	\$	IRB Meeting	/ /
Fiscal Year	FY	Provisos Received	/ /
		Provisos to Sponsor	/ /
		Provisos from Sponsor	/ /
		Proviso to PI	/ /
		Provisos from PI	/ /
		Provisos to IRB	/ /
		Date Approved	/ /
		Approval Sent to Sponsor	/ /