USC CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM

CQI Assessment Tool for HSC Studies

GENERAL INFORMATION iStar

Study Title			
IRB Protocol Number		**Level of Review**	
CQI assessor name		**Audit date**	
Funding Sources ***Please check all that apply:***	☐Industry ☐Government ☐Internal/Department ☐Foundation ☐No Funding ☐Other: _____		
Location	Health Sciences Campus: _____		
Department/Division			
Type of Study	☐Biomedical ☐Social/Behavioral ☐Other: _____		
Total # Enrollment	#Approved: _____ #Enrolled to date: _____		

Key Personnel		HSR	GCP	HIPAA	RCR	IC*
Principal Investigator						
Co-Investigator(s)						
Faculty Advisor						
Study Staff						

**authorized to obtain consent*

1. RECORDS / DATA STORAGE

1.1 iStar	What storage location is listed in iStar application **(26.3)?** Building: _____ Room: _____		
1.2	Where are study records physically stored? Building: _____ Room: _____		
1.3	Where are consent documents stored? Building: _____ Room: _____		
		YES	NO
1.4	Do file cabinets have locks?	☐	☐
1.5	Are computers password-protected?	☐	☐
1.6	Are consent documents stored in an orderly fashion?	☐	☐
Additional explanation/comments			

2. SUBJECT RECRUITMENT PROCEDURES

2.1 iStar	How are potential subjects identified **(23.1)**?	
2.2 iStar	Describe recruitment methods stated in the IRB approved protocol **(24.3)**	
2.3 iStar	If recruitment materials are used, specify: (check all that apply)	☐ Advertisements (posted) ☐ Flyers ☐ Web posting ☐ Letters ☐ Pre-Screening form ☐ Other _____ ☐ No recruitment materials used; go to section 4
2.4	Is the process for subject recruitment and identification consistent with IRB application and IRB policies? (Review Screening Logs)	☐ Yes ☐ No
2.5. According to iStar section **26.2**, how will data be recorded to protect privacy? Is the research team following this method? iStar		
Please use this space for additional explanation/comments		

3. INFORMED CONSENT PROCESS

3.1	How many versions* of the consent form are there? _____		
3.2 iStar	Consent Version Date (*see footer*) 1. 2. 3. 4. 5.	Consent approval period 1. 2. 3. 4. 5.	
3.3	Complete CIQ Consent/HIPAA Chart **If no subjects have been enrolled, check here ☐ and go to section 5**		
		YES	NO
3.4	Were any invalid consent forms used? (if no, go to 4.5)	☐	☐
3.4.1	If yes, was a protocol violation report submitted to the IRB?	☐	☐
3.5	Did anyone not approved by the IRB to consent subjects sign as study representative?	☐	☐
3.5.1	If yes, was a violation report submitted to the IRB?	☐	☐
3.6	Does the iStar application item **22.1** indicate inclusion of minors? iStar	☐	☐
3.6.1	If yes, was parental permission obtained?	☐	☐
3.6.2	Was parental permission waived?	☐	☐
Please use this space for additional explanation/comments			

4. SUBJECT SELECTION CRITERIA

Using the study files for subjects chosen for review (section 4.3), complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

		YES	NO
4.1	Is there an eligibility checklist containing inclusion/exclusion criteria?	☐	☐
4.2	Does each subject file indicate whether the subject was included/excluded appropriately? Indicate below: **(If no subjects have been enrolled, check here ☐ and skip to section 7)**		
	Subject #1:	☐	☐
	Subject #2:	☐	☐
	Subject #3:	☐	☐
	Subject #4:	☐	☐
	Subject #5:	☐	☐
4.3	If any subjects that did not meet eligibility criteria were enrolled, was a protocol violation submitted to the IRB?	☐	☐
Please use this space for additional explanation/comments			

5. SOURCE DOCUMENTATION AND CRFs

		YES	NO	N/A
5.1	Copy of all lab, radiology, physical exams including eligibility tests	☐	☐	☐
5.2	All notes or observations taken	☐	☐	☐
5.3	Adverse event reports	☐	☐	☐
5.4	Completed data collection sheet, questionnaires, etc.	☐	☐	☐
5.5	Case Report Forms (CRFs)	☐	☐	☐
5.6	Other:	☐	☐	☐
Please use this space for additional explanation/comments:				

6. ADVERSE EVENTS, UNANTICIPATED PROBLEMS AND PROTOCOL DEVIATIONS

6. 1. Is there documentation of **adverse event(s)**? Was this reported in iStar? iStar
6.2. Is there documentation of **unanticipated problems**? Was this reported in iStar? iStar
6.3. Is there documentation of **protocol deviations**? Was this reported in iStar? iStar

7. REGULATORY BINDER INSPECTION

		Check	Drug/Device Studies Comments
7.1	Investigator's Drug or Device Brochure (*current and all prior versions)*		
7.2	Protocol *(current and all prior versions)*		
7.3	Consent form *(current approved and all previously approved)*		
7.4	Any written material (other than consent form) distributed to subjects		
7.5	Applications and reports submitted to the IRB		
7.6	Correspondence between the PI and IRB		
7.7	IRB approval notices		
7.8	Sample Case Report Forms		
7.9	Copies of all adverse events reported to the sponsor or FDA and IRB		
7.10	Form FDA-1572		
7.10	Correspondence between PI and study sponsor		
7.12	Sponsor monitoring log and corresponding reports		
7.13	Investigators' CVs		
7.14	Lab certification for all labs involved in the conduct of the study		
7.15	Range of normal values for labs performing study analyses		
7.16	Participant screening log		
7.17	Participant enrollment log		
7.18	Drug or device accountability records		
Please use this space for additional explanation/comments:			

8. IRB DOCUMENTATION

Date of Initial IRB Approval	iStar	Expiration Date	iStar

8.1	Continuing Review	Date submitted	Date approved	IRB approval letter on file YES	IRB approval letter on file NO
Number of Continuing Reviews (CR)? _____ (If study has not undergone CR to date, skip to 8.2) iStar				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐

		YES	NO
8.1.1	Was each CR submitted on time? (45 days prior to expiration) iStar	☐	☐
8.1.2	Was there any lapsed period(s) between expiration date and CR approval date?	☐	☐
8.1.3	Was any subject enrolled during this lapse period?	☐	☐
8.1.4	If yes, was a protocol violation submitted to the IRB?	☐	☐
8.1.5	Were any study procedures done during the lapse period? (If no, go to 2.4)	☐	☐
8.1.6	If yes, were they approved by an IRB Chair?	☐	☐
8.2	Have there been any changes to the study? (If no, go to section 3)	☐	☐
8.3	If there have been changes to the study, were the amendments approved by the IRB before implementation?	☐	☐

Amendments	What was amended?	IRB approval YES	IRB approval NO
Number of Amendments: _____ iStar		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

9. DATA AND SAFETY MONITORING *(only if applicable)*

9.1 iStar	Did the PI specify a DSM plan in the iStar application? **(27.4)**
9.2 iStar	Is the study monitored by a DSMB?
9.3	Does the PI have copies of DSMB reports and have they been submitted to the IRB?
Please use this space for additional explanation/comments:	

10. SPONSOR-INVESTIGATOR RESPONSIBILITIES *(only if applicable)*

		YES	NO
10.1 iStar	Is the original IND/IDE application on file?	☐	☐
10.2	Is the FDA Form 1571 on file?	☐	☐
10.3	Are all participating investigators listed on the FDA Form1572?	☐	☐
10.4	Is FDA correspondence on file?	☐	☐
10.5	Were issues raised by the FDA resolved prior to the study's initiation?	☐	☐
10.6	Have all required IND safety reports or reports of unanticipated adverse device effects been reported to the FDA in accordance to FDA regulations?	☐	☐
10.7	Have protocol amendments and reports of new findings been reported to the FDA?	☐	☐
10.8	Have annual progress reports been submitted to the FDA?	☐	☐
10.9	**Coordinating centers only:** If there are other participating sites, are IRB approvals on file for each site?	☐	☐
10.10	**Coordinating centers only:** If there have been any new findings during the course of the study, have reports been submitted to the local IRBs?	☐	☐
10.11	How is investigator monitoring conduct of the study?		
Please use this space for additional explanation/comments:			

Sections	*Audited*	*Notes*
1. Records/Data Storage		
2. Subject Recruitment Procedures		
3. Informed Consent Process		
4. Subject Selection Criteria		
5. Source Documentation and CRFs		
6. Adverse Event, Unanticipated Problems and Protocol Deviations		
7. Regulatory Binder Inspection		
8. IRB Documentation		
9. Data and Safety Monitoring		
10. Sponsor -Investigator Responsibilities		
Comments and Follow-up Items:		
Report Submitted:	*Emailed to PI:*	

INTERVIEW WITH PI / RESEARCH STAFF

1. Ask the PI/research staff to give an overview of study and procedures.
2. Did the investigator encounter any problems in recruitment, subject retention or other areas? If so, what was the nature of the problem and how was it addressed?
3. Has the investigator encountered any adverse events or unanticipated problems? How were they handled?
4. Do the investigator or research coordinator have any problems with the IRB, IRB staff or IRB reviews? If so, what are the problems and proposed solutions? How has the iStar submission process been?
5. How does PI maintain privacy and confidentiality as far as recruitment, consent, data storage and retrieval?
6. Ask PI/research staff to describe the subject population and demographics. Are they vulnerable? If yes, what extra protections are being provided?
7. Ask PI to describe how they disseminate results back to the subject community.
8. Have there been any disclosures of confidential information in studies?