USC CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM

CQI Assessment Tool for UPC 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	University Park: _____		
Department/Division			
Type of Study	☐Biomedical ☐Social/Behavioral ☐Other: _____		
Total # Enrollment	#Approved: _____ #Enrolled to date: _____		
Key Personnel Roles			
Principal Investigator			
Faculty Advisor			

**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. IRB DOCUMENTATION

		YES	NO
2.1	Is all correspondence (signed/dated applications, responses, approvals) to the IRB on file?	☐	☐
2.1.1	Is other correspondence (e.g., e-mails) to and from the IRB on file?	☐	☐

Date of Initial IRB Approval	iStar	**Expiration Date**	iStar

2.3	**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 2.4)				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
iStar				☐	☐

		YES	NO
2.3.1	Was each CR submitted on time? (45 days prior to expiration) iStar	☐	☐
2.3.2	Was there any lapsed period(s) between expiration date and CR approval date?	☐	☐
2.3.3	Was any subject enrolled during this lapse period?	☐	☐
2.3.4	If yes, was a protocol violation submitted to the IRB?	☐	☐
2.3.5	Were any study procedures done during the lapse period? (If no, go to 2.4)	☐	☐
2.3.6	If yes, were they approved by an IRB Chair?	☐	☐
2.4	Have there been any changes to the study? (If no, go to section 3)	☐	☐
2.5	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		☐	☐

3. SUBJECT RECRUITMENT PROCEDURES

		YES	NO
3.1	Is there a subject enrollment log?	☐	☐
3.1.1	If yes, is subject enrollment log up to date?	☐	☐
3.2	Is there a subject screening log?	☐	☐
3.2.1	If yes, is subject enrollment log up to date?	☐	☐

Additional explanation/comments

3.3	How are potential subjects identified **(23.1)**?		
3.4 iStar	Describe recruitment methods stated in the IRB approved protocol **(24.3)**		
3.5 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	
3.6	Is the process for subject recruitment and identification consistent with IRB application and IRB policies? (Review Screening Logs)	☐ Yes	☐ No

3.7 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

4. INFORMED CONSENT PROCESS

4.1	How many versions* of the consent form are there? _____	
4.2 iStar	Current Consent Version Date	Consent approval period
4.3	Complete CIQ Consent/HIPAA Chart **If no subjects have been enrolled, check here ☐ and go to section 5**	

		YES	NO
4.4	Were any invalid consent forms used? (if no, go to 4.5)	☐	☐
4.4.1	If yes, was a protocol violation report submitted to the IRB?	☐	☐
4.5	Did anyone not approved by the IRB to consent subjects sign as study representative?	☐	☐
4.5.1	If yes, was a violation report submitted to the IRB?	☐	☐
4.6	Does the iStar application item **22.1** indicate inclusion of minors? iStar	☐	☐
4.6.1	If yes, was parental permission obtained?	☐	☐
4.6.2	Was parental permission waived?	☐	☐
Please use this space for additional explanation/comments			

5. 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
5.1	Is there an eligibility checklist containing inclusion/exclusion criteria?	☐	☐
5.2	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:	☐	☐
5.3	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			

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. RECORD KEEPING

		YES	NO
7.1	Is there a binder/folder for study documents? (e.g. items listed in section 1 of checklist)	☐	☐
7.2	Is there a binder/folder for IRB correspondence? (e.g. items listed in section 2 of checklist)	☐	☐
7.3	Is there a study file for each subject? (ok, if no)	☐	☐
7.4	Have there been any disclosures of confidential information in this study?	☐	☐
Please use this space for additional explanation/comments:			

Sections	*Audited*	*Notes*
1. Records/Data Storage		
2. IRB Documentation		
3. Subject Recruitment Procedures		
4. Informed Consent Process		
5. Subject Selection Criteria		
6. Adverse Event, Unanticipated Problems and Protocol Deviations		
7. Record Keeping		
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 storag 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.