

Site Assessment Worksheet to Support Baseline Assessment of Proficiency Skills

Version 2, 19 March 2009

>> Each observation question is linked to the Proficiency Skills document in the Skill Ref # column as follows (refer to the Proficiency Skills document):

KSDI = **K**ey **S**ystems **D**evelopment **I**ndicators (numbered 1 - 4 in each of the Subheadings)

PISI = **P**erformance **I**ndicators for **S**ite **I**ndependence (the numbers correlate to the numbered items in the far left column titled: "Skill: The following systems are implemented at each study site")

Subheadings of the current Proficiency Skills document (9 Dec 2008) are:

- General Information
- Regulatory Compliance (items 1 to 4)
- Financial Management (item 5)
- Protocol Implementation (items 6-10)
- Site Management (item 11)
- Team Management (item 12)
- Network Participation (item 13)

SITE SELF RELIANCE ASSESSMENT CHECKLIST

1. General Information

Principal Investigator			
Full Name			
Institution			
The Site Number			
Department/Division			
Country	<input type="checkbox"/> Indonesia <input type="checkbox"/> Thailand <input type="checkbox"/> Vietnam <input type="checkbox"/> Other: _____		
List of current studies	Department /Division	Types of studies	Sponsors
1.		<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____	
2.		<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____	
3.		<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____	
4.		<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____	
5.		<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____	
Name of person on the network assessment team			Date(s) of visit
Name of Study being assessed during this visit and Study No.#			
Type of Studies (Check all that apply)	<input type="checkbox"/> Observational <input type="checkbox"/> Epidemiology <input type="checkbox"/> Experimental <input type="checkbox"/> Other: _____		
Names and roles of study staff present during visit (attach sheet)			

2. Regulatory Compliance *Items 1 to 4 of the Proficiency Skills Document*

Depending on the type of study and sponsor, different regulatory documents are required. This section is consistent with ICH-GCP guidelines, local regulatory requirements, and/or US FDA or other international regulations as appropriate.

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
2.1	KSDI-1.1	Does the site have a designated staff who is responsible for regulatory compliance, including communication with IRB and regulatory authorities, proper filing of essential documents? <i>Check Delegation of Duties Log</i>				
2.2	KSDI-1.3 PISI-1	Does the site have copies of the local and international regulatory guidelines available?				
2.3	KSDI-1.2 PISI-1	Have designated staff received GCP training and passed? <i>Check training log</i>				
2.4	KSDI-1.2	Have designated staff received Research ethics training and passed? <i>Check training log</i>				
2.5	PISI-3	Is there a filing system for regulatory (essential) documents in place that meets the needs of the site staff and the sponsor? <i>Ask to see it and staff explain how it is structured</i>				
2.6	KSDI-1.4	Does the site have written SOPs for regulatory submissions?				
2.7	KSDI-1.4	Is there a Quality Assurance and Quality Control system in place to review the regulatory SOPs and ensure they are being followed?				
2.8	KSDI-1.4	Is there a Quality Assurance and Quality Control system in place to ensure documents are properly filed?				
2.9	PISI-2 PISI-4	Have all regulatory and IRB/EC submissions been completed within applicable timelines?				

For **NO** answers, details should be provided in the Comments section below and prefixed with the relevant question number.

Comments section:

3. Regulatory submissions detail

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
3.1 IRB approvals and communications						
3.1.1	PISI-2	Is the initial submission to the IRB/EC on file?				
3.1.2	PISI-2	How many protocol amendments are there? ___				
3.1.3	PISI-2	Are all the amendment submissions to the IRB/EC on file?				
3.1.4	PISI-2	Is there a complete file of IRB/EC correspondence?				
3.1.5	PISI-2	Are all notifications of IRB/EC approval on file?				
3.1.6	PISI-2	Are all continuing review (annual) submissions to IRB/EC on file?				
3.1.7	PISI-2	Are all protocol versions ever active at this site on file?				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
3.2 Safety Reports						
3.2.1	PISI-2	Does the site have a designated staff who is responsible for managing the reporting of Serious Adverse Events (SAE) to the sponsor and IRB/EC? <i>Check Delegation of Duties Log</i>				
3.2.2	PISI-2	Have all SAEs been reported to the sponsor, IRB/EC and regulatory authorities according to the required timeframes?				
3.2.3	PISI-2	If this is an investigational trial: Does the site submit all IND safety reports from the sponsor to the IRB/EC and regulatory authority according to required timeframes?				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
3.3 Protocol violations and deviations						
3.3.1	PISI-2	Does the site have a designated staff responsible for recording and tracking protocol violations and deviations? <i>Check Delegation of Duties Log</i>				
3.3.2	PISI-2	Have there been any protocol violations or deviations from the IRB/EC approved protocol?				
3.3.3	PISI-2	If yes, have all protocol violations and deviations been properly recorded per protocol?				
3.3.4	PISI-2	Is there a procedure in place for recording and tracking protocol violations and deviations?				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
3.4 Storage and maintenance of essential documents						
3.4.1	PISI-2	<i>Visit the office where the essential documents are kept.</i>				
3.4.2	PISI-2	Are the documents filed neatly, and easily retrievable?				
3.4.3	PISI-2	Is there a location for all key documents per GCP guidelines (ICH E6, sections 8.2, 8.3, 8.4)? (or use the study-specific regulatory files table of contents as a guide) <i>Monitoring reports will identify missing essential documents</i>				
3.4.4	KSDI-3.4	Ad hoc finding: were any documents filed incorrectly?				
3.4.5	PISI-2	Are copies of (external) monitoring reports on file?				

Comments section:

4. Protocol Implementation *Items 6 to 10 of the Proficiency Skills Document*

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
4.1 Informed Consent Process (Item 6)						
4.1.1	KSDI-6.1	Does the site have designated staff responsible for obtaining informed consent from study candidates? <i>Check Delegation of Duties Log</i>				
4.1.2	KSDI-6.2 PISI-6	If yes, are they properly trained? <i>Check training logs or other documentation for training for each staff</i>				
4.1.3	KSDI-6.3	Is there an SOP for consenting study participants?				
4.1.4	KSDI-6.3	If yes, does it address the consenting of illiterate, incapacitated and minor (child) participants?				
4.1.5	KSDI-6.3 PISI-6	If yes, is the SOP sufficient? If no provide comments below				
4.1.6	KSDI-6.4	Is there a Quality assurance and Quality Control system in place to review the SOPs for consenting, and ensure they are being followed?				
4.1.7	PISI-6	<i>Review at least 10 completed consent forms, asking for examples of illiterate, incapacitated and minor child consents if there are any.</i>				
4.1.8	PISI-6	Were the consent properly signed per GCP and the SOP?				
4.1.9	PISI-6	If one or more were not properly signed, comment below on the deviations.				
4.1.10	PISI-6	If site has been monitored by an external monitoring group, review the monitoring reports for any issues noted that relate to the consenting process; have there been any significant findings that indicate the site needs additional training or guidance? If so specify below.				
4.1.11	PISI-6	If an action plan for corrections was put in place, has the site made progress?				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
4.2 Compliance with study procedures (Item 7)						
4.2.1	KSDI-7.1	Does the site have sufficient staff to properly manage the study site and implement the study protocol? <i>Check Delegation of Duties Log</i>				
4.2.2	KSDI-7.2	Are the staff adequately trained to perform their duties? <i>Check training logs for each staff</i>				
4.2.3	KSDI-7.3	List all study specific SOPs the site has generated; did the site write the SOPs or are they adapted from a sponsor?				
4.2.4	KSDI-7.3	Is the site staff comfortable and able to draft its own SOPs?				
4.2.5	KSDI-7.4	Is there a Quality Assurance and Quality Control system in place to review site management SOPs and ensure they are being followed?				
4.2.6	PISI-7	If site has been monitored by an external monitoring group, review the monitoring reports for any issues noted that relate to protocol implementation; have there been any significant findings that indicate the site needs additional training or guidance? If so specify below.				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
4.3 Laboratory - Routine Clinical Laboratory only (Item 8)						
4.3.1	KSDI-8.1 PISI-8.1	Does the site have sufficient staff to manage the laboratory requirements of the protocol? <i>Check Delegation of Duties Log</i>				
4.3.2	KSDI-8.2a	Have appropriate staff trained on specimen collection, transport and delivery to the laboratory? <i>Check training logs for each staff</i>				
4.3.3	KSDI-8.2b	Have laboratory staff trained on specimen storage and routine and study specific laboratory tests? <i>Check training logs for each staff</i>				
4.3.4	PISI-8.2a PISI-8.2b	Is documentation on file for staff training on laboratory procedures?				
4.3.5	KSDI-8.3 PISI-8.3	Are SOPs or work instructions for routine and study specific tests available to staff who do the work?				
4.3.6	KSDI-8.3a	Are study specific SOPs, chain of custody and other standard SOPs such as equipment maintenance, safety, etc., in place and followed?				
4.3.7	KSDI-8.4 PISI-8.4	Is there an external quality assurance system in place?				
4.3.8	KSDI-8.4 PISI-8.4	If yes, is the laboratory making progress in improvements?				
4.3.9	PISI-8.5	Is there a plan in place for achieving ISO certification?				
4.3.10	PISI-8.5	If no, is the site laboratory Director interested in pursuing ISO?				
4.3.11	KSDI-8.4	Is there a Quality Assurance and Quality Control system in place to review the laboratory SOPs and ensure they are being followed?				
4.3.12	KSDI-8.3b	Is there a system in place to maintain the confidentiality of research subjects?				
4.3.13	KSDI-8.3b	If yes, is it adequate, and followed? <i>Ask staff to explain the process for protecting confidentiality and ask if there are any problems with the process.</i>				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
4.4 Research Pharmacy (Item 9)						
4.4.1	KSDI-9.1	Does the site have sufficient staff to manage the research pharmacy? <i>Check Delegation of Duties Log</i>				
4.4.2	KSDI-9.2	Have staff received appropriate training for managing a research pharmacy? <i>Check training logs for the pharmacy staff</i>				
4.4.3	KSDI-9.3	Is there a pharmacy plan in place?				
4.4.4	KSDI-9.3	If yes, was the plan developed by the sponsor or the site staff?				
4.4.5	KSDI-9.3	If created by the sponsor, determine if the pharmacy staff are comfortable and able to develop a pharmacy plan on their own.				
4.4.6	PISI-9	<i>Review the pharmacy facility- check items below if OK</i>				
4.4.7	KSDI-9.3	<ul style="list-style-type: none"> ○ Clean and hygienic ○ Clean water for washing hands ○ Sufficient space for product storage ○ Sufficient work space to prepare study drugs ○ Sufficient space for filing pharmacy records ○ Space is secure, only delegated staff may enter 				
4.4.8	KSDI-9.3 PISI-9	Are SOPs available and followed for: <ul style="list-style-type: none"> ○ Dispensing study drug ○ Receipt ○ Accountability ○ Storing study drug ○ Final disposition of study drug ○ Protecting participant confidentiality ○ Emergency unblinding ○ Other SOPs (list) 				
4.4.9	KSDI-9.4	Is there a Quality Assurance and Quality Control system in place to review pharmacy SOPs and ensure they are being followed?				
4.4.10	KSDI-9.3	Is there a system to provide study drug outside of normal pharmacy hours?				

Comments section:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
4.5 Data management: Source Documentation and CRF Completion (Item 10)						
4.5.1	KSDI-10.3b	Is there an SOP for source documentation?				
4.5.2	KSDI-10.3b	If yes, is it adequate for this protocol?				
4.5.3	KSDI-10.3b	Do staff follow the SOP? <i>Ask staff to define what source documentation is, and why it may be important</i>				
4.5.4	KSDI-10.3a	Is there a data management plan for the protocol at this site?				
4.5.5	KSDI-10.1	If yes, does the site have sufficient staff for completing, filing and handling the CRFs per the data management plan? <i>Check the Delegation of Duties Log</i>				
4.5.6	PISI-10	If there is a DM plan, do site staff follow the plan? <i>There will be information from the Data Management Center about compliance.</i>				
4.5.7	KSDI-10.2 PISI-10	Have there been external monitoring reports that have reviewed the adequacy of CRF completion (properly filled out, level of transcription errors, correctly filed, etc)?				
4.5.8	KSDI-10.2 PISI-10	If yes, have problems been reported that the monitor considered to be serious (e.g., an action plan was put in place)?				
4.5.9	PISI-10.2 PISI-10	If yes, has the site made progress on improvements?				
4.5.10	KSDI-10.2 PISI-10	<i>Review a sampling of the CRFs</i>				
4.5.11	KSID-10.2	Are the CRFS completed neatly and filed in a secure area?				
4.5.12	KSDI-10.3a	Does the site have an SOP for CRF completion and filing?				
4.5.13	KSDI-10.3c	If yes, does it describe a system for protecting the confidentiality of the study participants?				
4.5.14	KSDI-10.4	Is there a Quality Assurance and Quality Control system in place to review Data Management SOPs and ensure they are being followed?				

Comments section:

5. Site Management *Item 11 of the Proficiency Skills Document*

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
5.1	KSDI-11.1	Are there sufficient staff to properly manage the study site and implement the study protocol? <i>Check the Delegation of Duties Log</i>				
5.2	KSDI-11.2	Are the staff adequately trained to perform their duties? <i>Check the training logs for each staff.</i>				
5.3 Participant recruitment						
5.3.1	KSDI-11.3	Is there an SOP for participant recruitment?				
5.3.2	PISI-11 recruitment	If yes, is it being followed? <i>Ask staff to explain the recruitment process and if there are any problems with it</i>				
5.3.3	PISI-11 recruitment	Is it an adequate process for this protocol?				
5.3.4	KSDI-11.3	Did the site develop the SOP, or did the sponsor?				
5.3.5	KSDI-11.3	If the site did not draft the SOP, do they feel comfortable and able to draft one on their own? <i>Ask the staff to describe what should be in a recruitment SOP</i>				
5.4 Participant flow through hospital or clinic						
5.4.1	PISI-11	Has the study been ongoing for at least 3 months?				
5.4.2	PISI-11 Patient flow	If yes, is the participant flow adequate? <i>Ask staff to describe the flow system and to point out any problems they have with it; ask if they have changed their original system and if so, why.</i>				
5.5 Retention of study participants after enrollment						
5.5.1	PISI-11 retention	How many participants have enrolled and how many have dropped out before completing the study?				
5.5.2	PISI-11 retention	Does the staff feel the dropout rate is normal?				
5.5.3	PISI-11 retention	Is the site staff concerned/worried about the dropout rate or the retention rate?				
5.5.4	PISI-11 retention	<i>Ask staff to describe the methods they use to keep patients in the study. Note if there appears to be coercion in the process.</i>				
5.6 Participant tracking						
5.6.1	PISI-11 tracking	Describe the system in place for tracking enrolled participants and ensuring they return for follow up visits				
5.6.2	PISI-11 tracking	Is the tracking system adequate? <i>Ask staff if they have any problems getting participants to return for study visits, and if so what they do to fix the problems. Record in Comments below.</i>				
5.7 SOPs						
5.7.1	KSDI-11.3	Are there SOPs for any of the site management topics?				
5.7.2	KSDI-11.3	If yes, list them.				
5.7.3	KSDI-11.4	Is there a Quality Assurance and Quality Control system in place to review site management SOPs and ensure they are being followed?				

Comments section:

6. Team Management *Item 12 of the Proficiency Skills Document*

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
6.1	KSDI-12.2b	Do all study staff have a written job description?				
6.2	KSDI-12.2a PISI-12	Do all staff understand what is expected of them? <i>Ask staff to explain their roles on the team</i>				
6.3	PISI-12	Does the study team have regular team meetings?				
6.4	KSDI-12.2 PISI-12	Ask team for examples of problems that have been identified and solved; describe in Comments				
6.5	KSDI-12.2c PISI-12	Does the staff have regular performance reviews with their supervisor and feedback on their work? If yes, is this done in a positive way?				
6.6	KSDI-12.3	Is there a communication plan in place for the study team? <i>If yes, ask staff to explain it</i>				
6.7	KSDI-4	Is there an administrative plan to ensure or encourage regular meetings, information dissemination and performance review?				

Comments section:

7. Network Participation *Item 13 of the Proficiency Skills Document*

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
7.1	KSDI-13.2 PISI-13	Does the PI or representative participate in protocol team calls and/or site management committee calls, and/or TOC calls?				
7.2	KSDI-13.2	Do study staff have access to the Network Newsletter?				
7.3	PISI-13	Does the PI or representative volunteer to serve on Network committees?				
7.4	KSDI-13.3	Is the Network Manual on file, available to staff, and understood? <i>Ask questions about the Network Manual to assess this</i>				
7.5	KSDI-13.4	Does the site have an internal QA checklist or other system to encourage Network participation?				
7.6	PISI-13	Does the PI/staff participate in country level team meetings?				

Comments section:

8. Financial System Management *Item 5 of the Proficiency Skills Document*

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
8.1	KSDI-5.1	Does the site have designated staff responsible for the financial management of the research contracts and grants?				
8.2	KSDI-5.2	If yes, have staff received training in basic accounting for clinical research including allowable expenses?				
8.3	PISI-5	Does staff take the lead on creating budgets for research sponsors? (or do they use sponsor-generated budgets?)				
8.4	KSDI-5.4	Is the staff able to report and monitor expenses by budget category?				
8.5	KSDI-5.2	Does staff understand and apply compliance with cost allowability in clinical research?				
8.6	KSDI-5.4	Are there SOPs for financial management processes?				
8.7	KSDI-5.4	If yes, are the SOPs being followed?				
8.8	KSDI-5.4	Is there a Quality Assurance and Quality Control system in place to review financial SOPs and ensure they are being followed?				
8.9	KSDI-5.3	Are pertinent local and international accounting guidelines available?				

Comments section:

9. Extra Section (there was interest in keeping this on the checklist even though it is not mentioned in the Proficiency Skills document:

Item	Skill Ref#	Observation / Question	YES	NO	N A	C*
9.1 Data and Safety Monitoring Board (DSMB)						
9.1.1		Is there a DSMB active for this study?				
9.1.2		Are all DSMB reports or notices of review with recommendations on file?				
9.1.3		Have all DSMB reports been submitted to the IRB/EC?				

Comments section: