Study Coordinator Name:_____ Employment Start Date:_____

Requisite Knowledge & Skills **Demonstrated Competency**

CLINICAL KNOWLEDGE OF HIV	**Yes**	**No**	**N/A**
-pathophysiology of HIV infection			
-epidemiology of HIV infection			
-HIV testing and counseling			
-natural history of HIV (men and women)			
-transmission			
-prevention - safe sex guidelines			
-surrogate markers - CD4, P24, HIV RNA			
-approved treatments for HIV infection			
*side effects			
*patient monitoring/nursing implications			
*complementary therapies			

Requisite Knowledge & Skills **Demonstrated Competency**

CLINICAL KNOWLEDGE OF HIV (cont'd)	**Yes**	**No**	**N/A**
-investigational treatments for HIV			
*anti-retrovirals			
-immune base therapies			
*vaccines			
*immune modulators			
-common OI's and malignancies			
*symptoms and diagnoses			
*approved treatments			

*investigational treatments			
-psychosocial issues of HIV infection			
-Substance abuse issues in the era of HIV			
-multicultural context of HIV care			

****SUGGESTED REFERENCES****

1. Bartlett, J., MD.(Ed.)(1999). Medical Management of HIV Infection.(Glaxo)Updates:www.hopkins-aids.edu

2. DHHS Guidelines for the Treatment of Persons with HIV/AIDS/ *www.hivatis.org*

AVEG(AIDS Vaccine Evaluation Group)/ *www.scharp.org/public/index.htm*

Complementary therapies: *www.MSNBC.com* (good article review of alternative therapies)

3. Dolin, R, MD/ Masur, H, MD/ Saag, M, MD (1999). AIDS Therapy. Churchill and Livingston.

4. Flaskerud, J. and Ungvarski, P. (Eds.) (1992). HIV/AIDS: A Guide to Nursing Care. Philadelphia. W.B. Saunders Co.

5. Grady, C., MS, RN, CS and Vogel, S., BSN, RN. "Laboratory Methods for Diagnosing and Monitoring HIV Infection." JANAC. April-June; (4.2) (1993).

6. Sande, M., MD and Volberding, P., MD. (Eds.) (1997). The Medical Management of AIDS, 5th Edition. Philadelphia. W.B. Saunders Co.

7. Websites: Center for Substance Abuse Treatment *(http://www.samhsa.gov/csat/csat.htm)*

Do No Harm – harm reduction article and extensive resources *(www.realsolutions.org/donoharm.htm)*

8. Bradley-Springer, L. "Patient education for behavior change: Help from the transtheoretical and harm reduction models. JANAC, 7, 23-40 (1996)

Requisite Knowledge & Skills **Demonstrated Competency**

INTRODUCTION TO DART PRIVATE RESEARCH TRIALS	**Yes**	**No**	**N/A**
-mission/locations/history			
-Private/Industry v. investigator generated/independent v. ACTG trials Site Trial Coordination/Management DART Community Advisory Board (CAB)			
-protocol development process			
-protocol team			
-communications			
- abbreviations/terminology			

Requisite Knowledge & Skills **Demonstrated Competency**

STUDY PRACTICES	Yes	No	N/A
-ethical principles and policies for clinical research			
-informed consent procedures			
-use of human subjects, role of IRB			
-drug approval process			
-screening and enrollment visits			
-components of protocol visit			
*on drug - on study: nurse assessment, symptom assessment, diagnoses update, concomitant medication review, study drug compliance, lab tests, drug dispensing, lab review, toxicity / adverse event / endpoint determination			
*off drug - on study: clinic visit or phone contact, protocol specifies method of contact and frequency of visits			
Eligibility determination and checklists			
Serious Adverse Events and Adverse Events Reporting			
reporting requirements			
Endpoint determination and verification			
Blinding and unblinding procedures			
-quality assurance/internal and external QA			

Requisite Knowledge & Skills **Demonstrated Competency**

STUDY PRACTICES (cont'd)	Yes	No	N/A
Management of Patients Lost to follow-up			
Procedure for Patient Transfer			
-external monitoring program			
*site visit procedures - scheduling, guidelines for monitors, correction deadlines			
SUGGESTED REFERENCES			
1. Duke Medical Center IRB Teaching modules and references.			

Requisite Knowledge & Skills			
INDUSTRY/INDEPENDENT PROTOCOLS	**Yes**	**No**	**N/A**
-study design			
-inclusion/exclusion criteria			
-study procedures			
-endpoints			
SUGGESTED REFERENCES			
1. Provide copies of protocols. Site monitor can train via conference call or site visit.			

Requisite Knowledge & Skills

Demonstrated Competency

DATA COLLECTION, REVIEW AND RETRIEVAL	**Yes**	**No**	**N/A**
- overview of data expectations: source documentation and case report forms (CRF)			
- overview of Clinical Research Organizations (CROs) Monitor visits - overview of Industry Audit and/or Federal Audit			
- introduction to CRF			
Expectations			
Terminology/abbreviations			
- Monitor/Audit reports and follow up			
- Data clarfications/queries			
SUGGESTED REFERENCES			
1. Protocol			
2. Pharmaceutical Sponsored Investigator Meeting/Site Initiation			
3. Good Clinical Practice			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE/SOURCE DATA COLLECTION AND MANAGEMENT	Yes	No	N/A
-record keeping systems			
-source documents			
*chart system, files			
-flow of records			
-case report forms at the site			
*CRF and source documentation site deadlines (by SOP)			
-confidentiality			
-laboratory requisitions			
-lab reports			
-lab hours			
-contact persons			
-specimen handling requirements			
-tour of labs			
-pharmacy procedures/pharmacy plan			
*****SUGGESTED REFERENCES*****			
1. Grady, C., MS, RN, CS and Vogel, S., BSN, RN. "Laboratory Methods for Diagnosing and Monitoring HIV Infections." JANAC. April-June; (4.2) (1993).			
2. FDA website: *www.fda.gov* **(includes code of federal regulations**			
3. Center for Drug Evaluation and Research(FDA): ***www.fda.gov/cder/index.html***			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE MANAGEMENT OPERATIONS	Yes	No	N/A
-organizational chart/site mission			
-job description review			
-staff orientation checklists			
-performance evaluation criteria			
-performance evaluations			
-standard operating procedures for: payroll, vacation, absences, compensatory time, sick leave, professional meetings, continuing			

education, reimbursement travel, study operations			
-staff meetings/QA meetings			
-corrective or disciplinary action policies			
-record keeping systems			
*site establishment plan			
*protocol-related book/files			
IRB/protocol/approvals/communication)			
investigational brochures, safety reports			
adverse experience records			
*patient-related			
electronic patient database (useful for potential study candidates as well as active participants)			
screening/enrollment logs			
*source documentation (chart system, files)			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE MANAGEMENT OPERATIONS (cont'd)	**Yes**	**No**	**N/A**
-clinic/medical records, shadow files, letters to primary care provider, filing process (who, what, how)			
-case report forms (CRFs) management			
-subunit activities			
-community advisory board			
-outreach programs			
-project resources			

1) Consultation with Study Coordinator Mentor.

2) Maggon, Krishan K. and Brandt, Daniel. "Standard Operating Procedures and the Conduct of Clinical Trials." Applied Clinical Trials. July 1994. Volume 3, No. 7.

3) Kirby, Louis. "Total Quality Management at Investigative Sites." Applied Clinical Trials. July, 1996.

4) Helpful Research Websites: www.researchpractice.com - Information on Site SOPs. www.actmagazine.com.

Requisite Knowledge & Skills **Demonstrated Competency**

SITE CLINIC POLICIES/PROCEDURES	Yes	No	N/A
-occupational exposure			
*OSHA requirements			
*use of universal precautions			
*post exposure management			
*employee health surveillance			
-PPD testing			
-appointment scheduling procedures			
-phone system, local networks, computer information systems			
SUGGESTED REFERENCES			
1. Bradley-Springer, L., Phd, RN. "Human Immunodeficiency Virus Infection in the Healthcare Worker." JANAC. January-March; (4.1) (1993).			
2.Centers for Disease Control. "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures." MMWR. July; 40(RR-8) (1991).			
3. Gerberding, J., MD, MPH; Luce, J., MD; Stamm, W., MD; and Wofsy, C., MD. HIV and the Healthcare Worker. Glaxo Inc. (1992).			

Requisite Knowledge & Skills **Demonstrated Competency**

REGULATORY ACTIVITIES	Yes	No	N/A
IRB submissions			
IRB current roster/meeting schedule/submission deadlines			
protocol amendments, annual renewals, termination reports Develop a tracking mechanism for IRB documents from submission to site registration			
safety reports			
signing consents			
notification of IRB of all SAES			
Regulatory files			
definition/completion of Form 1572			

(protocol and site specific)			
include version # on IRB approvals/consents			
completion of checklists – email receipt			
DAIDS procedure for approval of registration			
deregistration procedure			
safety reports and annual renewals			
monthly status report of registrations			
enrollment of inmates in ACTG trials			
protocol-specific regulatory audits conducted by CSMG during quarterly site visits			

Requisite Knowledge & Skills **Demonstrated Competency**

REGULATORY ACTIVITIES (cont'd)	**Yes**	**No**	**N/A**
current IRB membership roster			
IRB approval for all versions of the protocol			
IRB submission of all applicable safety reports			
current laboratory certifications and normal ranges			

1. Local Institutional Review Board (IRB) Manual/Website.
2. Office of Human Research Protection (OHRP): http://ohrp.osophs.dhhs.gov/

Requisite Knowledge & Skills **Demonstrated Competency**

SITE STUDY IMPLEMENTATION PROCESS	**Yes**	**No**	**N/A**
*protocol submitted to IRB			
*IRB approval			
*site registration, fax/mail documents to Site Registration Desk, email confirmation of receipt/approval			
*protocol and consent distributed to all involved staff (clinical, pharmacy, laboratories, investigators, etc.)			
-protocol implementation, study design, eligibility, evaluation schedule			
*study drug ordered/received			

*CRFs ordered/received			
*randomization screens downloaded/eligibility checklist printed			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE STUDY IMPLEMENTATION PROCESS (cont'd)	**Yes**	**No**	**N/A**
-laboratory arrangements (hematology, chemistry, virology, immunology, pharmacokinetics, etc.)			
*budget accounts set up locally with administrator			
*lab requisitions available			
*supplies ordered/received			
*specimen handling procedures set up (processing, storage, shipping)			
-other clinic arrangements, if needed (ophthalmology, CRC, GYN, etc.)			
-start-up training for staff			
*eligibility criteria/screening checklist			
*flow sheet/menu/lab requisitions developed, lab/nursing/QA/data staff instructed			
*study initiation meeting			
*protocol training conference call			
*study design/endpoints/toxicities			
*study specific procedures			
*study specific forms			
-internal patient recruitment plan			
*abstract/memo to staff			
*patient information sheet			
*newsletters/advertisements to patients, community organizations, providers, community advisory board, etc.			
-pharmacy procedures and communication			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE STUDY IMPLEMENTATION PROCESS (cont'd)	**Yes**	**No**	**N/A**

*randomization needs			
*accountability for returned drug			
*concerns of non-compliance			
*procedure for notification of study treatment modifications			

Requisite Knowledge & Skills **Demonstrated Competency**

SITE ORGANIZATION AND LIAISONS	**Yes**	**No**	**N/A**
local: laboratory contact for each lab being used (i.e. hospital, immunology, virology, pharmacology, etc.)			
local: contacts for local data networks, computer systems			
local: budget manager/administratorName_____ Phone_____			
data: Study Monitor/CRO contact, phone number for computer problems			

Date of Completion of Orientation:_____

Research Nurse Signature:_____