Checklist for ACTG Site Pharmacist Orientation

Purpose: This checklist has been developed by the Pharmacy Subcommittee of the ACTG Site Management and Clinical Care Committee. It has been developed as a recommended tool to guide appropriate ACTU site personnel during the orientation of a new site pharmacist. It may be individualized to accommodate variations in site procedures and professional experiences.

Pharmacist Name:_____ **Employment Start Date:**_____

Required Knowledge and Skills: **Review Completed:**

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 Safer sex guidelines			
Partnership for Health			

CLINICAL KNOWLEDGE OF HIV (CONT.)	Yes	No	N/A
Occupational Health: Post Exposure Prophylaxis Guidelines. Include site specific policy and procedure.			
Surrogate markers – CD4, HIV RNA			
HIV genotype, HIV phenotype, mutations			
Approved treatments for HIV infection			
Side effects			
Patient monitoring			
Investigational treatments for HIV			
Anti-retrovirals (RTI's, NNRTI's, PI's, fusion inhibitors, integrase inhibitors, receptor inhibitors, etc)			
Immune base therapies			
Vaccines			
Immune modulators			
HIV related Opportunistic Infections and Malignancies (PCP, MAC, CMV, KS or local endemic OIs)			
Metabolic Disorders/Cardiac Problems – increased triglycerides, cholesterol, lipodystrophy, lipoatrophy, lactic acidosis, insulin resistance, etc.			
HIV and Hepatitis Co-infection (Hepatitis A, B and C): Review of current treatment guidelines and trends.			
Psychosocial issues of HIV infection: (substance abuse, isolation, stigma, depression, HIV disclosure, cultural issues)			

CLINICAL KNOWLEDGE OF HIV (CONT.)	Yes	No	N/A
Multicultural context of care, i.e. African American distrust issues, IVDU lack of trust, homelessness, incorporating research into the lives of various kinds of populations.			
Adherence to medical regimen			
HIV as a chronic illness			
Health promotion			
Food safety, nutrition, exercise, managing health care, employment			

INTRODUCTION TO ACTG	Yes	No	N/A
Mission			
Locations – Sites			
Committee structure			
Protocol development process			
Protocol specific web pages			
Downloading draft & final documents			
Communications			
ACTG abbreviations/terminology			
International and domestic collaborations			

RESEARCH ETHICS AND PRINCIPLES/BACKGROUND KNOWLEDGE	Yes	No	N/A
Ethical principles and policies for clinical research – NIH guidelines, OHRP guidelines, Certification in Human Protection, Declaration of Helsinki, Belmont Report.			
Use of Human Subjects, role of IRB (OHRP training on-line) http://ohrp.osophs.dhhs.gov/			
Drug Approval Process and the Phases of Clinical Research			

PHARMACOLOGICAL KNOWLEDGE	Yes	No	N/A
HIV drugs			
Other infectious diseases drugs			
Main drug classes (antibiotics, anti-inflammatory, etc)			
Incompatibility of HIV drugs			
Main HIV therapies			
Drug interactions			
Food-drug interactions			
Adverse Effects			
Effects on Lab Values			
Special Warnings			

PHARMACY PROCEDURES	Yes	No	N/A
Knowledge of FDA and regulatory instances of the country (in case of international sites)			
Importation of drugs (in case of international sites)			
Drug management			
Supervision of pharmacy staff			
Adherence and counseling interviews			
Accountability of returned drugs			
Temperature and humidity control			
Control of power generator supervision			
Destruction procedure of returned drugs			
Destruction procedure of returned drugs			
Security			
Physical surroundings			
Emergency evacuation procedures			
Document storage			
ACTG SOPs			
Patient Transfer SOP			
Unblinding Subjects SOP			
Site Evaluation Subcommittee Standards			

DOCUMENTS	Yes	No	N/A
Form 1572/IOR			
Prescribers signature list			
Most recent version of protocol and all amendments			
IRB approved consents			
SID list			
Drug supply statement			
Investigational agent accountability logs			
Ordering/shipping receipts			
SOP for pharmacy procedures			
ACTG Pharmacy Plan approved			
CV of Pharmacy staff, including current licenses			
Pharmacy staff signature list			
Most recent version of investigational drug brochures/manufacturer package inserts			
Patient records (prescriptions, chart notes, consults, etc.)			
Pharmacy licenses			

SITE PROCEDURES	Yes	No	N/A
Routine meetings with other ACTG staff members?			
Updating on protocols and procedures by study coordinator?			
Updating on ACTG site?			
Updating on Clinical Trials Procedures (for example, GCP)?			

DATA MANAGEMENT – OPTIONAL. TO BE COMPLETED ONLY IF A SITE PHARMACY STAFF MEMBER IS INVOLVED IN CASE REPORT FORM COMPLETION, DATA ENTRY, ETC.	**Yes**	**No**	**N/A**
Overview of Data Management Center (DMC) Web Site: http://www.fstrf.org/ACTG User name: lastname.firstname (all lower case letters) Password: unique password picked by user			
Assignment of DMC User account & password			
Overview of the Regulatory Compliance Center (RCC) web site: http://rcc.tech-res-intl.com/default.htm Password: sidewalk			
Commonly Used DMC Web Site Programs Order Entry Program: use to order Case Report Forms and supplies			
Calculator Utilities: temperature conversion, BSA calculator, CrCl calculator, etc			
Patient Calculator: use to create patient calendars with projected visit dates			
Patient Record History: used to get a list of all patient records in the main database.			
Patient Event Summary: used to retrieve a summary of events by patient or study.			
Accrual Report: used to check the number of patients accrued by your site.			
Subject Enrollment System: http://www.fstrf.org/ACTG Subject Enrollment System Manual			

DATA MANAGEMENT – OPTIONAL. TO BE COMPLETED ONLY IF A SITE PHARMACY STAFF MEMBER IS INVOLVED IN CASE REPORT FORM COMPLETION, DATA ENTRY, ETC. (CONT.)	Yes	No	N/A
Eligibility Check List (also called Protocol Screening Module or PSM)			
Randomizing/Registering a Subject			
Data Entry System New Data Entry			
Exporting data			
View/modify/delete data not yet exported			
Correct data already exported			
Site Management Plan – Quality Control Identify pertinent forms per visit			
Verify accuracy & completeness of header information			
Check that forms are completed properly, all questions answered, legible, etc			
Verify accuracy of codes & descriptions (drug codes, signs/symptoms, etc)			
Site Management Plan – Quality Assurance Who does it, how often is it done, what QA tools are used, etc.			
Order Entry Program: use to order Case Report Forms and supplies			
Calculator Utilities: temperature conversion, BSA calculator, CrCl calculator, etc			
Patient Calculator: use to create patient calendars with projected visit dates			

DATA MANAGEMENT – OPTIONAL. TO BE COMPLETED ONLY IF A SITE PHARMACY STAFF MEMBER IS INVOLVED IN CASE REPORT FORM COMPLETION, DATA ENTRY, ETC. (CONT.)	Yes	No	N/A
Patient Record History: used to get a list of all patient records in the main database.			
Patient Event Summary: used to retrieve a summary of events by patient or study. Accrual Report: used to check the number of patients accrued by your site.			
Subject Enrollment System Manual			
Eligibility Check List (also called Protocol Screening Module or PSM)			
Randomizing/Registering a Subject			
New Data Entry			
Exporting data			
View/modify/delete data not yet exported			
Correct data already exported			
Identify pertinent forms per visit			
Verify accuracy & completeness of header information			
Check that forms are completed properly, all questions answered, legible, etc			
Verify accuracy of codes & descriptions (drug codes, signs/symptoms, etc)			

Date of Completion of Orientation:_____

Pharmacist of Record Signature:_____