Expected CPU Audit Questions

General Capabilities
Length of existence of the CPU?
Any recent mergers? If yes, name of previous facility?
Is the Investigator / CPU restricted or debarred by the FDA?
Has the FDA audited the CPU?
Has Sponsor Compliance Dept. audited the CPU?
Number of studies per year? Planned?
Number of competing studies?

Specific Capabilities
Does CPU perform PK studies? If yes, what types (FTIH, food effect, etc.)
Does CPU perform PD/biomarker studies? If yes, what are the end points?
Does CPU perform Radiolabel / ADME studies?
Does the CPU do "first-in-man" studies? Close to ICU facility?
Does the CPU do ICU type monitored studies
What populations has the CPU studied (e.g., healthy volunteers, renal, hepatic, elderly)
Is there an active database? (If yes, number/subject type, how often updated?)
For food effect studies, does the CPU have capability for food preparation? If not, where handled?
Can special diets be prepared?
Does the CPU recruit through advertisement? Local paper? Radio? TV?
Is CPU set-up for telemetry?
Is the CPU accessible to emergency services?
How far away is the nearest Hospital with emergency capabilities?
Have they used Hospital services? If yes, what was the experience?
Is the Emergency Medical System clearly established

Physical Description of the Unit
Is the CPU appropriate for ambulatory / outpatient studies?
Is the CPU appropriate for confined / inpatient studies?
Is the CPU appropriate for short stay inpatient studies (up to 48hrs)?
Is the CPU appropriate for repeat dose inpatient studies (14 days)?
Does the CPU have an appropriate number of beds and chairs?
Does the CPU have adequate security/alarm systems?
Does CPU have fire and vermin protection and sprinkler system?
Is study documentation stored in a secure, limited access area?
Do they have an archival facility for study documentation? If so, where?
Is the archival facility or area in a secured, limited accessed area?
Does the archival facility have adequate security/alarms system?
Does the archival facility have procedures to retrieve study documents and how long does this take?

Is there a meal service or preparation area?
Can special diets be accommodated?
Does CPU have remote data entry experience?
Is the remote data entry system computer validated, Part 21 compliance?
Does the CPU have a documented disaster recovery plan
Are recreational facilities available?
Is there a designated area for monitors to work?

Unit Personnel and Infrastructure

Is staff training records kept up-to-date and available?
Are all investigators appropriately qualified?
Is the PI / Investigator certified (CPI) ?
Are written SOPs in place and do they reflect current practices?
Is there a system for maintenance, control, review and distribution of SOPs?
Are the CPU staff appropriately qualified and trained in: - Good clinical practice   - Basic life support (BLS), Advanced Life Support (ACLS)   - Emergency situations (eg fire)   - Unit SOPs   - Study specific protocol training   - Dosing procedures?
Describe the study team structure.
How is study staff trained?
Are training logs up-to-date
What is the stability (turnover rate) of staff?
How many staff are employees vs. per diem/bank?
Are the responsibilities different for employees vs. per diem staff?

Laboratory Facilities

Does the CPU have an internal (or external) clinical lab?
Is the clinical lab certification up to date?
Does the CPU/lab have facilities to process routine safety samples?
Does the CPU/lab have facilities to process PK/PD samples?
Is the lab in a secure, limited access area?
Is lab equipment on back-up generators?
Are refrigerators and freezers alarmed?
Is the chain of custody maintained? What is the process for handling and processing samples?
What is the turn around time for results?
Are daily temperature and humidity logs current?
Can the site make study specific tube labels if requested?
Is there a QA department or function?
IS the laboratory GLP complaint?

Pharmacy Facilities

Does the CPU have an onsite research pharmacy / Independent Drug Service (IDS)
Has the Pharmacy USP 797 compliant / certified equipment?
Does the CPU have a pharmacist on the staff? On call? Part-time?
Is pharmacy in a secure limited access area?
Is pharmacy equipment on back-up generators?
Is Sodium lighting available?
Are refrigerators and freezers alarmed?
Are daily temperature/humidity logs current?
Are the drug retention samples stored on or off site?
What is the process for drug receipt, storage, dispensing, and destruction?
Who maintains drug accountability records?
Is there a QA department or function?
What is the QA department process?

Study-Specific Procedures

Is there medical on call coverage 24hrs/day during studies? Describe.
Describe your study team.
Who consents subjects?
Who doses subjects?
What is the CPU internal process for AE reporting?
What is the CPU process for SAE reporting
Who assesses AEs / SAEs?
Who reviews ECGs?
Who reviews Safety labs?
Who performs screening physicals?
How is staff trained on each individual study protocol?
What is the process to ensure study flowsheet, source document, and protocol are consistent?
What is the standard turn around for CRF completion?

Regulatory Matters

Does the CPU have a local or use a central independent ethics committee / IRB?
Are there any Sponsor restrictions on the IEC / IRB?
How often does the IEC / IRB meet?
What is the turn-around time from submission to approval or denial?
How long before the meeting is the submission deadline?
How long before the approval letter is available?
Is there an expedited review process for amendments and advertisements?
Does the membership list include member roles and other GCP requirements?
Has the CPU had a regulatory audit?

Equipment Inventory

Equipment Available in the CPU	Number	Make/model, maintenance record	Records up to date?
General Medical			Y / N
12-lead ECG		Mortara, Cambridge	
Lead II full disclosure monitors			
BP/ HR monitors		WelchAllyn, Dinamap model	
Telemetry system		Mortara	
Defibrillator			
Scales			
Crash Cart			
Intubation / ventilation equipment			
Oxygen supply equipment / in-wall?			
Suction Equipment			
Emergency drugs (inc extra anaphylaxis drugs)			
Synchronized clocks			
O2 detectors			
Specialized			
Spirometry (FVC, FEV1 etc)		KoKo	
Peak Flow measuring equipment			
Plethysmography			
NO analyser			
Laboratory			
Centrifuges	2	e.g.: VanGuard V6500 & Horizone mini E	
Refrigerated Centrifuges	2 large	e.g. ;Jouan CR3I & Beckman Coulter Allegra 6R	
4°C Refrigerator			
-20°C Freezers			
-70°C / -80°C Freezers			
Thermostat (R / T control)			
Pharmacy			
USP 797 Complaint Hood		Nuaire	
Balance			
4°C Refrigerator			
-20°C Freezers			
-70°C / -80°C Freezers			
Thermostat (R / T control)			
Sodium Lighting			

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