

The Plan

**For the development of a
Clinical Pharmacology Unit (CPU)
or Clinical Research Unit (CRU)
to carry out medical research in
the early Drug Development period
(Phase I and IIa)**

Overview

The ideal clinical trial facility (CPU / CRU) would be set-up so that 1) any study of the early clinical drug / device development program including First-in-man, Drug metabolism, Dose finding, Pharmacokinetics, Organ system failure (renal or Hepatic), First-in-patient, Bioavailability, Bioequivalence, or even Thorough QT/QTc studies can be undertaken with a minimum of effort and 2) The data generated is integrated on-line with the automatic transfer (or as near to this as possible), compiling and reporting of study data. Central to the above is the overriding importance of the primacy of safeguarding the safety of subjects.

By

Charles H. Pierce, MD, PhD, CPI

2 June 2007

Table of Contents

I.	Physical Requirements of a CPU (Phase I, Ila medical research facility)	
		page
A.	On-site - CPU requirements in order of importance	
1.	Research Subject Amenities (listed #1 on purpose)	3
2.	Subject Rooms and Areas (sleeping and private time facilities)	3
3.	Outside / Courtyard area	4
4.	Dining area	4
5.	Special bathroom facilities for specimen collection	4
6.	Specimen taking and preparation area	4
7.	On-site office area or "situation room" for key personnel	5
8.	On study examination / emergency treatment rooms (2)	5
9.	Special Equipment area / room	6
10.	Special Procedures area	6
11.	Secure storage room	6
12.	Food preparation area	6
B.	Near-by or Adjacent - CPU requirements	
1.	Data collation, retrieval and CRF recording room	7
2.	Investigational Drug Service (IDS) / 'Compounding Pharmacy'	7
3.	Administrative offices	7
4.	Study Monitor rooms	7
5.	GLP Safety Laboratory facility (or remote)	8
C.	Remote or Non-adjacent - CPU requirements	
1.	Subject Screening area	9
2.	Study Participant Recruiting phone bank	9
3.	Training areas	10
4.	IT / Computer server area	10
II.	Electronic Data Capture (EDC) system described	10
III.	Emergency Medical System	10
A.	Rationale for an "EMS"	11
B.	Importance of On-Study Safety	11
C.	External EMS Set-up	11
IV.	GCP Requirements of a CPU	12
A.	Code of Conduct	12
B.	Plan of Action- 17 Areas to put in place	13
C.	Standard Operating Procedures	14
D.	Employee Safety Policies	16
E.	Quality management - The ISO 9001 Process	17
APPENDICIES		
I.	Electronic control of Entry and exit	19
II.	Research Subject / Patient Recruitment Plan	20
III.	CPU / CRU House Rules for SP	22
IV.	21 CFR Part 11 Complaint Measures	29
V.	References	33