

AUDIT WORKSHEET 5

Auditor:		Date:		IRB#	
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SUBJECT RECORDS

1. Subject records/source documents organized, readable and secured.: Yes No N/A
Comments:

2. Subject case history documented to include information, data, and observations of subjects condition at time of enrollment: Yes No N/A
Comments:

3. Study events and progress notes on the conditions of the subject throughout participation in the study: Yes No N/A
Comments:

4. Data collected in source documents are also recorded on Case Report forms as appropriate or equivalent record: Yes No N/A
Comments:

5. Direct Data entry system is thorough, accurate, complete and captures study events: Yes No N/A
Comments:

6. All copies correspondence with the subject is in the official record:

Yes No N/A

Comments:

7. Information, data, observation of subjects condition at end of study:

Yes No N/A

Comments:

8. Subject withdrawal from research participation including reason documented:

Yes No N/A

Comments:

9. Subject compensation is documented and concurs with the IRB approval for compensation in the informed consent document:

Yes No N/A

Comments: