# 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:  

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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 form 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: