

Clinical Trial Observation Checklist

Trial & Observer Information

Study Title

Protocol Number

Site

Date

Observer Name

Role

Checklist

| Item | Yes | No | Not Applicable | Comments |
|--|--------------------------|--------------------------|--------------------------|----------------------|
| Informed Consent obtained and documented | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| Study drug/device administered as per protocol | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| Eligibility criteria verified | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| Adverse events monitored and recorded | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| Protocol deviations noted | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| CRF completed and up to date | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |

General Observations

Action Items / Follow-Up

Observer Signature

Date