|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | HUD TREATMENTLOCAL PROTOCOL CHECKLISTProtocol Section: | YES | No | N/A |
|  | Title, PI Name, Department, Phone Number, E-mail Address |[ ] [ ] [ ]
|  | Version Number |[ ] [ ] [ ]
|  | Study Summary: Research Site, Funding |[ ] [ ] [ ]
|  | Revision History |[ ] [ ] [ ]
|  | Device Information |[ ] [ ] [ ]
|  | Objectives |[ ] [ ] [ ]
|  | Background |[ ] [ ] [ ]
|  | Clinical Use |[ ] [ ] [ ]
|  | Inclusion and Exclusion Criteria |[ ] [ ] [ ]
|  | Risks of Harm and Potential Benefits to Health |[ ] [ ] [ ]
|  | HUD Management: Clinician Qualifications, Training, Clinical Sites |[ ] [ ] [ ]
|  | Device Accountability and Storage |[ ] [ ] [ ]
|  | Consent Process |[ ] [ ] [ ]
|  | Privacy and Confidentiality: Privacy Protection, Data Security |[ ] [ ] [ ]
|  | Safety Reporting |[ ] [ ] [ ]
|  | References |[ ] [ ] [ ]

Notes: