|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | HUD TREATMENT  LOCAL PROTOCOL CHECKLIST  Protocol 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: