

**VA HUMAN STUDIES**  
**APPROVAL REQUIREMENTS**

Deadlines: The Human Studies Subcommittee of the Research & Development Committee meets on the 4<sup>th</sup> Tuesday of every month. The deadline for submission for that meeting is the 2<sup>nd</sup> Friday of every month.

Principal Investigator: \_\_\_\_\_

Title of Project: \_\_\_\_\_

| <b>PI Check</b> | <b>Document</b>  | <b>Research Check</b> |
|-----------------|--|-----------------------|
|                 | Protocol (if available, as submitted to IRB)   |                       |
|                 | Investigator's Brochure (if applicable, as submitted to IRB)   |                       |
|                 | BRAAN protocol   |                       |
|                 | HIPAA authorization form and/or waiver   |                       |
|                 | IRB Approval letter  |                       |
|                 | Approved IRB VA Form 10-1086 consent form  |                       |
|                 | VA contact and VA phone number on consent form   |                       |
|                 | Research Methods Form, Pharmacy (if applicable)  |                       |
|                 | Attestation Form, procedures & devices (If applicable)   |                       |
|                 | Pharmacy sign-off on Methods Accountability Form (if applicable)   |                       |
|                 | VA Pharmacy use initiation fee letter (if applicable)  |                       |
|                 | Clinical Trials Data Sheet   |                       |
|                 | Investigational Drug Information Record VA Form 10-9012 (if applicable)  |                       |
|                 | Clinical Research Projects Form  |                       |
|                 | ISO Data Security Checklist for Research Protocols   |                       |
|                 | Biohazard Safety Form (if applicable)  |                       |
|                 | CITI/GCP, VA Privacy Policy, VA Cyber Security and VA Data Security training completed by all research personnel (annually) who are recruiting or contacting pts at the VA |                       |
|                 | If principal investigator is a physician, is credentialed at the VA Medical Center.  |                       |
|                 | Research staff have WOC appointment to the VA if not an employee and recruiting at VA  |                       |