

VA-Submissions Guidelines

| | A | B | C | D |
|-----------|---|--------------------------------|--|--|
| 2 | ITEMS | PHARMACY | R&D OFFICE | FULL/FINAL APPROVAL |
| 3 | | Required for Pharmacy | Required for R&D | Required for R&D |
| 4 | | Review of an | Committee Scientific | Committee full Approval |
| 5 | | Investigational Drug(s) | PROVISIONAL review | *(16 copies needed ONLY |
| 6 | | | (Inform Research Office if Provisional) | if Provisional review was |
| 7 | | | | NOT done) |
| 8 | SPONSOR Consent form template | X | N/A | N/A |
| 9 | Protocol | X | X 16 copies to research | X 16 copies to research* |
| 10 | Investigation Brochure | X | N/A | N/A |
| 11 | General Information Sheet (GIS) | X | X 16 copies to research | X 16 copies to research* |
| 12 | VA Impact Statement Attachment A (Signed by PI) | X | X 16 copies to research | X 16 copies to research* |
| 13 | 10-1436 Initial Report In-cluding Abstract and Page 18 if New PI. Both signed by PI | X | X 16 copies to research | X 16 copies to research* |
| 14 | PI Credentialed Verified with the Research Office | | X | X Verified by Research office |
| 15 | PI CITI Education Requirement Verified with Research Office | | X | X Verified by Research office |
| 16 | 10-9012 Investigational Drug Information Record with Attachment B - Chief Pharmacy Service (Signed by PI) if study uses drug (s) | | X Photo copy of form.(15 copies to research) Original should be sent to IRB for Chairman signature | X 16 copies to research |
| 17 | IRB Approval Letter | | | X 16 copies to research |
| 18 | IRB (STAMPED) VA Approval Consent | | | X 16 copies to research |
| 19 | Attachment B's (Signed by all appropriate Service Chiefs) | | | X 16 copies to research |
| 20 | Attachment B-Decision Support System (DSS) Confirm adequate population available | | X | X 16copies to research |
| 21 | Attachment B-Chief Mental Health Verification of mental health resources | | X | X 16 copies to research |
| 22 | 10-0398 Biosafety Survey Form (Approved and Signed) If Applicable | | | X 16 copies to research |
| 23 | VA HIPAA Authorization (Approved) | | | Verified by Research Office |
| 24 | UK/VA HIPAA Wavier (If Applicable) | | | X 16copies to research |
| 25 | VA Education Certificate for all key personnel involved with VA Subjects | | | X |
| 26 | Scope of Practice (If Applicable) | | | X |
| 27 | 10-1223 Report on Subcommittee on Human Subjects (Signed by IRB Chair) | | Needs to go to IRB for chairman signature | Please send this to IRB with original IRB package (PI needs to forward to Research after IRB Chair signs) |
| 28 | Security Agreement (signed by PI) | | | X 16 copies to research |
| 29 | Updated 5/3/07-LM | | | |