RESEARCH & DEVELOPMENT CHECKLIST FOR NEW HUMAN STUDIES
IRB Submissions Full Board, Expedited, and Exempt

VA R&D documents must be submitted within IRBNet prior to IRB submission

Upload this combined CHECKLIST and STATEMENT OF COMMITMENT AND UNDERSTANDING and all other forms indicated below into IRBNet.

☐ Yes

1. Project Cover Sheet (Start a Wizard on IRBNet Designer Page)

   *List all study personnel– **PI must ensure that listed VA personnel have obtained required VA research privileges. The VA does not allow residents/contractors/fellow/students to serve as the PI at the VA.**

☐ Yes

2. IRB Information Sheet (Start a Wizard on IRBNet Designer Page) – IGNORE "Exemption Request Form (2.0A)" unless using VA CIRB studies (with STVHCS as lead site).

☐ Yes

3. Abstract (IRBNet Template Library in STVHCS R&D Administration-Documents for Researchers)

☐ Yes

4. Draft IRB application – UTHSA IRB Forms

☐ Yes

5. Research Protocol Safety Survey (IRBNet Template Library in STVHCS R&D Administration-Documents for Researchers)

☐ Yes

6. Enterprise Research Data Security Plan (ERDSP) Template (IRBNet Template Library in VHA ORPP&E, Washington, DC-Documents for Human Subjects Researcher)

   *Please note that Information Security Officer will only approve storage at the VA on the Research Service server (will be created for study after approval)… use following format: \\vhastxfpcres02\STX_Research_PI\PI_LastNameFirstInitial\ShortProjectTitle\Data (as in: \\vhastxfpcres02\STX_Research_PI\PI_BrownJ\COVID\Data) make sure this is consistently used in Privacy Checklist and IRB forms. Storage/sharing outside of STVHCS VA firewall requires either an "Agreement" (e.g., CRADA or DUA) or VA-Approved DUA (whether for data with PHI or without PHI).

☐ Yes

7. Privacy Checklist (IRBNet Template Library in STVHCS R&D Administration-Documents for Researchers)

   *See Privacy Checklist Instruction Sheet – NOT required for VA CIRB study that has received review by National VA Privacy Officer – please note information must match draft copies of all IRB forms referenced on the Privacy Checklist in the "comments" boxes (e.g., consent, HIPAA authorization, HIPAA waiver, etc.)

☐ Yes ☐ NA

8. H-VA Form 10-0493 HIPAA Authorization Form (IRBNet Template Library in STVHCS R&D Administration-Documents for Researchers)

   *A separate HIPAA authorization is required for all VA research that involves a repository or any voluntary/optional component of the study requiring a separate informed consent.

☐ Yes ☐ NA

9. Investigational Drug Information Record(s), 10-9012s, signed by PI (IRBNet Template Library in STVHCS R&D Administration-Documents for Researchers)

☐ Yes ☐ NA

10. Funding notification (Letter, email etc.) & budget page

☐ Yes ☐ NA 11. Material Transfer CRADA or Agreement **(for protocols that involve VA receiving materials from or providing materials to a third party (e.g., for profit entity, non-profit entity, and/or academic institution) – see VA ORD Technology Transfer page** Forms, Templates and Model Agreements (va.gov) and contact R&D Office

☐ Yes ☐ NA 12. VA Radiation Safety Approval Letter
(Contact Elizabeth Garces in the VA Radiation Safety office at x14035)

☐ Yes ☐ NA 13. Evaluation of Resources VA Employees-Union Approval (IRBNet Template Library in STVHCS R&D Administration)
(Required only if you will be including hospital staff in surveys or focus groups)

☐ Yes ☐ NA 14. Evaluation of STVHCS Resources for Clinical Research (IRBNet Template Library in STVHCS R&D Administration) - For BRU and other applicable clinical resources e.g., Pharmacy, Path/Lab, Nursing, that will be required to support your research project

☐ Yes ☐ NA 15. RDC Non-Veteran Application - **if requesting to enroll non-Veterans at VA** (IRBNet Template Library in VHA ORPP&E, Washington, DC-Documents for Human Subjects Researcher)

☐ Yes ☐ NA 16. VA Form 10-5386, Investigator Data Sheet - **for Principal Investigator only, if this is first research proposal submitted at STVHCS** (IRBNet Template Library in STVHCS R&D Administration

☐ Yes 17. Financial Conflict of Interest Forms
Each PI and any investigator(s) must create a Disclosure in IRBNet under the "My COI" page

STVHCS Study Site (check all that apply)

- ☐ Audie Murphy Hospital
- ☐ Kerrville Hospital
- ☐ Balcones Heights VA Clinic
- ☐ Beeville Clinic
- ☐ Data Point VA Clinic
- ☐ Frank Tejeda VA OPC
- ☐ New Braunfels VA Clinic
- ☐ North Central Federal VA Clinic
- ☐ San Antonio VA Clinic
- ☐ San Antonio-Northeast 410 VA Clinic
- ☐ San Antonio-Southwest Military VA Clinic
- ☐ Seguin VA Clinic
- ☐ Shavano Park VA Clinic
- ☐ South Bexar County Clinic
- ☐ Victoria VA Clinic
- ☐ Other: _____

Statement of Commitment & Understanding (next page) – must be **signed by PI and VA Service Chief or VA Section Chief**

Project Title: _____

STATEMENT OF COMMITMENT AND UNDERSTANDING BY THE PRINCIPAL INVESTIGATOR FOR THE CONDUCT OF VA HUMAN SUBJECT RESEARCH

Principal Investigators must understand their obligation to protect the rights and welfare of research subjects. The following highlights continuing responsibilities of the Principal Investigator in the conduct of VA research. While this list is comprehensive it is not all inclusive and the principal investigator is encouraged to consult the STVHCS R&D Office, the UTHSCSA IRB Office, and other sources for additional information regarding National, State, and Institutional requirements.

1) Ensuring that the research protocol has sound design, minimizing risks to subjects while maximizing research benefits. Non-research procedures and data should be used to avoid adding risk or inconvenience to the subject when possible.
2) Conducting the study in such a way as to protect the rights and welfare of human subjects, in accordance with the principles, standards, and requirements set forth in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U.S. Department of Health and Human Services regulations, and any other applicable National, State, or Institutional laws or regulations.
3) Conducting the study and enrolling subjects in accordance with the IRB and R&D approved current protocol and making changes to the protocol only with approval of the sponsor (if any), IRB, and R&D Committee, except in emergent situations when the changes are necessary to protect the safety, rights or welfare of subjects.
4) Ensuring that research subjects are fully informed of the investigational purpose of the study and the potential risks, and that all requirements relating to the adequacy of both the informed consent document and the informed consent process, including its documentation, are met.
5) Exercising effective oversight of all activities related to the protocol and ensuring that all research personnel involved in the conduct of the study are informed about their responsibilities, have been appropriately trained, and work within their approved Scope of Practice.
6) Ensuring appropriate data safety and monitoring for the protocol, monitoring of subjects for potential harm, promptly modifying the research design to mitigate any potential risks, and reporting any changes in the risk-benefit ratio to the IRB.
7) Ensuring that resources are adequate to effectively and safely perform the research as described in the protocol.
8) Reporting to the sponsor and the IRB any unanticipated problems involving risk to subjects or others (UPIRSO) that occur in the course of the research as defined by and in compliance with the IRB UPIRSO policy
9) Maintaining appropriate documentation (enrollment, research progress, and termination notes) in the subject's electronic medical record.
10) Maintaining adequate and accurate source documentation and regulatory records in accordance with the Sponsor's regulations and GCP. Records must be properly secured and available for inspection in accordance with applicable National and Institutional regulations.
11) Ensuring that VHA and STVHCS pharmacy regulations are followed if the study involves any test article, including that a drug or device has an IND or IDE or meets criteria for exemption. Conducting research involving FDA-regulated products in compliance with all applicable FDA regulations, and fulfilling all FDA-directed investigator (or Investigator-Sponsor) responsibilities (including maintaining an accurate FDA 1572 form when appropriate).
12) Ensuring that the privacy and personal information of research subjects and research data is protected and disclosures are accounted for according to VA, Federal, State, and Institutional regulations.
13) Ensuring timely submission of information to the IRB, R&D Committee, and Compliance Office so that effective oversight of the research is maintained.
14) Providing the R&D Office with all STVHCS Report of Clinical Research Monitoring Visit forms from all external study monitoring visits.
15) Disclosing any financial Conflict of Interest relevant to the study to the STVHCS Financial Conflict of Interest Administrator and the IRB.
16) Ensuring that recruitment of subjects is performed in a fair and equitable manner and in accordance with all IRB, STVHCS, VHA, and other federal regulations.
17) Reporting any concerns, complaints, allegations of research improprieties, or research misconduct to the R&D office, who will assure communication to the appropriate component of the HRPP.
18) Responding to participants' questions, concerns, and complaints in an efficient and appropriate manner.
19) Study data will be kept in accordance with the department of veterans affairs record control schedule 10-1 (RCS 10-1).

Typed Name of PI	Signature	Date
Typed Name of VA Service Chief or Section Chief	Signature	Date