b.

d. **Communication with Research Participants**

(1) The STVHCS HRPP maintains an open-door policy. Any individual, including a past, current, or prospective research participant is welcome to contact the research office or any other component of the HRPP with a question, concern, complaint, comment, or suggestion. Contact information for the UTHealthSA IRB is provided in the Informed Consent document, and contact information for the R&D Office is listed on posted pamphlets and posters and the R&D Office website.

(2) The STVHCS R&D Office proactively reaches out to past, current, or prospective participants in research through the inclusion of contact information on posters and pamphlets displayed in public areas of the STVHCS and the R&D Office website.

(3) The ACOS for R&D is responsible for ensuring that complaints, concerns, allegations, questions, or requests for information related to research are reviewed and appropriate actions are taken.

e. **Communication with the STVHCS Research Compliance Officer (RCO)**

(1) The STVHCS RCO's primary responsibility is oversight of research projects for compliance to applicable Federal, VHA, and local regulations/policies. The RCO/RCC coordinates auditing activities with, but works independently of, the R&D Office. The RCO reports directly to the Medical Center Director or a senior individual who reports directly to and is supervised by the VA medical facility Director and whose primary responsibility at the VA medical facility pertains directly to compliance, and reports results of auditing activities to the R&D Committee and UTHealthSA IRB.

(2) The

outlined in VHA Handbook 1058.1. The PI will be promptly notified of significant findings and will be given instructions on the next step(s) in the reporting process. The audit report will be communicated promptly by the Research Compliance Officer via phone and/or in writing through paper copy or encrypted email to the Medical Center Director, ACOS for R&D, R&D Committee Chair, and Director of the IRB. Where applicable, noncompliance may be reported to the Office of Research Oversight, Office of Research and Development, Office of Human Research Protections, and FDA. The Research Compliance Office will be copied on any communications related to any noncompliance-related evaluation and action of the IRB or R&D Committee.

f. **Communication with the Information Security Officer (ISO)**

(1) **Protocol review.** The ISO or Alternate ISO will review the protocol and "Enterprise Research Data Security Plan (ESDSP)" template and provide comments directly on the template or through IRBNet. The ISO or a designated representative will attend the convened R&D Committee meetings to participate in discussion and offer expert advice in matters pertaining to research information security. A research protocol will not be approved by the R&D Committee without review by the ISO or Alternate ISO.

(2) Any real or suspected violation or compromise of VA Information Security related to a VA research protocol reported by an investigator or research staff to the ACOS/Research will be reported to the facility director, R&D committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility ISO has been notified. Communication in writing will follow as appropriate.

g. **Communication with the Privacy Officer**

(1) **Protocol review.** The Privacy Officer, or Alternate Privacy Officer will review the protocol and the Privacy Checklist and provide comments directly on the Privacy Checklist or through IRBNet. The Privacy Officer, or Alternate Privacy Officer will attend the convened R&D Committee meetings to participate in discussion and offer expert advice in matters pertaining to human subject privacy. No approval will be given by the R&D Committee until the Privacy Officer either reviews the protocol, or when applicable, the Privacy Officer is notified that privacy review is not required per the Privacy Checklist.

(2) Upon receipt of a report of any real or suspected unauthorized use, loss, or disclosure of individually identifiable information related to a VA research protocol reported by an investigator or research staff to the ACOS/Research will be reported to the facility director, R&D committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility Privacy Officer has been notified. Communication in writing will follow as appropriate.

h. **Communication with the Research Pharmacy**

(1) **Protocol review.** Prior to R&D Committee review and approval of a research protocol that involves medications and/or investigational test agents, the Research Pharmacist will review the protocol, focusing on safety of the medication/test age

investigational drugs unless the research pharmacist documents that resources are adequate for the conduct of the study.

(2) Following approval of a research protocol that involves medications and/or investigational test agents, the R&D Office will ensure the Research Pharmacist has access to the following:

(a) The signed VA 10-9012 form(s).
(b) An IRB approval letter signed by the IRB Chair or designated reviewer.
(c) The R&D Committee approval letter.

(3) If the Research Pharmacist becomes aware of any real or suspected violation or compromise of local or federal regulations related to research involving investigational test agents, he/she will notify the ACOS for R&D and the IRB.

i. **Communication with Non-Research Units and the Bartter Research Unit (BRU)**

(1) **Protocol review.** Prior to R&D Committee review and approval of a research protocol that involves services provided by a non-research unit (e.g. Nursing Service, Radiology, Pathology and Laboratory, Nuclear Medicine, BRU), the relevant service will review the protocol and the *Evaluation of STVHCS Resources for Clinical Research,* focusing on the service's adequacy of resources needed to support the research.

(2) The non-research unit or BRU designated reviewer will determine if the service can or cannot provide the resources necessary to effectively and safely conduct the research. The R&D Committee will consider the input from the *Evaluation of STVHCS Resources for Clinical Research* in its review of the protocol. The

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