VA Video Connect to Improve Access to Multi-disciplinary Specialty Care

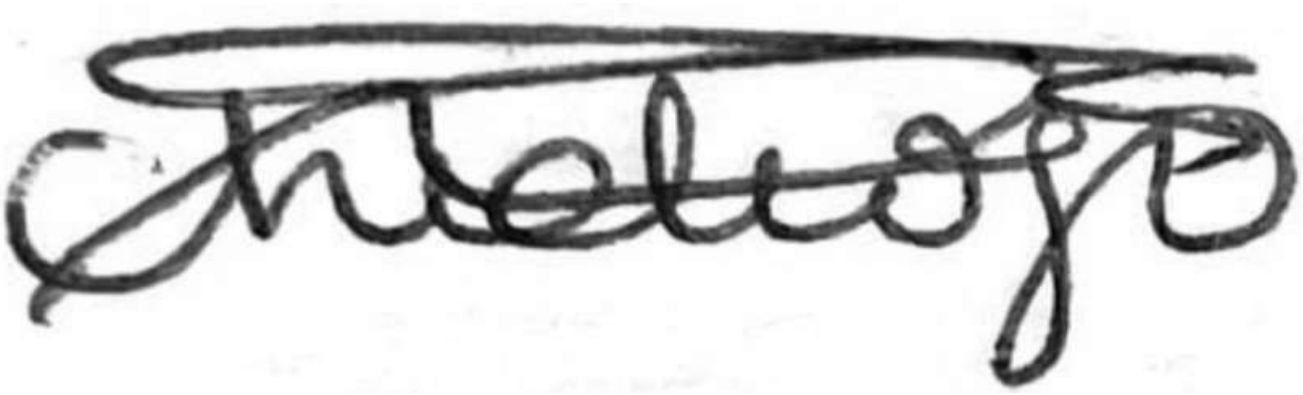
NCT04055207

February 27, 2024

Baylor College of Medicine

MEMORANDUM

TO: JAN LINDSAY
PSYCHIATRY & BEHAVIORAL SCIENCES



TRACEY
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FROM: Designee of IRB Chair GABRIEL HABIB, M.D., M.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

DATE: February 27, 2024

RE: **H-45072 - VA VIDEO CONNECT TO IMPROVE ACCESS TO MULTI-DISCIPLINARY SPECIALTY CARE**

The IRB, through expedited procedures has approved on 8/27/2021, a consent procedure which waives the requirement to obtain informed consent/HIPAA authorization for this research, and hereby describes how both of the following are found and documented in this protocol:

Waiver of consent and HIPAA authorization has been approved for the research as described here: We are requesting a waiver of consent and authorization for Aim 1 (clinical effectiveness trial) of the study in order to randomly assign scheduled patients to be offered VVC or not and to collect quantitative medical record data from the medical record for those who are randomized and entered into the study data set. We are requesting a waiver of HIPAA authorization for the entire study, as we are also requesting a waiver of written documentation of informed consent for qualitative interviews to be conducted for Aim 2.

a) The research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals because:

Patients assigned to receive the offer of VVC delivery of care will have the option to receive some, all, or none of their care via this modality. The study does not change or limit the treatment options available to Veterans with HIV. All treatment as usual options for HIV care at MEDVAMC will be available to all patients in both randomized conditions. VVC has been available as standard practice in VA since 2013, though it has not been used widely for specialty medical care. Clinical data gathered for the study are data gathered in routine care, hence those procedures do not add risk. Research to date suggests that treatment delivered via video telehealth is equivalent to in person care. Standard safety protocols for use of VVC are developed and will be in place, so risks are not expected to be greater than from those associated with receiving care in person. There is a risk of loss of confidentiality. Stringent methods will be employed to protect against this risk. All electronic data will be stored behind the VA firewall on a VA server, and access will be restricted to study personnel. Paper data will be kept in a locked cabinet in a locked storage room at IQuESt, and access will be restricted to study personnel.

1. An adequate plan exists in order to protect health information identifiers from improper use and disclosure, because:

   Identifying information will be stored separately from chart data, which will be coded via a study ID number. Significant protections are in place to minimize the risk of a breach of privacy. All PHI will be kept secure and not shared outside of the study team. All information will be stored in a locked file cabinet in a locked storage room at IQuESt. We will store information collected on a secure computer server behind the MEDVAMC firewall. This means that the information will be in a computer that no one outside the VA can access. A number will be assigned to each patient, which will be kept separate from all identifying information, except for a password-protected master list stored on a secure server behind the MEDVAMC firewall. The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

2. An adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so), because:

   Research records, including identifiers, will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

3. Adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule, because:

The research team has been adequately trained and is prepared to adhere to standards of operations for handling the PHI of subjects per federal guidelines. Combined with secure storage of paper and electronic files, VA and IQuESt have established written policies concerning storage and transmission of data including PHI which will be strictly followed by the research team.

b) The informed consent waiver will not adversely affect the rights and welfare of the subjects, because:

No one involved in the study will identify, directly or indirectly, any Veteran subject in any report of such research or otherwise disclose identities of participants in any manner. All subjects will continue to receive all forms of medical and mental health care available to them at MEDVAMC. Clinical data gathered for the study are data gathered in routine care, hence those procedures do not add risk.

c) The research could not practicably be carried out without the waiver or alteration, and the research could not practicably be conducted without access to and use of the requested information because:

Limited identifying information is required for 1) lists of patients with HIV who are scheduled daily in the Infections Diseases Clinic at MEDVAMC and 2) lists of patients with HIV who are considered "out of care" according to VA standards in order to randomly assign patients to receive the offer of VVC care delivery or not. In order to fully evaluate the impact of care delivered via VVC, quantitative medical record data are needed for all Veterans in care in the Infectious Diseases Clinic at VA. Aside from the randomization to be offered VVC or not and whether the Veteran accepts or declines that offer, all data collection will occur from the medical record. All data (other than randomized arm, in-person or out of care status, and whether VVC is accepted or declined) will be collected directly from the electronic medical record in order to 1) reduce participant burden; and 2) prevent research assessments from impacting clinical care. Without the waiver, we would need to obtain consent from every person in the clinic for the study, including Veterans who do not attend appointments. Excluding these Veterans who miss appointments would invalidate the scientific merit of the study. There is no practical way to conduct the research without a waiver.

d) The research could not practicably be carried out without using identifiable private information and/or identifiable biospecimens because:

N/A

e) Informed consent is being waived, and providing participants with additional pertinent information after participation is not appropriate, because:

Participants will only be provided additional information in the instance that significant information, either positive or negative, is discovered about VVC during the study that could have immediate and substantial benefit or harm to participants. If this occurs, the IRB and patients will be so informed. The purpose of collecting information regarding HIV diagnosis and treatment, alcohol use, and mental health treatment (38USC7332) is to conduct scientific research. No personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

The following is a brief description of the PHI and the specific subject identifiers for which the IRB has determined use or disclosure to be necessary:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning HIV
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Partial Social Security # (Last four digits)

Given the assurances provided above, this memorandum serves as documentation that the BCM IRB has approved a waiver of consent/HIPAA authorization and has determined that all requirements are met by this protocol in order to grant the waiver.

Note to File
This authorization letter is being issued to remediate an omission of a portion of the signature on the previous waiver granted by the IRB. The waiver was valid but now appropriately reflects the complete signature of the IRB designee.