Study Title: Telehealth-Clinical Advocacy Project (T-CAP)

IRB Protocol Approval Date: 12/07/2022

NCT04911426

-INSTITUTIONAL REVIEW BOARD

PROTOCOL REVIEW REQUEST

The TCU Institutional Review Board (IRB) is responsible for protecting the welfare and rights of the individuals who are participants of any research conducted by faculty, staff, or students at TCU. Approval by the IRB must be obtained prior to initiation of a project, whether conducted on-campus or off-campus. While student research is encouraged at both the undergraduate and graduate level, only TCU faculty or staff may serve as Principal Investigator and submit a protocol for review.

Please submit this protocol electronically to IRBSubmit (Word preferred).

1. **Date: 12/15/2021**

2. **Study Title:** Telehealth-Clinical Advocacy Project (T-CAP)

3. **Principal Investigator (must be a TCU faculty or staff):** Jennifer Pankow, Ph.D.

4. **Department:** Institute of Behavioral Research

5. **Other Investigators: List all faculty, staff, and students conducting the study including those not affiliated with TCU.**
   Wayne Lehman, Ph. D., Kevin Knight, Ph. D., Amanda Wiese, Ahrein Bennett

6. **Project Period (mm/yyyy - mm/yyyy):** 08/2019 – 07/ **2023**

7. **If you *have* external and/or internal funding for this project – for Funding Agency: :**
   08/01/2019National Institute on Drug Abuse **Project #:** 1 R21 DA048232-01 **Date**

8. **If you *intend to seek/are seeking* external funding for this project – Funding Agency:**
   N/A **Amount Requested From Funding Agency:** N/A **Due**
   Date for Funding Proposal: N/A

9. **Purpose: Describe the objectives and hypotheses of the study and what you expect to learn or demonstrate:** This application proposes the Telehealth-Clinical Advocacy Project

(T-CAP), a technology-based intervention **development** and **feasibility** R21 study to examine the impact of integrating clinical telehealth services within an existing Illinois (IL) police Opioid Diversion Program (ODP). The study includes three key components: 1) Development and testing of the proposed multidisciplinary telehealth intervention integrated within a state-supported police diversion program; 2) use of telehealth technology to provide ODP participants with access to clinically qualified staff (referred to as the Coach); and 3) expanding and strengthening the available service infrastructure including pain management alternatives to the use of potentially addictive medications and by having the Coach reach out to new and underutilized providers in local communities (e.g., underutilized physicians and other medical providers such as certified nurse practitioners). Modifications target use of virtual consenting and utilizing FedEx mail to issue study cell phones to participants, replacing in-person meetings with the T-CAP research assistant. No modifications have been made to the T-CAP telehealth intervention and **no in-person interactions will occur as a part of this study**. 10.28.2022 modification will include the removal of the randomization procedure; specifically, no one will be assigned to what was previously referred to as the "Treatment as Usual" condition. All participants will receive the T-CAP telehealth intervention.

The specific aims for the proposed research are as follows: (Aim 1) Demonstrate intervention feasibility by measuring study participant receptivity and utilization of the telehealth approach, and (Aim 2) Evaluate the proposed T-CAP measures to assess their performance in gauging the impact of telehealth on initiation of in-person Substance Use (SU) treatment, short-term retention in referred SU treatment, and access to other appropriate treatment services.

Successful completion of the aims is expected to: 1) establish preliminary evidence to support the efficacy of telehealth technology to augment SU treatment for individuals with misused any form of opioids, alcohol, or other substances, 2) provide support for integrating a clinical role in police opioid diversion practices recently expanded to include individuals at high risk for opioid and/or other substance misuse, 3) provide an empirical examination of how clinical advocacy and telehealth can support individuals with substance use treatment, and 4) demonstrate the value in building relationships with stakeholders to leverage community resources for addressing the SU treatment needs. Findings from this research will inform a future R01 application that will include a multi-site randomized clinical trial, testing the T-CAP intervention and taking a closer look at characteristics of individuals (e.g., sex and race/ethnicity) in relation to intervention response and outcomes in an effort to understand how best to tailor the T-CAP intervention for specific subgroups.

10. Background: Describe the theory or data supporting the objectives of the study and include a bibliography of key references as applicable.

This project focuses on opioid use and other serious substance and alcohol use placing individuals at high risk for behavioral and healthcare problems. The opioid crisis has reached epidemic proportions (Gomes et al., 2018), driven by abuse of prescription opioids and illicit use of fentanyl (CBHSQ, 2017; Moore et al., 2017; O'Donnell et al., 2017; Rudd et al., 2016). The overdose deaths attributed to these drugs (CDC, 2017; Warner et al., 2016) is impacting nearly every community.

In response, IL and several other states are experimenting with diversion program models (Addiction Policy Forum, 2017; Schiff et al., 2017) to intervene with people at the point of contact with police. These individuals are diverted into services designed to prevent further drug use and related problems (Schiff et al., 2017; Reichert et al., 2017). Diversion programs, such as established mental health courts, have been in operation for over two decades and have a proven record of efficacy

(Cosden et al., 2005; Ramirez et al., 2015). Similarly, the IL Police ODP offers an unprecedented opportunity to address the current widespread opioid use, evidenced by an increase of more than 70% from 2013 and a 32% increase from 2015 to 2016 (IDHA, 2017).

IL ODP programs are part of a State priority to improve access to a spectrum of justice involved treatment options, including linking individuals to SU treatment, Medication Assisted Treatment (MAT), and alternative pain management services. Major challenges are impacting uptake and adherence to opioid treatment services, consistent with those identified in multiple studies (Knudsen et al., 2011). While MAT is acknowledged as a best practice treatment option (Mattick et al., 2009; Mattick et al., 2014) and a key IL ODP component, access to the identified providers is limited (e.g., limited transportation options) and frequently underutilized. Another challenge is the ODP focuses on narrowly defined SU treatment options; the ODP and its participants would benefit from referrals to a wider spectrum of treatment options, including referral to alternative pain management services such as meditation or yoga centers (Cherkin et al., 2016). Treating the comorbidities of opioid use and chronic pain is critical; over 87 million adults report using opioids for pain management and over 10 million of this group indicate misusing these medications
(CBHSQ, 2017). Additionally, research shows an increased risk of developing opioid use disorder (OUD) from abusing opioid pain medication (Muhuri et al., 2013) and transitioning to heroin use when obtaining prescription opioids becomes challenging (Al-Tayyib et al., 2017; Cicero et al., 2014; Compton et al., 2016). **Thus, expanding the ODP service delivery infrastructure to include a broader array of services has significant potential to improve clinical practice and lessen the effects of the opioid crisis.**

The current IL ODP model 1) lacks inclusion of trained clinical staff (ODP staff receive 4 hours of training) and 2) provides limited clinical recovery support for clients after program intake. As outlined in a recent State report (Reichert et al., 2017), officers are being asked to make clinical-level decisions for which they have not been hired or trained. Furthermore, there is minimal ODP contact with clients after they enter SU treatment. **Integrating clinically qualified staff in the ODP process to work with the police during the screening and referral process, and providing ODP clients with continued clinical support after program intake, has significant potential to improve clinical practice and lessen the effects of the opioid crisis.** Inclusion of the clinical advocate role is based on research showing the importance of trained clinicians during brief client encounters and interventions (Gaume et al., 2014).

Bibliography:

Addiction Policy Forum. (2017, March). *Focus on innovation: Montgomery County STEER*. Retrieved June 1, 2018 from http://docs.wixstatic.com/ugd/bfe1ed_f5af4fa0a38444fab5259aad85ea6e59.pdf

Al-Tayyib, A. A., Koester, S., & Riggs, P. (2017). Prescription opioids prior to injection drug use: Comparisons and public health implications. *Addictive Behaviors, 65*, 224-228.

CBHSQ (Center for Behavioral Health Statistics and Quality). (2017, September). *2016 National Survey on Drug Use and Health: Detailed Tables*. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved June 1, 2018 from https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-

2016/NSDUHDetTabs2016.pdf

CDC (Centers for Disease Control and Prevention). (2017, December). *Drug overdose death data*. Retrieved June 1, 2018 from https://www.cdc.gov/drugoverdose/data/statedeaths.html

Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., . . . Turner, J. A. (2016). Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: A randomized clinical trial. *JAMA, 315*(12), 1240-1249. DOI: 10.1001/jama.2016.2323

Cicero, T. J., Ellis, M. S., Surrant, H. L., & Kurtz, S. P. (2014). The changing face of heroin use in the United States: A retrospective analysis of the past 50 years. *JAMA Psychiatry, 71*(7), 821-826. doi: 10.1001/jamapsychiatry.2014.366

Compton, W. M., Jones, C. M., & Baldwin, G. T. (2016). Relationship between nonmedical prescription-opioid use and heroin use. *The New England Journal of Medicine, 374*(2), 154-163. doi: 10.1056/NEJMra1508490

Cosden, M., Ellens, J., Schnell, J., & Yamini-Diouf, Y. (2005). Efficacy of a mental health treatment court with assertive community treatment. *Behavioral Sciences & the Law, 23*(2), 199-214. doi: 10.1002/bsl.638

Gaume, J., Magill, M., Longabaugh, R., Bertholet, N., Gmel, G., & Daeppen, J.-B. (2014). Influence of counselor characteristics and behaviors on the efficacy of a brief motivational intervention for heavy drinking in yo0ung men – A randomized controlled trial. *Alcoholism: Clinical & Experimental Research, 38*(7), 2138-2147. doi: 10.1111/acer.12469

Gomes, T., Tadrous, M., Mamdani, M. M., Paterson, J. M., & Juurlink, D. N. (2018). The burden of opioid-related mortality in the United States. *JAMA Network Open*, *1*(2):e180217. Retrieved June 4, 2018 from https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2682878

IDHS (Illinois Department of Human Services). (2017). *The opioid crisis in Illinois: Data and the State's response*. Retrieved June 4, 2018 from http://www.dhs.state.il.us/page.aspx?item=96730

Knudsen, H. K., Abraham, A. J., & Oser, C. B. (2011). Barriers to the implementation of medication-assisted treatment for substance use disorders: The importance of funding policies and medical infrastructure. *Evaluation and Program Planning, 34*(4), 375-381. doi: 10.1016/j.evalprogplan.2011.02.004

Mattick, R., Breen, C., Kimber, J., & Davoli, M. (2009). Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database of Systematic Reviews,* (3), CD002209. doi: 10.1002/14651858.CD002209.pub2

Mattick, R., Breen, C., Kimber, J., & Davoli, M. (2014). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database of Systematic Reviews,* (2), CD002207. doi:10.1002/14651858.CD002207.pub4

Moore, P. Q., Weber, J., Cina, S., & Aks, S. (2017). Syndrome surveillance of fentanyl-laced heroin outbreaks: Utilization of EMS, Medical Examiner and Poison Center databases. *American Journal of Emergency Medicine, 35*(11), 1706-1708.

Muhuri, P. K., Gfroerer, J. C., & Davies, M. C. (2013, August). *CBHSQ Data Review: Associations of nonmedical pain reliever use and initiation of heroin use in the United States* (Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality). Retrieved June 4, 2018 from https://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-painrelieveruse2013.pdf

O'Donnell, J. K., Halpin, J., Mattson, C. L., Goldberger, B. A., & Gladden, R. M. (2017). Deaths involving fentanyl, fentanyl analogs, and U-47700 – 10 States, July–December 2016. *Morbidity and Mortality Weekly Report*, *66*(43), 1197-1202. Retrieved January 4, 2018 from https://www.cdc.gov/mmwr/volumes/66/wr/mm6643e1.htm

Ramirez, A. M., Andretta, J. R., Barnes, M. E., & Woodland, M. H. (2015). Recidivism and psychiatric symptom outcomes in a juvenile mental health court. *Juvenile and Family Court Journal, 66*(1), 31-46. doi: 10.1111/jfcj.12025

Reichert, J., Gleicher, L., Mock, L., Adams. S., & Lopez, K. (2017). *Police-led referrals to treatment for substance use disorders in rural Illinois: An examination of the Safe Passage Initiative.* Chicago, IL: Illinois Criminal Justice Information Authority, Center for Justice Research and Evaluation. Retrieved June 4, 2018 from http://www.icjia.state.il.us/assets/articles/Safe_Passage_Report_100217.pdf

Rudd, R. A., Seth, P., David, F., & Scholl, L. (2016, December). Increases in drug and opioidinvolved overdose deaths – United States, 2010-2015. *Morbidity and Mortality Weekly Report, 65*(50 & 51), 1445-1452. Retrieved June 4, 2018 from https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051e1.pdf

Schiff, D. M., Drainoni, M.-L., Weinstein, Z. M., Chan, L., Bair-Merritt, M., & Rosenbloom, D. (2017). A police-led addiction treatment referral program in Gloucester, MA: Implementation and participants' experiences. *Journal of Substance Abuse Treatment, 82*, 41-47. Retrieved June 5, 2018 from https://doi.org/10.1016/j.jsat.2017.09.003

Warner, M., Trinidad, J. P., Bastian, B. A., Miniño, A. M., & Hedegaard, H. (2016, December). *Drugs most frequently involved in drug overdose deaths: United States, 2010-2014* (National Vital Statistic Reports, 65, No. 10). Hyattsville, MD: National Center for Health Statistics. Retrieved June 4, 2018 from https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf

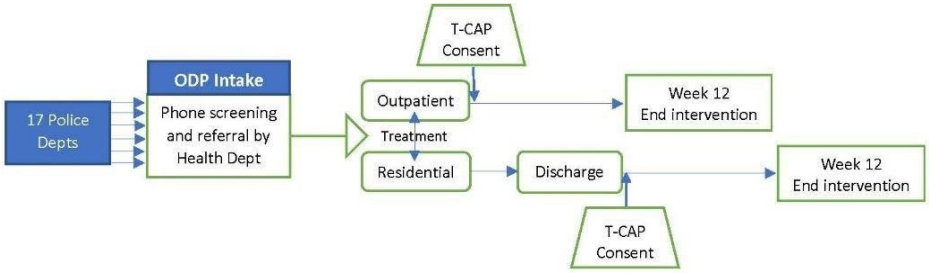
11. **Subject Population: Describe the characteristics of the participant population including the inclusion and exclusion criteria and the number of participants you plan to recruit:**

A total of 40 clients admitted to the Opioid Diversion Program (ODP) will be enrolled for the T-CAP study and all will receive the T-CAP intervention. Since the sample will be drawn from the existing ODP, sociodemographic characteristics are expected to be similar to census demographics for the corresponding communities, with approximately 59% male, 88% white, and average age of 32. In addition, we expect approximately 40% will need mental health services as part of their treatment and 60% will need services for medical problems. The ODP screens out individuals who have a criminal record of violent offenses. While all current ODP clients have a recent history (within the past 12 months) of opioid use or other substance use, we will confirm this during the RA's administration of the TCU Drug Screen 5 and TCU Drug Screen 5—Opioid Supplement. If this process reveals that the individual does not have a recent history of opioid or substance use, they will be offered the opportunity to remain in the study but excluded from the primary analyses. Furthermore, individuals who are not willing to consent to granting research staff permission to access their police and treatment services records, and individuals who do not understand the informed consent (see appendix for the Informed Consent Comprehension Questions), will be excluded from the study. Individuals must demonstrate the ability to speak and understand English and be at least 18 years old to participate in this study. At the Informed Consent meeting, the RA will determine that these criteria are met.

12. **Recruitment Procedure: Describe your recruitment strategies including how the potential participants will be approached and precautions that will be taken to minimize the possibility of undue influence or coercion. Include copies of the recruitment letters, leaflets, etc. in your submission.**
Recruitment will take place with clients who are recently accepted into the police Opioid Diversion Program (ODP) available in participating police agencies in Lake County, Illinois. We will coordinate with police agencies to put up an informational poster in each agency, introducing the research opportunity; length of the intervention (12 weeks); and eligibility criteria (stated in #11 above). The poster will also state that participation is voluntary , and (c) compensation for completed study activities. This same information will be included in a Recruitment Flier (see Appendix) that will be available to new ODP clients after they have completed the intake screening for the diversion program. Clients who are interested in hearing more about the study will be asked by Lake County Health Department (LCHD) staff to electronically sign a release authorizing LCHD to release the client's name and contact information to the T-CAP Research Assistant (RA). The release will be signed before ODP clients start outpatient or residential treatment, following ODP intake (screening and treatment referral). The TCU RA will contact the client a via phone to schedule a time for the virtual Informed Consent session that is convenient to the individual.

13. **Consenting Procedure: Describe the consenting procedure, whether participation is completely voluntary, whether the participants can withdraw at any time without**

penalty, the procedures for withdrawing, and whether an incentive (describe it) will be offered for participation. If students are used as participants, indicate an alternative in lieu of participation if course credit is provided for participation. If a vulnerable population is recruited, describe the measures that will be taken to obtain surrogate consent (e.g., cognitively impaired participants) or assent from minors and permission from parents of minors.



In T-CAP, the RA will be the only researcher who will Administer informed Consent. The RA will contact clients going into outpatient (OP) treatment by phone within 3 business days of the ODP intake to describe the study and answer questions. For clients who are entering residential treatment, the RA will contact the residential provider to speak to the client to describe the study and answer questions. For recruiting, we will call the residential provider phone number and ask to speak with individuals in treatment for the Opioid Diversion Program who are ready to be released from treatment. The provider will not be involved in recruiting for the study and will not have knowledge about an individual's decision to learn more about the project and plans to meet with the Research Assistant (RA) at an arranged location, once released. The RA will arrange ———— phone meetings with interested clients; within 4 days of the ODP intake for clients in OP treatment and within 4 days of discharge for clients in residential care. During the scheduled phone meeting, the RA will explain the consent process and steps to complete the virtual Consent form accessed through Qualtrics, describe the project, and answer any questions. The RA will then send the Qualtrics link to the individual's cell, tablet, or PC. Consent as well as responses to the Eligibility Questions (see Eligibility Questions in the Appendix) will be recorded via Qualtrics where participants will click on their responses for consent such as "I agree to participate" or "I do not agree to participate." The RA will confirm the consent agreement to participate in the study by reviewing the Qualtrics data, before calling back to ask if the participant has follow-up questions about the study and to describe the steps to complete baseline data collection. Participation will be completely voluntary and clients will be told that there are no legal consequences for declining participation, including having no effect on ODP status.

There are two Consent versions for the study activities in T-CAP; the *Primary Study Informed Consent* document will be used with the main study sample (N=40). In addition, we will contact participants by phone to recruit and consent a random sample of 6 to 8 of participants for a follow-up interview to be conducted virtually with the T-CAP app video feature at the end of the 12-week intervention, to ask about their experiences with T-CAP. The consent for this qualitative activity is the *Participant Interview Informed Consent*, as well as the *Media Authorization* to record interviews. [Virtual consent documentation is attached in the appendix].Consent documents are written with language that is appropriate for a 5th grade reading level (Consents and the Media Authorization are included in the Appendix). Both Consents will contain contact information for research staff and potential risks of participating. Compensation will be explained in the *Primary Study*

Informed Consent document; an $80 e-gift card for the time to complete intake surveys at the start of the study and $40 e-gift cards for completing assessments at week 6 (the midpoint) and week 12 (the end of the intervention period) during the 3-month study (eligible for up to $160) in the form of electronic gift cards to online merchants (e.g., Walmart, Amazon). Participants who use their own smartphone will get a $25 electronic gift card each month they participate in the study for messaging and data charges (a total of $75 for 3 months). Participants will not be responsible for any costs to participate in this study. The *Participant Interview Informed Consent* document will indicate that compensation is a $20 electronic gift card for completing a scheduled interview with a member of the research team. Participants who volunteer to be interviewed at the end of the study will be contacted by the RA to schedule a virtual interview. Both Consent documents will also have information indicating that participation or lack of participation will not affect the individual's status in the ODP, treatment, or treatment status in any possible way. Therefore, participation will be strictly voluntary and should clients choose not to participate or withdraw from the study at a later time, they may do so without repercussion. Participants can withdraw from the study by contacting the RA or Coach by phone and stating that they wish to stop participating. In cases where the Coach is contacted, the Coach will relay the decision to the RA for administrative purposes. The Consent will explain that the research-issued smart phone equipment will be collected by the RA at a time to be arranged with the participant. The Informed Consents will also describe the confidentiality assurances and the procedures employed to safeguard the data. In particular, it will be explained that information collected will be identified only by a random participant **Research ID** number and research reports will only be in aggregate form, whereby no individual can be identified. Recorded interviews will be redacted and identified only by the Research ID for tracking purposes. No individual data (survey, agency, or recorded opinions) will be reported to the ODP authorities or any other entity. The *Primary Study Informed Consent* will include language to allow release of behavioral healthcare agency data from the substance use treatment provider (providing services as part of the Opioid Diversion Program) to the research team for tracking participants across the 12-week intervention, thus providing treatment performance indicators. The *Primary Study Informed Consent* will also state that behavioral healthcare data will be requested by the research team using a variation of the Research ID (referred to as the **Treatment Code**) to link data to a participant. The Treatment Code is an arbitrary number assigned to each participant by the research team. The Code will be provided to the behavioral healthcare provider in a file that links the Code to the participant's name. Therefore, data requests from the research team will include only the Treatment Code, which providers will use to identify the client from the linking file. Behavioral healthcare providers will use only the Treatment Code in submitting data to the research team. Behavioral agency data will be shared with the research team via upload to TCU Box, a secure online data sharing platform. After an Informed Consent has been administered, the RA will answer questions and the client will then be asked to provide written consent.

Study Procedures: Provide a chronological description of the procedures, tests, and interventions that will be implemented during the course of the study. Indicate the number of visits, length of each visit, and the time it would take to undergo the

various tests, procedures, and interventions. If blood or tissue is to be collected, indicate exactly how much in simple terms. Flow diagrams may be used to clarify complex projects.

Research ID. After participants have electronically consented to participate on an Informed Consent document, they will receive the Qualtrics link to complete the Demographic Forms, and Contact Information Forms. Each participant, will then be assigned a Research ID that will be the only identification used on any project data. Because study participants are referred by the Diversion program to distinctly different forms of treatment (either outpatient or residential), the Research ID's will be based on two separate 3-digit series; 100 for participants in outpatient and 200 for participants released from residential. The Research ID will be written on the signed Informed Consent and entered into a Master Link File that will pair the participant name with the Research ID. This file will be kept on password protected laptops used by the RA and Coaches and password protected computers used by the PI and Project Coordinator at the IBR.

Baseline Survey Administration. After completing the Informed Consent, Demographics Form (e.g., age, gender, race/ethnicity, education level, previous use of telehealth), and Contact Information Form, the participant will receive the Qualtrics link via SMS text or email, to complete the Survey Baseline battery (included in the Appendix). The Qualtrics Survey Baseline assessment battery is completed on a participant's smart phone, hand-held tablet, or PC. The RA will provide the participant with their unique Research ID number, and this will be entered on the first screen by the participant. The Baseline assessment battery consists of forms available on our website (ibr.tcu.edu) and are widely used in substance abuse treatment settings and in our own research. The Baseline battery will also include a measure to gauge chronic pain. The Qualtrics Baseline battery, Demographics Form and Contact Information Form are expected to take up to1 hour to complete, in addition to the time it takes to complete the Informed Consent administration (estimated at 20 minutes). Following completion of the Qualtrics Survey Baseline assessments, participants will receive an electronic gift card in the amount of $80. At the end of the meeting, information on the next study meeting will be provided where participants will meet with their assigned Coach. Participants will receive instructions from the RA to (1) access the app on the phone equipment and (2) expect a text message from the Coach to schedule their first telehealth video call. The RA will explain the steps (listed below in "baseline procedures") that the Coach will use to schedule the first telehealth video call. The RA will further explain that the Coach will text message the participant the same day or next business day, except in cases where a participant joins the study on a Friday, in which case the Coach will text message the participant no later than the Monday that follows.

Procedures for Qualtrics surveys. Data from surveys completed using Qualtrics on a phone or tablet are accessible for download by authorized T-CAP research staff from the TCU Qualtrics server. Data will not be stored on the Qualtrics server after download to an Excel file on a secure server in the IBR offices. The server where the Excel files will be stored at the IBR follows TCU Information Technology security policies, including high-level security and encryption, and includes access password protection. In addition, the computer drives and partitions where the files are located are encrypted by BitLocker with a 256-bit key, and individual files will be password protected by the study PI. This file security protocol is NIH-compliant, and current TCU IRB-approved (as well as past IRB-approved studies) follow this protocol. Research data in paper form are kept for a period of 3 years and then shredded. Electronic data records will be maintained for a period of 5 years.

Procedures for handling of paper and pencil forms. The RA will have paper versions available as an alternate to the Qualtrics Survey versions in case of issues with technology. In the event that the participant encounters issues with accessing the Qualtrics link to complete the baseline documents, paper forms will be mailed to participants at their home address along with two stamped FedEx return envelopes (one for surveys and one to return the Demographics and Contact Information Form at baseline) addressed to the TCU IBR (attention to: Jen Pankow). However, paper forms are intended only as a back-up option and will not be offered to participants as an alternative to the virtual Qualtrics survey. Again, the data on paper forms will be identified only with the Research ID which will be entered by Jen Pankow, PI, into the participant tracking spreadsheet listing the issued Research ID's that are included in each FedEx package.
At the IBR, these documents will be stored in a locked file cabinet in a locked room, and all will be kept separate from all study data at all times, accessible only to authorized project staff at IBR offices. IBR project staff will enter the information from these forms into an excel database on a secure computer accessible only to authorized project staff at IBR offices.

Baseline procedures. The RA will describe the participant's options for phone equipment. In the event that the participant chooses to use their own phone for the study, the RA will assist the participant with downloading the T-CAP app. Participants who choose to use a study-issued phone will receive a FedEx delivered smart phone with the T-CAP app pre-loaded and instructions for use. For participants who choose to use their own phone equipment, the study will reimburse in the amount of $25 (in the form of an electronic gift card) per month to participants who are engaged in the entire 12-week intervention. For participants who opt to use the research smart phone equipment, phones will be on an unlimited plan maintained through the IBR.

After the phone equipment decision is made by the participant, the RA will document (in the participant tracking spreadsheet) the date, whether the phone is owned or research-issued, phone number, and the phone FCC ID number for each participant. In the event that a participant loses a research-issued phone, the participant will be advised by the RA, that the project will provide 1 replacement phone. In the event that a participant loses their own phone, they can request a research-issued phone or if they obtain another phone of their own, the same reimbursement at end-of-study will apply. Participants can arrange for a replacement phone by emailing or calling the T-CAP RA at the contact information on the T-CAP Flier, included with the participant's copy of the Consent document. In the event that a participant does not have access to email or a borrowed phone, they can contact the RA through the Lake County Health Department.

Phone and T-CAP app instructions, included in the mailed FedEx package, will explain the app to the participant, describing the app features (text messaging and video call options). The app will be pre-populated with phone numbers for the RA and the Coach. The app also features an icon for support, should a participant have an issue with a login or password. The instructions will guide the participant to turn on the phone. Participants will receive a welcome message from the RA, and the RA will provide the participant with the name of the Coach and describe the steps (below) for scheduling the first telehealth video call for later that same day or the next day. In cases where a participant joins the study on a Friday, the Coach will text message the participant no later than the Monday that follows (i.e., within 3 days after baseline surveys are completed).

After the baseline procedures are complete, the RA will confirm that all participant information has been entered in the tracking spreadsheet on the RA password protected laptop and then uploaded to TCU Box. The RA will then send a text message to the assigned Coach, indicating that there is an updated tracking spreadsheet with new participant information, ready for download.

Steps for scheduling the first telehealth video call:

(1) The participant will receive a text message from the Coach indicating the day, date, and time for the first telehealth session.
(2) The participant will send a reply to confirm the scheduled video call.
(3) At the scheduled time, the Coach will initiate the video call and the participant will have the option to "Accept" or "Decline" the call (similar to the feature on Zoom). During the first telehealth session, the participant and Coach will determine a standing day and time for the remaining 6 telehealth calls.

The standing video call arrangements will be entered into the tracking spreadsheet by the Coach and uploaded to TCU Box. The Coach will then alert the RA that the spreadsheet is ready for download. The RA will download and proceed to set up the 6 remaining telehealth sessions in the app scheduling feature. The RA will send a confirmation text or email to the participant with the schedule. The day prior to each of the 6 telehealth calls, the app will generate an automated reminder message about the upcoming telehealth call. We anticipate that there will be changes to the video call schedules, and participants will be advised to contact the RA for any schedule changes on video calls.

T-CAP Intervention. Coaching will be provided to the total study sample (N=40) by two licensed substance use treatment counselors, currently available through the Lake County Health Department. The Coach position requires professional training as a substance abuse counselor or equivalent (e.g., counselor with mental health credentials). Each Coach will be responsible for 20 participants during the 11-month implementation period. The study calls for two half-time Coaches, one to cover responsibilities in the event that one Coach is not available (e.g., due to vacation). In the event that one or both Coaches are unable to continue the study, replacements will be engaged for the project [the IBR has a strong collaborative relationship with several behavioral service provides in Lake and Cook Counties in Illinois.] Each participant will be assigned to only one of the Coaches for the duration of the intervention.

The 12-week telehealth intervention features 7 video calls on a smart phone, that will connect the participant with a Coach who will deliver the 3 components of the intervention: brief Motivational Interviewing (MI) sessions (see Appendix for MI scripts), recovery support, and assertive referrals to services that are intended to augment ODP substance use treatment or during post-treatment when there is an additional treatment need during recovery, as identified by the participant.

MI telehealth sessions are scripted; session 1 introduces the participant to MI, sessions 2-6 continue the dialog aimed at motivating the participant to identify issues and solutions, and session 7 focus is on continuing recovery with a plan. Coaches will keep brief case notes on paper versions of the MI scripts, and this information will be entered into the Coach Procedural Fidelity Checklist in Qualtrics . Coaches will use the information to prepare for the upcoming telehealth session. In addition, 10% of MI sessions will be audio-recorded for further evaluation of the fidelity to the MI script content. For each Coach, this is 7 MI sessions during the 11-month study window. MI sessions will be randomly selected for recording by the Project Coordinator, who will add an entry in the caseload tracking spreadsheet, flagging the video call MI portion to be recorded. This information will be provided to the Coaches in the caseload tracking spreadsheet that is downloaded by the Coaches from TCU Box-our secure file-sharing method. Coaches will be provided with hand-held recorders to capture only the MI portion of the video call. Coaches will upload the recordings to TCU Box, for download by the Project Coordinator. Coaches will delete the recording off the recorder. MI recording will be evaluated by only the PI and Project Coordinator, who is trained in MI. Downloaded files will be kept on the IBR secure server for the duration of the study. When the project is completed, the audio files will be destroyed. No MI fidelity recordings will be stored in TCU Box.

Scheduled Telehealth Sessions. Planned telehealth sessions (N=7) are front-loaded during the 12-week intervention, with 1 telehealth MI each week for the first four weeks, MI 5 in week 6, MI 6 in week 8, and MI 7 in week 12. The MI portion of each session is designed to be a brief 15 minute activity. In addition to MI, the Coach and participant will update on relapse concerns and recovery progress, and identified treatment needs for medical or additional behavioral healthcare treatment. The Coach will assist the participant with arranging services/appointments with an *assertive referral*, which involves the Coach providing the participant with treatment options and contacting a prospective provider on behalf of the participant to arrange for an appointment. To support the Coaches with

resources to complete the assertive referrals, the RA will maintain an Excel spreadsheet with area providers, available services, payment options, and contact information. Before the end of the telehealth session, the Coach will also confirm the next scheduled telehealth session with the participant. Overall, the telehealth sessions with MI and coaching support are expected to last up to 30 minutes. In addition to the Coach-initiated telehealth sessions, participants will be encouraged by the Coach to request additional telehealth sessions as needed. Participants will send a text message to the RA requesting a video call. The RA will reply via text message with scheduling options, based on availability of the Coach. We anticipate that special requests for video calls will be a response to a pressing issue that is weighing on the participant, so these calls will occur within the same day as the request whenever possible. The T-CAP research procedures for RA and Coach will be monitored with a monthly Procedural Fidelity Checklist (included in the Appendix).

Telehealth app data collection. There are two types of data from the T-CAP app: (1) function data (e.g., frequency of messaging, date/time of video calls and duration of calls), and (2) two telehealth satisfaction questions completed by participants at the end of each telehealth session (see appendix). Both data types will be available for download (from the cloud) to TCU Box. The data will be identified by the phone number. The phone number will be replaced with the Research ID by the Project Coordinator, so that no identifying information will be included in the analytic dataset.

Qualtrics Survey Mid-Intervention battery (T2). Participants will be contacted in week 5 by the RA to schedule a date and time to complete Mid-Intervention assessments battery in Qualtrics on a smart phone. The Mid-Intervention battery (and follow-up survey battery) repeats the baseline measures. To start the survey, The RA will confirm the unique Research ID number with each participant before sending the Qualtrics survey link, and this will be entered on the first Qualtrics screen. To start the survey, the participant will receive an SMS message with the Qualtrics survey link. At this timepoint in the study (and at follow-up), participants will also be asked to complete the Qualtrics version of the Telehealth Usability Questionnaire (TUQ), a 21-item measure rating the telehealth experience. The Qualtrics Survey Mid-Intervention assessment battery is expected to take 60 minutes to complete.Following completion of the battery, participants will receive an electronic $40 gift card.

Follow-up surveys (T3). Following the same scheduling procedures used for the Mid-Intervention survey battery, participants will be contacted in week 11 to arrange the Follow-up Survey battery, expected to take 60 minutes to complete. Following completion of the assessments, participants will receive an electronic gift card in the amount of $40. Following completion of the Qualtrics survey, the RA will contact the participants to thank each for their contributions to the project. All individuals will be invited to participate in an interview with a member of the research team. Our goal is to obtain feedback at the study closeout (Time 3) from a minimum of 6-8 participants. Interested participants may have the Participant Interview Informed Consent administered with the Media Authorization at this time, or the RA will schedule another meeting on a date and time that is convenient for the participant to complete the Informed Consent. The RA will FedEx the signed

documents overnight to the IBR research team and enter the information into the tracking spreadsheet, which is then uploaded to TCU Box for download by authorized project staff.

Individual interviews. A member of the research team will coordinate interview scheduling with the RA, who in turn will text message virtual meeting options to the participant. The scheduled meeting will be confirmed by the RA with both parties. The semi-structured interview with a member of the research team will take via meeting-specific HIPAA compliant Zoom chat or by phone. Audio recordings will be processed at the IBR. Participants will be advised that all identifying information will be removed from the transcribed interview and no identifying information will be reported for the project. Interviews are expected to take 30 minutes to complete and participants will receive an electronic gift card ($20) for their participation. Participants who are interested will receive a Qualtrics link for the Participant Interview Consent and Media Release documents. Responses will be recorded via Qualtrics where participants will click on their responses such as “I agree to participate” or “I do not agree to participate.” Audio files will be transcribed for qualitative analysis. Agency Records. Behavioral healthcare data will be obtained for participants in both conditions.
Participants will authorize the release of these data to the research team by signing the *Primary Study Informed Consent* at the start of the study. As part of the data-sharing piece, the research team will also obtain a Memorandum of Understanding (MOU), signed by the behavioral provider and the T-CAP PI. To request treatment data, the IBR research staff will send via email, monthly requests to providers with an attached Provider Data Request Form (included in the Appendix) for each participant receiving services at their agency. The form will include only a unique identification number (i.e., Treatment Code) which the provider will use to identify the participant. No participant name will appear on the form or in the email. The form has space for the provider to include the following information items:

- Primary diagnosis
- Level of care (outpatient, intensive outpatient, residential, detox)
- Length of program (number of weeks)
- Treatment initiation date
- Number of sessions scheduled this month
- Number of missed sessions this month
- Drug test results for this month
- Treatment discharge date

Completed Provider Data Request Forms will be uploaded by the provider to TCU Box and available for download by authorized project staff. Data from the forms will be entered into a provider data tracking Microsoft Excel file at the IBR and maintained on a secure server at the IBR office.

14. Data Analyses: Describe how you will analyze your data to answer the study question
Aim 1: *Demonstrate intervention feasibility by measuring study participant receptivity and utilization of the telehealth approach.* Feasibility will be primarily assessed by descriptive analyses of participation, satisfaction, and telehealth usability data. We will examine distributions on these measures as well as characteristics of participants with high and low participation sample size, we will be more interested in trends than in statistical significance. Receptivity and utilization will be assessed by self-report measures as well as participation data from the T-CAP app. Self-report measures will include the Telehealth Usability Questionnaire (TUQ), Telehealth Session surveys, and semi-structured closeout interviews. The TUQ gauges constructs that are consistent with those in the telehealth literature and include: Usefulness, Ease of Use Interaction Quality, Satisfaction and Future Use, Interface Quality; and Reliability. TUQ scores of 4.0 (agree) and above on each domain indicate high receptivity. Scores below 4.0 will be interpreted as an indication that the participant encountered some challenge in that area of using the telehealth system. Data from the TCAP app will provide evidence of utilization (i.e., process data on session completion, duration, and number of unscheduled contacts). Two satisfaction questions are asked after each video conferencing session. We will primarily examine counts and distributions of these data but will also examine characteristics of participants with high and low levels of participation. All individuals will be invited to participate in an interview with a member of the research team. Our goal is to obtain feedback at the study closeout (Time 3) from a minimum of 6-8 participants. Drawing on our extensive qualitative experience, a semi-structured interview with questions from the TUQ, paired with relevant probes, will guide the interview to help us gain a better understanding about how the telehealth experience impacted participants.

Aim 2: *Evaluate the proposed T-CAP measures to assess their performance in gauging the impact of telehealth on initiation of in-person Substance Use (SU) treatment, short-term retention in referred SU treatment, and access to other appropriate treatment services (e.g., MAT)*. Our multidimensional approach includes data from self-report attendance and treatment engagement, self-report drug use, Coaches' advocate records on number of completed assertive referrals, and agency records from police and BH providers (including intake and during-program UA test results). In order to examine groups differences for intervention completers (C) vs non-completers (NC) (i.e., individuals who do not complete the 7 coaching video calls), group differences using t-tests and chi-square tests and we will estimate effect sizes needed for determining a sample size for a future R01 proposal. To assess potential assignment bias, we will test to see if there are baseline differences in demographics: participant race, gender, age and other demographic characteristics, as well as baseline measures of opioid use frequency and amount will be examined using chi-square and t-tests. Effect sizes will be computed for group differences on multiple outcomes (treatment initiation, retention, referrals to expanded SU service options, missed appointments). Service attendance records will be corroborated monthly with service provider records. Examinations of referrals to MAT and alternative pain management care between the C and NC groups, utilizing agency records data and the Coach tracking, will be conducted using a z-score to test differences in proportions of referral types. This will be calculated for all assertive referrals (resulting in scheduled appointments) collectively for a participant, as well as for different types of services.

Analyses of Secondary outcomes. We will examine differences between C and NC groups on several secondary outcomes. Analyses will typically involve t-tests, chi-square tests, and correlations. For example, we will use t-tests to assess differences between groups on the 3-month follow-up measures

of treatment motivation and psychosocial function from the TCU Client Evaluation of Self and Treatment (TCU CEST), a widely used form listed on the IBR web page. Validation of recent (last few days) self-reported opioid use will be compared with drug testing outcomes at each assessment time point using McNemar's test for change of state, as well as computing sensitivity and specificity statistics and the kappa statistic as a measure of agreement. We will compare self-report, as well as urinalysis (UA) results from agency drug screens between the two groups.

15. Potential Risks and Precautions to Reduce Risk: Indicate any physical, psychological, social, or privacy risk which the subject may incur. Risk(s) must be specified. Also describe what measures have been or will be taken to prevent and minimize each of the risks identified. If any deception is to be used, describe it in detail and the plans for debriefing.

Breach of confidentiality. This risk will be minimized with procedures to safeguard the confidentiality of participants include assigning Research ID's to subjects. This number will be used as an identifier for all study materials including the participant's responses to the surveys, data stored from existing records, qualitative data, and T-CAP telehealth session data. Data from the T-CAP telehealth app will be stripped of participant phone number by the Project Coordinator, and the Research ID will be entered into the dataset. Participants will only be identified using this number and data will be reported in aggregate only. Consent forms with participant study numbers will be kept in a locked filing cabinet in a locked room in the IBR offices, accessible by authorized researchers. Electronic research data will be encrypted and password protected. Participants will be made aware during the consent process and prior to every research session that all information provided is considered to be confidential. Further procedures to protect confidentiality are described below. Only authorized research staff will have access to the de-identified data. Only the PI and Project Coordinator will have access to the T-CAP app data with the phone number when it is downloaded to the IBR secure server. These same authorized researchers will also have access to qualitative interview data, behavioral healthcare provider data, Qualtrics survey data with Research ID, and case notes from the Coaches. The RA will use the Research ID for reporting scheduling information (electronic files and demographic forms) to the IBR research team, and the Coach will use the Research ID when reporting case notes to the research team (electronic and paper files).

Coercion. While both the ODP participation and T-CAP participation are completely voluntary, there is a risk of perceived coercion that clients in the police diversion program may experience. This risk will be minimized in several ways. Participants will be informed that participation in this study will not in any way affect their status in the ODP. Further, ODP staff and officers will not be actively included as part of the study and will not be given feedback about any participant or any progress they have made in the study. Before the full rollout of the study, we will conduct presentations with ODP leadership and Lake County Health Department staff, and other stakeholders (e.g., community behavioral healthcare providers) to provide an overview of the study, and we will stress that study participation is voluntary and the participants may drop out of the study at any time if they wish.

Possible discomfort to study materials. Participants in the study will be asked to complete three survey batteries and seven telehealth sessions featuring MI with the Coach. Study participants may

experience some personal embarrassment or emotional discomfort from some of the survey questions or talking with the Coach. However, participants will be instructed that they can skip questions in surveys or during MI sessions that they do not feel comfortable answering.

16. Procedures to Maintain Confidentiality: Describe how the data will be collected, deidentified, stored, used, and disposed to protect confidentiality. If protected health information is to be re-identified at a later date, describe the procedure for doing so. All signed consents and hard data must be stored for a minimum of 3 years in a locked filing cabinet (and locked room) in the principal investigator's office, lab, or storage closet at TCU. Your professional society may recommend keeping the materials for a longer period of time.

Data from five sources will be subject to confidentiality procedure: (1) Qualtrics Surveys at baseline, 6 weeks and 12 weeks, (2) data from telehealth sessions, (3) data from Coaches, (4) data from community behavioral health providers, and (5) qualitative data from participant interviews.

The first step in maintaining confidentiality is to assign each participant an arbitrary Research ID that will be used on all data for that participant. A Master Link File will be maintained by the PI, Project Coordinator, Coaches and the field RA that will include the participant's name, Research ID, and study phone number. Treatment Code (described below) will only be included in the Master Link File maintained by the PI and Project Coordinator. This file will be encrypted and stored at the IBR on a secure computer separate from any other participant data. The Master Link File will be password protected, stored electronically, and kept separate from all other data files. It will be accessible only to authorized project staff.

Surveys. The RA will need to have the Master Link File on their TCU-owned secure laptop computer for tracking participants and obtaining Research IDs to enter on project materials. The laptop will be protected by a strong password and the link file, a Microsoft Excel database, will be encrypted and protected by a strong password. Every time a participant comes to complete a survey battery, the RA will use the participant name to look up the Research ID in the database. This will bring up the name and Research ID for that participant. The RA will enter the Research ID on the Qualtrics survey battery or on the paper version alternative. Updated Master Link Files will be uploaded by the RA via TCU Box for download by the IBR authorized researchers (PI or Project Coordinator).Master Link Files will not be stored in a TCU Box folder.

The RA will instruct the participant not to put their name or other identifying information on any paper forms. The Demographics Form—completed only at baseline—includes questions on demographics and background information, and does not have any questions of a sensitive nature. When the participant returns the Demographics Form, it will be mailed to the IBR in an envelope with the Contact Information Form. In the event that the Baseline battery of assessments is completed on paper (this is a back-up option in the event that internet access is not functioning), the survey will be mailed to the IBR in a FedEx envelope, separate from the Demographics Form and Contact Information Form. Data collection on Qualtrics will not have other data that could be used to identify the participant. When

surveys are completed using Qualtrics, the resulting data file is not readable until it is uploaded to the secure Qualtrics server on the TCU campus.
Telehealth session data. The 2-question telehealth satisfaction survey completed on a smart phone at the end of each telehealth session will be available for download through the TCAP app to TCU Box, accessible only by the PI and Project Coordinator. The data will be linked to the phone number and will not include any information that can identify the participant. The phone number in the .csv dataset will be replaced by the Research ID when the data is downloaded by the Project Coordinator at the IBR.

Data from Coaches. Each Coach will need to have a caseload tracking file with participants' name, Research ID, and phone number, accessible on their TCU-owned secure laptop computers in a Master Linking file. Each laptop will be protected by a strong password and the caseload tracking file—a Microsoft Excel database—will be encrypted and protected by a strong password and used for documenting assertive referrals and other support services (e.g., assistance with obtaining clothing, housing, or transportation) for individual participants, as well as case notes on MI telehealth sessions. The tracking files maintained by Coaches will be uploaded to TCU Box on a weekly basis for the duration of the study. Downloaded caseload tracking files will be stored at the IBR on a TCU-secure computer accessible by authorized IBR researchers; tracking files will be separate from the Master Link File.

Behavioral healthcare provider data. Data requests to behavioral healthcare treatment providers will be conducted on a monthly basis. To facilitate the requests and maintain confidentiality, providers will be given a Treatment Code number (not the Research ID) at the start of the study for individuals receiving services at their agency. The Provider Data Request Form (included in the Appendix), will include only the Treatment Code; no participant name or Research ID will appear on the form or in the email requesting the data. Completed forms will be uploaded by the provider to TCU Box and available for download by authorized project staff. Data from the forms will be entered into a provider data tracking Microsoft Excel file at the IBR. The Treatment Code will be maintained in the Master Linking File that will be encrypted and stored at the IBR on a secure computer separate from any other participant data.

Participant interviews. The semi-structured interview (Individual Interview Guide is included in the Appendix) with a member of the research team will take place via meeting-specific HIPAA compliant Zoom chat or by phone. Audio recordings will be processed at the IBR. Audio files will be uploaded on password protected computers the IBR by the PI or Project Coordinator and transcribed for coding by a transcript service that we have used on multiple Federally-funded projects. Transcription files will be redacted and formatted before upload to Atlas.ti coding software. Original audio files and transcripts will be stored at the IBR on a separate secure computer, accessible only to authorized project staff.

17. **Potential Benefits: Describe the potential benefits of the research to the participants, to others with similar problems, and to society.**

Participation in this research may increase individuals' knowledge, self-efficacy, and skills that they can use to deal with life problems that impede successful recovery. From a larger perspective, participation may help to improve the quality of care for persons experiencing life-threatening use of opioids or other substances, and this may benefit not only the individual by reducing his/her pain and risk of overdose, but also by lessening the burden

placed on their family and society at large. A more effective intervention for supporting recovery also benefits behavioral healthcare programs by improving health outcomes thereby saving staff time and program costs. We anticipate that this research may also have important benefits for public health by reducing the risk of opioid overdose fatalities.

Participation in this intervention will provide information on the usefulness of telehealth services for changing attitudes and intentions and subsequent behavioral risks with regard to serious opioid or other substance use. We will also gain valuable information about the use of telehealth technology for delivering the intervention with individuals in recovery.

18. Training for Protecting Human Research Participants: Submit training certificates for all the study investigators. The training link is available on the TCU IRB webpage at www.research.tcu.edu.

19. Check List for the Items That Need to be Submitted: Please combine all the files into one pdf document before submitting the materials electronically to the IRB. To prevent any delay in the approval of your protocol, use the most recent template for the protocol, consent document, and HIPAA form by downloading them from www.research.tcu.edu each time you prepare your materials.

a. Protocol	☒
b. Consent document	☒
c. HIPAA form if applicable	☐
d. Protecting Human Research Participants Training certificate for each investigator	☒
e. Recruitment fliers, letters, ads, etc.	☒
f. Questionnaires or other documents utilized in screening and data collection	☒

Principal Investigator Assurance

20. By signing below, I certify to the following:

- The project described herein will be conducted in accordance with applicable TCU policies and procedures, as determined by the IRB of record. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Protection ("OHRP") regulations at 45 CFR 46 and all other applicable federal and state laws and regulations (collectively "Applicable Law")

- I have a working knowledge of Applicable Law

- All personnel who work with human participants under this protocol have received, or will receive, appropriate training in protocol procedures and protection of human subjects prior to working with humans.

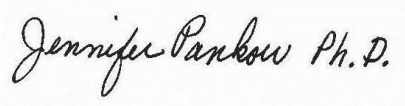
- All experiments involving human participants will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.

- Procedures on experimental subjects described in this IRB protocol accurately reflect those described in the funding applications and awards, if externally supported.

- I and all personnel have read and will comply with any pertinent safety information, IRB requirements, and security procedures.

- I will maintain records of all human participants and the procedures carried out throughout the entire term of my project.

- As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care, treatment, and protection of the human participants.



12/13/2021_____

Signature of Principal Investigator Date