NIH Collaboratory Ethics and Regulatory Core: Initial Consultation Call
Personalized Auricular Point Acupressure for Chronic Pain Self-Management in Rural Populations (APA-SM)
December 13, 2024; 2:00-3:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Luke Gelinas (Advarra), Beda Jean-Francois (NCCIH), David Magnus (Stanford University), Kayla Mehl (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Tammy Reece (Duke University), Damon Seils (Duke University), Jeremy Sugarman (Johns Hopkins University), Wendy Weber (NCCIH), Dave Wendler (NIH)
- Study team: Elizabeth Gendel (UTHealth Houston), Peiyin Hung (University of South Carolina), Jennifer Kawi (UTHealth Houston), Laura Lincoln (UT Health Houston), Hulin Wu (UTHealth Houston)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
Overview of the trial	Meeting attendees received the approved IRB protocol for the UG3 qualitative and feasibility work and the trial's data management and sharing plan (see supplementary material attached). Jeremy Sugarman facilitated introductions. The APA-SM team members present were Jennifer Kawi and Hulin Wu (principal investigators with Jane Bolin [not present]), Elizabeth Grendel (director for research compliance, UTHealth Houston), Peiyin Hung (site investigator, University of South Carolina), and Laura Lincoln (IRB manager, UTHealth Houston). **Project overview**: Jennifer Kawi gave an overview of the project, which is supported through a UG3/UH3 award mechanism. The goal of APA-SM is to test the effectiveness of a 4-week auricular point acupressure (APA) intervention for self-management of chronic pain in rural communities in Texas and South Carolina. The project is currently in the UG3 planning phase. **Healthcare system partners**: UTHealth Houston (The University of Texas Health Science Center at Houston), Texas A&M University Health Science Center, University of South Carolina.		

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	NIH Institutes Providing Support/Oversight: National Center for Complementary and Integrative Health (NCCIH), National Institute of Neurological Disorders and Stroke (NINDS). **Study design**: In the UG3 planning phase, the study team is conducting 2 qualitative studies. First, to understand the perspectives of community partners, collaborators, healthcare providers, healthcare system administrative staff, and patients and their partners regarding their perspectives on the intervention and integrating it into the healthcare system, they completed 6 focus groups with 24 participants. In addition, the study's community advisory board has met once to consider these issues. Second, they are currently conducting a pilot study of the intervention, for which they have almost completed enrollment. For the UH3 implementation phase, the study is proposed to be a 3-arm, hybrid type 2 effectiveness-implementation trial in adults with chronic pain. Participants will be individually randomized to self-guided APA, self-guided APA with in-person education, or an education control group. Patients in the APA arms will have access to a smartphone app with training videos that are specific to their pain location, diagrams and other visuals of the ear, and answers to frequently asked questions. Throughout the trial, text messages delivered from a REDCap platform will prompt patients to complete REDCap-based ecological momentary assessment surveys regarding their pain level and their adherence to the intervention. The study team is currently drafting the trial protocol and memoranda of understanding with partnering healthcare systems. Training of prospective APA educators will begin in the spring. **Outcomes**: The primary outcomes of the UH3 study include pain intensity, pain interference, and function. Key secondary outcomes are based on the HEAL Clinical Pain Core Common Data Elements. The study team will also evaluate implementation outcomes, cost-effectiveness, and predictors of treatment response. **Smartphone and app**: Access to a smartphone is not an inclusion criterion of the trial. Smartphones and a data plan will be provided at no cost to patients who indicate during screening that they need them. Study personnel will guide enrolled patients through downloading the app. Each patient will enter a digital token and a patient-specific survey ID number. The app will provide education and instruction		

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	only and will not be used for data collection. The app will pull data from the REDCap database to show patients their progress based on their survey responses. The Core encouraged the study team to investigate whether the app and the study-provided smartphones have associated user agreements. Such agreements sometimes include exculpatory language, and it will be important to ensure that the language included in any user agreement does not limit the rights of participants. Likewise, the study team should investigate whether there will be any passive collection of analytics data. The study team is not currently planning to collect analytics on app usage. Core members encouraged the study team to have a discussion with their institution's IT team about whether the study-provided smartphones or the app will have built-in analytics data collection the study team is not aware of. Policies governing analytics may need to be disclosed to participants. **Data bandwidth challenges**: Members of the Core emphasized that bandwidth may be a barrier for some patients, especially in rural areas. This could pose a threat to trial integrity if there are insufficient data for analyses. Accordingly, the Core encouraged the study team to have a discussion with the DSMB about the feasibility of looking at interim data during the trial to understand whether bandwidth challenges are affecting data collection and the implications for trial integrity, including sample size.		
Status of IRB approval	The study team received approval for the qualitative work described above that is being conducted as part of the UG3 planning phase. The trial protocol for the UH3 implementation phase has not yet been submitted.		
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. There is no plan to request a waiver of documentation of consent or a waiver or alteration of consent. The study team will use REDCap to obtain informed consent from all participants. Participants in the in-person group will manually sign the consent form. Participants in the remote group will sign via DocuSign.		
Privacy (including HIPAA)	The study team will require standard language for HIPAA authorization.		

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	The group discussed whether the smartphones provided to patients will be restricted to the capabilities needed for the study only and how this and related privacy issues will be addressed in the consent process, including any possible passive data collection by the device manufacturer and the service provider, the disposition of the devices at the end of the study, and retention or deletion of data on returned and lost devices. Materials used in the All of Us Research Program may offer useful examples.		
Monitoring and oversight	The study team is already meeting with the DSMB as part of the UG3 planning phase activities and intends to use the same DSMB for the UH3 implementation phase. Wendy Weber stated that the NCCIH DSMB probably will not be convened for this trial, but that NCCIH will review the membership of the study's DSMB to ensure its independence and will participate in an ex officio capacity. The study's community advisory board will continue to meet quarterly through the UG3 phase, then shift to a less frequent meeting schedule during the UH3 phase.		
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		

Protocol Title:	Refining and Testing the APA-SM Program for Chronic Musculoskeletal Pain Using Community-Engaged Research in Rural Populations
Principal Investigator:	Jennifer Kawi
Co-Investigators:	Hulin Wu, Maria Fernandez
Study Coordinator:	Coordinator, research nurse, research assistant TBD
Population:	Screen 50 to enroll 30 to 40 subjects, gender-all, 18-85 y/o, general health status-all, rural
Number of Sites:	Multi-site / UTHealth Houston is lead in multi-site study
Study Duration:	State duration of study-March 2024 to February 2025
Subject Duration:	Aim 1: approximately 1½ hour per participant in the focus group interviews; Aim 2: approximately 3-4 weeks

General Information

- This project will facilitate the refinement of our existing Auricular Point Acupressure â€“ Self-management (APA-SM) program for chronic musculoskeletal pain through community-engaged research, followed by pilot testing of the program in rural care.

Background Information

- **Chronic musculoskeletal pain (CMP) is a major health problem,**[1] a primary reason to seek healthcare,[2] and the leading cause of disability.[3,4] Individuals with CMP often rely on medication to manage pain, contributing to the opioid epidemic.[5-7] Clinical guidelines advocate for nonpharmacologic therapies and self-management (SM) for CMP,[8,9] but these options are challenging for rural individuals with limited resources.[10,11] Since CMP occurs any time and cure is mostly unrealistic, therapies that are effective, accessible, affordable, and sustainable for lifelong SM are critical for optimizing quality of life.
- **Auricular point acupressure (APA), based on acupuncture principles, delivers acupuncture-like stimulations to ear points and is a needleless, evidence-based, and active SM therapy for CMP**.[12-17] Our team our recently completed R01, we found that 4 weeks of APA had significant and sustained effect to improve pain (Cohen d 0.69) and function (Cohen d 0.53), compared to control, at 6 months (M) follow-up.[18] To maximize accessibility, we developed a user-centered app teaching patients to self-administer APA, thereby fostering a habitual SM skill for CMP.[19-22] Our team successfully integrated APA into real-world clinical practice at Johns Hopkins, including APA in their electronic health records (EHRs) for patient referral.[23] Owing to the simple, noninvasive, and sustained effects of APA, pursuing the next stage is imperative.
- **APA-SM, a digital approach, is grounded in the reality that rural populations have limited resources and are less likely to access specialty pain care, but most will have access to the intervention using smartphone**.[24] APA-SM includes **(1)** personalized APA protocols based on

each patientâ€™s pain problem; **(2)** a mobile-enabled app with instructional and demonstrational videos on APA with FAQs and self-monitoring/tracking capability; **(3)** ecological momentary assessment (EMA) to collect real-time outcomes; and **(4)** data-driven, personalized motivational messages (based on EMA data) using Banduraâ€™s self-efficacy model[25,26] to promote adherence.[27] APA-SM will be adapted, embedded, and implemented within community partners in rural areas so that providers can include this in their routine care. To be successful, we will first conduct community-engaged research where we will partner with individuals in rural healthcare involved or affected by chronic pain in order to achieve outcomes that will impact these same individuals as collaborators throughout the research process. We will refine the APA-SM program based on these stakeholderâ€™s perspectives and conduct a pilot study to test the feasibility of the program. Therefore, we hypothesize that we will be able to refine the APA-SM using community-engaged research and pilot test this prior to a full-scale trial.

Objectives

- The study purpose is to refine and pilot test the APA-SM program. Specifically, we aim to:
  - Conduct interviews to elicit stakeholdersâ€™ perspectives on the APA-SM program and itâ€™s integration into pain care.
  - Pilot test the refined APA-SM program to explore participantsâ€™ experiences and barriers in self-administering APA. Specifically:
    - 2-weeks post APA-use: participant experiences on the APA-SM app using individual interviews (e.g., barriers), and
    - Feasibility outcomes (primary measures)
      - Daily for 2 weeks: % completion of survey measures, % adherence to APA (frequency and duration)
      - 2-weeks post APA-use: # of participants completing the pilot study

Study Design

A descriptive design primarily using a qualitative design with some quantitative measures (e.g., demographics) will be conducted with expected duration and subject participation up to 1-2 years. Focus group interviews or semi-structured individual interviews will be used to elicit participantsâ€™ perceptions and identify barriers to/facilitators of implementation.

Study Aim 1: The first study aim will provide us with thematic understanding of stakeholdersâ€™ views and perceptions on the APA-SM program and itâ€™s integration into rural pain care through focus group interviews. Stakeholders for this aim will include primary/specialty care providers, staff, community partners, individuals with CMP, and their family/significant other.

Study Aim 2: The second study aim will provide valuable information as to the feasibility of APA-SM from the perspectives of individuals with CMP as to their experiences, including facilitators, barriers, or any concerns with the program through pilot testing the APA-SM. Individuals with CMP will also be evaluated as to their adherence, retention, and satisfaction.

Study Population

- Inclusion criteria for the first study aim are as follows: 18-85 y/o and is a rural provider, staff, community partner; individual with CMP; or family/significant other. Providers, staff, and community partners who are not engaged in the rural communities will be excluded. For individuals with CMP, those who do not have discomfort in the muscles, bones, joints, and

contiguous connective tissues of at least 4 out of 10 for at least 3 months (or pain on at least half of the days in the past six months) will be excluded based on the definition of CMP. Family members/significant others who do not have individuals with CMP within their family/relationship will be excluded.

- Inclusion criteria for the second study aim are as follows: 18-85 and an individual with CMP. Individuals who do not have discomfort in the muscles, bones, joints, and contiguous connective tissues of at least 4 out of 10 for at least 3 months (or pain on at least half of the days in the past six months) will be excluded based on the definition of CMP. Individuals with severe ear skin disorder or use any type of hearing aid that may obstruct seed placement from APA will also be excluded.
- For both study aims, we will engage with our rural health care community partners in-person, via telecommunication, or any digital means. We will also use informational flyers for recruitment.
- Study settings will be rural populations in the areas of University of South Carolina and Texas A & M.

Study Procedures

- Study Aim 1: We plan to conduct 4 focus group interviews (individuals with CMP and family/significant others; providers, staff, and community partners) to generate rich discussions and reach saturation of themes. Each focus group will have about 6 participants and we anticipate that each interview will take about 1.5 hours to gather sufficient information. We will ask open-ended questions and facilitate discussion to get in-depth perspectives (facilitators, barriers/challenges, suggestions/recommendations) related to the APA-SM program and itâ€™s integration into rural pain care. We will recruit a 5th focus group with about 4 individuals to conduct interviews focused on improving intervention relevance for our Hispanic population. The total number of participants recruited for Aim 1 will be 24-28 participants.
- Study Aim 2: We will recruit 6-12 individuals with CMP; these will not be the same individuals as in Aim 1 apart from those with CMP. They will be instructed to install our APA-SM app into their smartphones, view the videos and information in the app, and self-administer APA for 2 weeks. They will be provided with pellets using Vaccaria seeds (natural, non-toxic botanical seeds of no medicinal value, â‰ˆ 2 mm in diameter) that are tightly embedded into latex free, waterproof tape (â‰ˆ 6 mm^2), a tweezer (to apply the tape-embedded pellets), and a probe (to probe for tender ear points). They will be instructed how to identify points in the ear that they will probe based on the location of their CMP according to standardized acupressure ear points. They will apply the pellets and evenly stimulate (press) these (without rubbing) at least 3 minutes for 3 times per day to total nine minutes per day and additionally if they are in pain. A 2-second pause will occur between pressings. Optimal pressure is achieved when the participant feels localized tingling or mild discomfort. The treatment duration will be 2 weekly cycles. Each weekly cycle will include 5 days of wearing the taped pellets and 2 days without pellets. Participants will be instructed to remove the taped pellets at the end of the fifth day, let the ear points rest for 2 days, and re-apply after 2 days.

The total participants for both study aims will be 30-40 considering the qualitative nature of this proposal to reach saturation.

- Feasibility on the use of APA will be measured, during the 2 weeks of APA, using EMA that is incorporated in the app. Participants will automatically receive 2-3 random prompts throughout the

day to answer brief surveys asking about real-time pain intensity (from 0 to 10, 10 being the worst) and pain interference (from 0 to 10, 10 being the worst) to assess feasibility of these measures. The last random prompt will also be used to evaluate feasibility of measures including questions about APA practice (how many times a day, how many minutes each time, and total minutes per day), side effects, and analgesic use. The last 2 queries will have options and an open comment entry box. EMA data are stored via secured server.

- After the 2-week APA, we will conduct individual semi-structured interviews and we anticipate that each interview will take about 1 hour. We will use open-ended questions to delve into the participantsâ€™ experiences with the APA-SM program including facilitators, barriers/challenges, suggestion/recommendations, and also feasibility (e.g., usability, satisfaction).
- For both study aims, we will conduct purposive sampling, taking caution to ensure representation of each stakeholder. The inclusion of Spanish-speaking individuals will also help provide a culturally and linguistically appropriate intervention. If new information continues to emerge and saturation is not achieved, we will continue to conduct more interviews. Otherwise, study commitment/visit for the participants will only be one time for each study aim. Interviews will be conducted remotely or in-person according to participantsâ€™ schedules in a private area of their preference. Interviews will be audiotaped, transcribed, and de-identified to ensure accuracy and anonymity. Audit trails will be maintained. Trained interviewers will be cognizant of non-verbal cues throughout the interviews. Compensation will be 30$ per participant after their interview.

Data and Safety Monitoring

Participant safety remains a top priority. The PI and study team will review reports reflecting data quality, safety, and monitoring as indicated in the following table and monitor for potential adverse events and protocol adherence. There will be weekly meetings with project coordinators and other study staff within and across sites to review the progress of the study. There will be monthly meetings with members of the investigative team within and across sites to support the study. A Data and Safety Monitoring Report will be submitted to the UTHealth Houston IRBs at the time of annual renewal and at the time of study termination. Any instances of adverse events will be reported immediately to the local IRB site and UTHealth Houston IRB, using standard forms and/or procedures that have been established locally and by the UTHealth Houston IRBs. The yearly UTHealth Houston IRB renewal for this study will include a summary report of the Data and Safety Monitoring Plan findings from the prior year.

Data Safety Monitoring, Data Type, & Frequency of Review			
Data Type	***Frequency of Review***		
	MPIs, Co-Is, & Project Coordinators	**MPIs, Co-Is, Project Coordinators, & Staff**	**Research Team**
Participant recruitment and enrollment	Recruitment and enrollment reports weekly, monthly, and at the completion of the study	Monthly and as needed informal meetings with Co-Is. Meeting every quarter to review participant recruitment and enrollment	Recruitment and enrollment reports every month during study, more frequently if recruitment issues arise and warranted
Adherence to study protocol for inclusion and exclusion criteria and	Adherence to inclusion and exclusion criteria weekly during recruitment and enrollment phases	Monthly and as needed informal meetings with Co-Is. Meeting every quarter	Inclusion and exclusion adherence reports and demographic sample

demographic sample representation	of study; review of demographic sample representation every month, sooner as needed	to review adherence to study protocol	representation report every month during study
Adherence of participants to treatment protocol	Adherence statistics (e.g., EMA) every 2 days, weekly, and at study completion	Monthly and as needed informal meetings with Co-Is. Meeting every month to review adherence of participants to treatment protocol	Every month during study
Adverse event rates	Immediate notification and review for each event; monthly rate reporting	Immediate notification as needed, review monthly	Immediate notification and review for each adverse event; review report monthly
Data coding, entry, and preparation for analyses	Monthly	Monthly meeting	Monthly meeting
Participant complaints	At all project meetings	As needed in informal meetings with Co-Is. Monthly meeting to review	Every month and as needed

- APA-SM is a minimal risk intervention, so we do not anticipate the occurrence of Serious Adverse Events (SAEs) that would require stopping the pilot study. During the intervention, it is expected that participants may experience mild physical discomfort or itching. These will all be monitored regularly (daily) through the EMA and evaluated accordingly. Participants can withdraw from the intervention at any time. Participants will be instructed to report any adverse events experienced after treatment without delay. SAEs which are unanticipated, serious events, and possibly related to the study intervention will be reported to the DSMB, IRB, and NIH in accordance with requirements. In the Annual AEs summary, the DSMB report will state that they have reviewed all AE reports.

Statistics

- Qualitative data collection and analysis will occur concurrently until data saturation is achieved. Data will be analyzed using NVivo. To confirm that no data were omitted during the interviews, we will conduct member checking and ask participants to provide any additional information as necessary through a subsequent email or follow-up phone call.
- Demographic data will be summarized using means and frequencies. For the second study aim, we will also sum up data on pain, adherence to APA, and satisfaction using frequencies. Power and level of significance will not be necessary since this is a very small pilot. We anticipate enrolling 24 participants (4 focus groups x 6 participants) for Aim 1 (program refinement) and 6 participants for Aim 2 (pilot testing).

Ethics

- UTHealth Houston will be the single IRB of record. The 2 study sites (Texas A&M University) and University of South Carolina will cede to the single IRB.
- Eligible individuals will be recruited and asked to consent to the proposed study using a Letter of Information for Aim 1 and a written informed consent for Aim 2. Consenting will occur privately based on participantâ€™s preference as to location and may be done either remotely or in-

person ensuring all information in the consent is verified as having been understood and agreed with any questions answered.

Data handling and record keeping

- No personal identifiers will be connected with the data collected during the proposed study. A unique study identification number will be assigned to each participant, and a log accessible only to the investigators and key study personnel will link the study identification number to the participant. Only appropriate and authorized personnel will be able to view, access, and modify study data. No data will be shared with any other persons. Any personally identifiable information will be kept strictly confidential, stored in a password-protected computer, saved separately from the study data, safely/secured stored in a double-locked PI office with data storage duration for at least 3 years after study completion according to IRB requirements.

Quality control and assurance

- Given the nature of this proposed study, no third-party monitoring will be necessary but the PI will oversee quality control and assurance. The PI and study team will review the consenting process and 50% of the completed consent documents and feedback will be provided to ensure compliance. We will use standardized questionnaires and interviews across all sites to facilitate consistency and ensure that our study Aims are addressed completely and reliably. Since data analyses occur concurrently with data collection as is typically done in a qualitative study design, we will be able to ensure that data collected will be consistent with the study aims. Data entered into study database will be reviewed for consistency. Any protocol deviation will be reported to the PI and corrective actions taken as appropriate.

Publication Plan

- We plan to publish deidentified and aggregated data.
- Member checking will be conducted with participants from the interviews.

ATTACHMENTS

1. Schematic of Study Design and Study Schedule
2. Consent Documents (2)
3. Data Collection Forms (2)
4. Linking Log
5. Study Flyers (2)
6. APA Kit and APA-SM App Sample Feature

DATA MANAGEMENT AND SHARING PLAN

Element 1: Data Type

A. **Types and amount of scientific data expected to be generated in the project:** This study will provide demographic and qualitative data (interviews) from 40 participants in the UG3 phase. In the UH3 phase, a broad, representative data from 693 adults with chronic musculoskeletal pain will include demographic and clinical responses to self-report surveys (5 time points entered directly into secure REDCap and Ecological Momentary Assessment [EMA] system through a secure online survey link provided to participants) with interview findings on a subset of at least 50 participants. Interviews will be transcribed verbatim and de-identified (with a linking code to the quantitative data in the UH3 phase). All data will be encrypted, password protected, date/time stamped, and deidentified prior to receipt by the repository. Data will be archived in the Inter-university Consortium for Political and Social Research (ICPSR).

B. **Scientific data that will be preserved and shared, and the rationale for doing so:** All self-report survey responses including real-time data from our EMA and raw interview data, as well as data for administrative linkages will be stored in ICPSR. Any participant identifiers (e.g., name) will be removed and maintained in a secure file, accessible only to few trained and designated members of the research team who may need the information for future participant contact needs. All other scientific data (e.g., coded interview data, scale scores [including EMA data], and any recodes) will be preserved and shared. No personally identifiable information will be shared. Data preservation preparation will be handled in consultation with the UTHealth data management services and the Center for Nursing Research. The quantitative analysis dataset (UH3 phase) will be person based. Datasets made available will be prepared for the broadest level of accessibility feasible through our project's efforts removing identifying information, while retaining utility of remaining information for reference or further use. Following data collection, we will remove identifiers not required for analyses and employ fuzzing techniques for fields such as dates if necessary. We will consider secondary alternative variables and fields with less specificity (e.g., broader categories, location data, age ranges) to be sure that no person in the archived dataset can be identified. In the dataset that is preserved, all variables and values will be labeled.

C. **Metadata, other relevant data, and associated documentation:** Codebooks (or data dictionaries) and other study documentation will be made available as PDFs on the ICPSR website along with the data. ICPSR will produce a codebook with full variable-level details and frequencies for each quantitative dataset. ICPSR will also release metadata about the project that adheres to the Data Documentation Initiative (DDI) disciplinary metadata standard.

Element 2: Related Tools, Software and/or Code: ICPSR makes quantitative data available in multiple widely-used access and preservation formats, including SPSS, SAS, Stata, R, Delimited, and ASCII. Other types of data collected will adhere to ICPSR recommended submission formats to maximize access.

Element 3: Standards: In consultation with the HEAL Data Stewardship Group, we will follow the NIH Pragmatic Trials Collaboratory Data Sharing Policy. We will use ICPSR which will release standardized project-level and variable-level metadata that adheres to the Data Documentation Initiative (DDI) metadata standard. DDI is a widely-used disciplinary metadata standard that allows for compatibility with other data archive catalogs. ICPSR's metadata use controlled vocabularies to ensure consistency across studies; quality reviews of metadata are also performed. Metadata are available for bulk export in a variety of metadata formats (Dublin Core, DDI, and MARCXML), as well as exportable from and embedded in dataset landing pages, including in structured Schema.org data markup indexed by leading search engines. ICPSR processes are based on the Reference Model for an Open Archival Information System (OAIS), which is an ISO standard (ISO 14721) that provides the functional framework for sustaining digital objects in managed repositories. ICPSR is also a CoreTrustSeal certified trustworthy data repository.

Element 4: Data Preservation, Access, and Associated Timelines

A. **Repository where scientific data and metadata will be archived:** The data and metadata from this project will be archived at the ICPSR. ICPSR is a CoreTrustSeal certified repository providing long-term access to and preservation of data packages curated by domain specialists.

B. **How scientific data will be findable and identifiable:** Every ICPSR data collection receives a globally unique and persistent identifier, which are registered with DataCite (a global DOI provider) and included in the citation and metadata record of each ICPSR data collection. ICPSR creates rich study- and variable-level metadata records in the Data Documentation Initiative (DDI) disciplinary metadata format using information

supplied by data depositors and other sources. Metadata are available for bulk export in a variety of metadata formats (Dublin Core, DDI, and MARCXML), as well as exportable from and embedded in dataset landing pages, including structured Schema.org data markup indexed by leading search engines. Metadata are organized using standardized, well-established formats, templates, and vocabularies, and are released with a clear and accessible data usage license.

C. When and how long the scientific data will be made available: Research data will be available upon publication of related work or the end of the project period, whichever comes first and will remain available at ICPSR indefinitely, or as long as required by institutional policy or the sponsor. The investigator/project team will contact ICPSR 3-4 months before the required release date to determine if there would be lag time between data submission and ICPSR's release of the data. ICPSR permanently archives deposited files, supporting the data through changing technologies, new media, and data formats.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

a. Restricted-Use Data Access: Human subject information will be fully de-identified before ICPSR disseminates it to the public. Access to information that may be used to identify human subjects, even indirectly, will be managed according to ICPSR restricted-use data access policy and procedures to maintain privacy and confidentiality protections of human subjects.

b. Reuse, Attribution and Redistribution: Users agree to: make no attempt to identify human subjects, cite the data/DOI, not redistribute the data without ICPSR written permission.

c. Non-ICPSR Membership Access: Support for curation and dissemination of the study is provided by the institutional members of ICPSR and users associated with non-member institutions will pay an access fee.

B. Whether access to scientific data will be controlled: The only requirements to access downloadable, de-identified data through ICPSR are user registration and agreement to ICPSR's Terms of Use, which require users to agree to not redisseminate data, to use appropriate data citation, and to maintain human subjects protections. In the case of restricted-use, sensitive data, ICPSR requires an application to access the data. As part of the application process, the data user's institution must enter into a Restricted Data Use Agreement with ICPSR among other application components and data security requirements. Restricted data users are approved to access the data for a limited time period and in a controlled environment through the Virtual Data Enclave or a local computing environment that they secure themselves.

C. Protections for privacy, rights, and confidentiality of human research participants: ICPSR's curation staff performs a reidentification risk and harm risk review of all data to ensure confidentiality is protected in released datasets. Data cleared for public access have minimal reidentification and harm risk, and therefore, no restrictions on access. When necessary, ICPSR works with the research team to protect respondent confidentiality by removing, masking, or collapsing variables in the deposited data to produce a public version of the dataset. Restricted access is used in cases where removing the potentially identifying information would impair the analytic potential of the data or in cases where data contain highly sensitive information. If the data are restricted access, they will further be protected by terms set forth in a Restricted Data Use Agreement between the user's institution and ICPSR. Additionally, restricted data users must follow data security protocols, have Institutional Review Board approval or exemption, take training, and meet other requirements prior to being approved to access the data. ICPSR offers tiers of access to restricted data based on data sensitivity, including a Virtual Data Enclave. Public data users must protect human subjects' confidentiality by agreeing to ICPSR's Terms of Use. Consent for data archiving and future sharing will be obtained from all research participants in accordance with IRB regulations.

Element 6: Oversight of Data Management and Sharing: The Office of the Executive Vice President & Chief Academic Officer (EVP/CAO) and The Office of Data Science (ODS) at UTHealth Houston will provide joint institutional oversight for the DMS plan. Datasets resulting from this research will be cataloged within the institutional DEPUT system. DEPUT is the institutional oversight management portal supported by UTHealth Houston for DMS validation and tracking. DEPUT is the university's tracking system to ensure data is archived per the plan (for compliance) and the catalog of where to find UTH data (not an archive itself). Project Contact PI will update data status in DEPUT, and the institutional office of Sponsored Projects Administration (SPA) will perform annual validation according to the DMS plan. Validation results will be reported to EVP/CAO and ODS for review. Gaps, if any, will be identified with appropriate correcting measures implemented. The MPIs will have overall responsibility for compliance with data collection, storage, and safety protocols.