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Protocol

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Equity Using Interventions for Pain and Depression (EQUIPD) – Phase 1

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1.0 Background & Rationale

Nonpharmacological pain treatments (NPTs) are increasingly supported by evidence and are widely recommended in treatment guidelines. However, these approaches remain underused. Even as access increases, several patient-related barriers remain, including lack of knowledge about NPT availability and effectiveness, poor patient-provider communication, and challenges to engagement and adherence. This last barrier is particularly important as NPTs typically require more commitment, time, and effort than taking medications. These patient-level barriers may be especially difficult for patients with comorbid pain and depression, since depressive symptoms can interfere with engaging in pain management. Such patients may require additional support and structure to successfully use and benefit from NPTs. These challenges are further exacerbated for Black patients, who continue to experience disparities in pain treatment, such as being offered fewer treatment options—including NPTs—compared to their White counterparts. Therefore, NPT use may be especially difficult for Black patients with comorbid pain and depression, given the unique challenges that depression adds to pain management and the persistence of racialized disparities in pain care.

The overall goal of this proposal is to refine, test, and prepare to implement a novel approach to overcoming patient-related barriers to NPT use that is tailored to Black patients with comorbid pain and depression. EQUIPD (**Eq**uity **U**sing **I**nterventions for **P**ain and **D**epression) combines 1) a decision aid focused on NPTs to increase their use, and 2) a coach to foster patient engagement and NPT adherence. Drawing on a heuristic model of multi-level mechanisms of racial injustice in pain outcomes, EQUIPD is centered at the individual and interpersonal levels, while laying the groundwork for later intervention at the structural level (i.e., clinic/healthcare system) through subsequent system-wide implementation.

The EQUIPD coaching manual and decision aid have been pilot tested with patients for acceptability, but not in the context of a randomized pilot. Procedures for a full trial, including recruitment strategies that may differ in a randomized controlled trial (RCT), need to be piloted. In addition, although the decision aid has been useful for patients, it is essential that we also learn from providers how it might better be used in the context of clinic visits. Finally, while we have incorporated patient perspectives throughout the development of EQUIPD, their continued involvement is critical for this next phase of our work in order to sustain use and achieve meaningful impact. This research will take place at Eskenazi Health, an urban safety-net health system that provides healthcare to underserved, socioeconomically disadvantaged patients.

Chronic pain is prevalent, burdensome, and costly. Chronic pain affects tens of millions of Americans and is associated with depression, anxiety, reduced quality of life, and increased suicide risk.[1, 2] Musculoskeletal pain is considered the most common, disabling, and costly of all pain complaints.[3]

Depression is present in 30-50% of patients with pain and has additive effects on adverse health outcomes.[4-6] Depression can increase pain and pain-related disability, ultimately reducing quality of life.[1, 5] Depression can also interfere with effective pain management, especially nonpharmacological pain management approaches, which require active, consistent participation and engagement.[7, 8 1] Indeed, depression has been identified as a significant barrier to engaging in pain self-management, with patients feeling overwhelmed by their pain, unable to focus on or engage in pain management activities, and feeling hopeless about being able to manage their pain.[9] Clearly, depressive symptoms can reduce patients' motivation to be active participants in their own care.[10-12]

Non-pharmacological treatments (NPTs) for chronic pain are recognized as safe and effective. NPTs include both traditional (e.g., cognitive-behavioral therapy, exercise/movement) and complementary or integrative approaches (e.g., acupuncture, yoga).[13] In response to high-quality evidence supporting NPTs for chronic pain,[13-16] the Centers for Disease Control and Prevention, the American College of Physicians, Department of Defense, and Veterans Health

Administration have released guidelines or adopted policies recommending multi-modal approaches that prioritize evidence-based NPTs.[13, 17, 18] These guidelines are grounded in evidence from numerous studies and systematic reviews demonstrating safety and effectiveness.[13, 14, 19-29] For example, the American College of Physicians strongly recommends that NPTs, including exercise, cognitive-behavioral therapy, yoga, and spinal manipulation, be considered as first-line treatments for chronic low-back pain.[16] Thus, NPTs are a promising approach for patients seeking safe and effective pain treatment. Moreover, increasing NPT use is consistent with calls from the National Academy of Medicine and the National Pain Strategy to equip patients with tools to play an active role in managing pain.[1, 30]

Despite the promise of NPTs, numerous barriers lead to their continued underuse.[30-35] Recent studies indicate notable gaps between patients' interest in NPTs and actual use.[34, 36] Even in integrated healthcare systems such as Kaiser Permanente and the Veterans Health Administration, which have made concerted efforts to increase NPT access, patient-related barriers remain.[31, 33, 36, 37] These barriers include (1) lack of knowledge about NPT options, (2) poor patient-provider communication about NPT options, and (3) challenges to engagement/motivation (because NPTs require more time and commitment than many other treatments, such as analgesics).[13, 31, 33-35, 38, 39] Moreover, barriers such as skepticism and reduced motivation impact not just initial use, but long-term adherence—which is critical for NPTs to be effective.[1, 13, 33]

Barriers to NPT use are exacerbated for Black patients. Disparities in pain treatment are well-documented and persist despite national priorities focusing on health equity. Minoritized groups, particularly Black patients, continue to experience greater pain severity, worse pain outcomes, and inadequate pain treatment.[40-42] This includes being offered fewer treatment options—including NPTs—than their White counterparts.[43-46] Racialized disparities in communication compound these disadvantages. Black patients report poorer quality communication with healthcare providers; they receive less health information and show reluctance to share health concerns and articulate their opinions and treatment preferences.[47-50] These disparities have direct implications for pain care, particularly NPT use, which requires thoughtful evaluation of options and effective communication with providers to understand patients' goals and preferences and find the NPT(s) that are the best fit for each patient.[31, 33, 38, 51, 52] Thus, the barriers to NPT use are intensified for Black patients compared to their White counterparts.

In summary, NPTs represent a safe and effective—but underused—means to manage chronic pain. However, there are numerous barriers to NPT use, and these barriers are especially pronounced for Black patients and further exacerbated for patients with comorbid depression. Interventions are needed that address these disparities and provide tools for minoritized patients with comorbid pain and depression to benefit from NPTs. Notably, multi-level factors, such as those at the structural and cultural levels, work together to create and maintain racial injustices, and these factors exert influence on individual experiences.[53] Therefore, to fully address these injustices, intervention at multiple levels is needed. EQUIPD begins this process by equipping individuals with tools to exercise autonomy and control over their pain care. Such patient-level empowerment is a necessary step in the multi-step process of achieving equity in chronic pain care. If effective, we will build on this work to effect change at the structural level in a follow-up project focused on implementing EQUIPD's coaching and decision aid into everyday clinical practice at Eskenazi Health (see letter of support from Eskenazi leadership).

Decision aids are promising tools for overcoming barriers to NPT use and improving pain-related outcomes. Decision aids (DAs) are evidence-based tools that help patients make choices among treatment options. They help facilitate discussions with providers and are often used prior to clinic visits to promote shared decision-making.[54-56] DAs are typically used when there is no clear "best" choice, but rather when decisions are "preference-sensitive," meaning

there is a need to weigh features of different options to evaluate how these options align with a patient's own values and priorities.[57] In other words, "patient decision aids may help clinicians and patients to come to quality decisions, grounded in patients' values and taking into account the potential trade-offs in benefits and risks of different options."[56]

DAs can help overcome the barriers to NPT use described above. A 2017 Cochrane review of 105 studies[56] found high to moderate quality evidence that DAs (1) improve patient knowledge about treatment options, including helping them to have more accurate treatment expectations; (2) engage patients by helping them clarify what goals and priorities are most important to them; (3) improve patient-provider communication by facilitating greater patient participation in decision-making; and (4) can be used in time-limited clinic visits. Of note, Cochrane review authors found that DAs added only 2.6 minutes, on average, to the clinic visit, indicating that these benefits are attainable without exacerbating existing clinic time constraints.

Decision aids are especially well-suited for chronic pain and NPTs. First, as noted above, DAs are useful for preference-sensitive decisions and when different treatments may need to be tried. This is especially true for chronic pain because no single chronic pain treatment works for everyone, and frequently treatments must be used in combination (multi-modal care).[1, 58] Second, DAs facilitate communication, which is critical to foster shared decision-making.[56, 57] This is especially important because minoritized patients experience poorer quality communication with providers,[47-50] and because communication is often difficult in chronic pain care.[59-62] Third, DAs provide a means to weigh different options, which is especially important when deciding among NPTs. Numerous NPTs are available, and they vary widely; consequently, patients and providers have indicated difficulty navigating NPT options.[33, 38] Moreover, unlike pharmacological treatments, such as pills or injections, NPTs require varying levels of patient participation and commitment, which patients need to consider as they choose among options. For example, a patient with long work hours might not have time for a series of chiropractor appointments, but might choose an NPT with flexible scheduling or that can be done on one's own (e.g., walking). DAs help to make these tradeoffs explicit so patients can evaluate how different options fit into their lives. Fourth, DAs can help alleviate provider burden regarding informing, encouraging, and making decisions about NPT use with patients. By helping patients to define and state their goals and priorities for treatment, informing them of NPT options, and helping them to weigh these options against their own values and priorities, DAs equip patients to come to the visit prepared and primed to engage in a productive decision-making process.

Although some studies have trained physicians in shared decision-making for pain and a few have used DAs for patients with pain, these studies focused on specific conditions or clinical situations such as chest pain, orthopedic surgery, fibromyalgia, opioids, or medications for rheumatoid arthritis.[63-67] Despite the importance of promoting NPT use for chronic pain and the demonstrated effectiveness of DAs, there have been no studies examining the effectiveness of a DA focused on NPTs for chronic pain.

Patients need support to use and remain adherent to NPTs. In addition to the barriers to NPT use discussed above, once an NPT is selected, adherence can become challenging. In contrast to treatments such as analgesics, NPTs typically require considerably more time, effort, patience, and commitment.[1, 13] Moreover, NPTs often take several months to show effects, which can be discouraging to patients.[33] Indeed, challenges to adherence have been widely recognized in pain treatment, particularly those that are nonpharmacologic.[1] Furthermore, these challenges are compounded for patients experiencing comorbid depression, who may need additional structure and support to maintain a treatment plan.[9-12] In light of these challenges, the National Academy of Medicine recognizes the need to optimize adherence in pain management, especially for behavioral approaches such as NPTs.[1] Our own work has highlighted the integral role of coaching to help patients in their daily efforts to manage pain. In multiple studies, including studies of patients with comorbid pain and depression, patients have noted that such

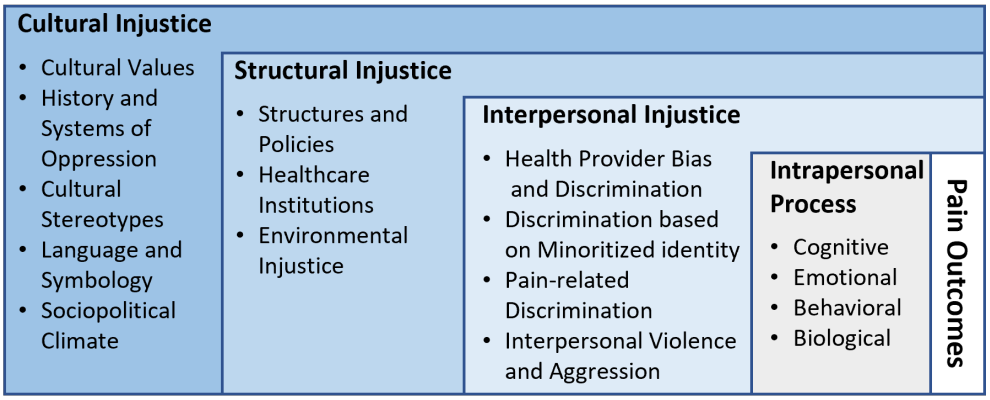
support is essential to their adherence to treatment regimens: coaching provides accountability toward goals and pain management activities, as well as encouragement to keep going when motivation is low.[9, 68-71] Given the unique challenges associated with NPT uptake, which are compounded for minoritized patients with comorbid depression, additional support is needed to enhance the potency of the DA. Individual, tailored coaching can serve to (1) overcome initial barriers to NPT use, in conjunction with the DA; and (2) improve NPT adherence.

Despite guidelines that encourage NPTs as first-line treatments, challenges to NPT use and adherence persist. These challenges are particularly resonant for minoritized patients with depression. This is the first study to tailor a patient-centered approach to empower Black patients with comorbid pain and depression to use and benefit from NPTs. EQUIPD's approach takes an evidence-based tool – decision aid – pairs it with motivational coaching, and applies it to the problem of chronic pain. This is innovative for several reasons. First, although DAs are typically used in the context of one-time decisions, such as cancer treatment,[56] DAs contain relevant features that have largely been overlooked in chronic pain. DAs facilitate side-by-side comparison of different options. This is essential for NPTs because they vary widely in delivery and what is expected of patients—including time commitment, flexibility, and delivery mode (self- versus provider-delivered). When patients are not given the opportunity to weigh these different features against what they prioritize as important—and what they are realistically able to accomplish—they are more likely to discontinue treatment. Second, DAs are typically designed only for use in a provider visit. This is a major constraint on their impact. By contrast, EQUIPD uses a DA in an innovative way—with a coach—who takes the time to explore the particulars of different NPTs and how they align with a patient's values and lifestyle. Third, a DA-coaching model is novel and may be especially effective for patients with depressive symptoms. By using the DA with a motivational interviewing style, coaches help patients find treatments that best match their goals and lifestyle and work with them to build the self-efficacy to self-manage and adhere to treatment—thereby helping to overcome pain management barriers related to depression and ultimately leading to improved outcomes.

Project Overview. This is phase 1 of a two-phase, 5-year project with the overarching goal of testing a decision aid/coaching intervention, tailored to Black patients with comorbid chronic pain and depression, to encourage use of and adherence to NPTs. Guided by the chronic care model and a heuristic model of multi-level mechanisms of racial injustice in pain outcomes, we begin by centering at the intrapersonal and interpersonal levels, while laying the groundwork for further intervention at the structural (i.e., clinic/healthcare system) level through subsequent system-wide implementation. Toward this end, we propose a Hybrid Type 1 trial[99] , which will test for effectiveness while assessing factors relevant for system-wide implementation in a subsequent project.

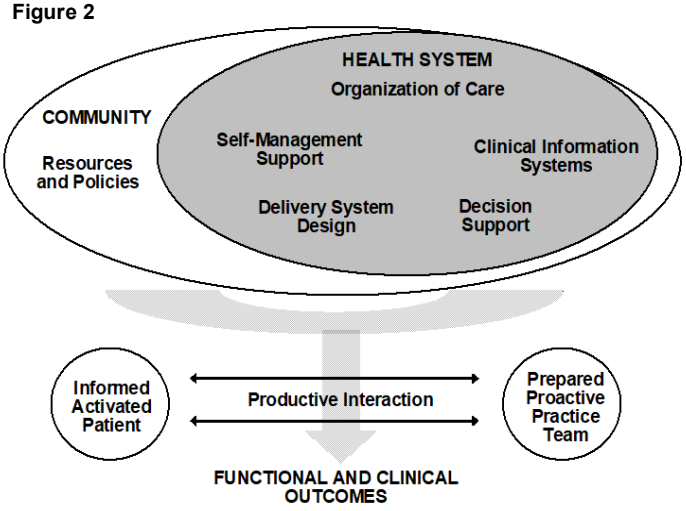
Conceptual Frameworks. Our overall approach is guided by a heuristic model of multi-level mechanisms of racial injustice (Figure 1).[53] This model posits that injustice at the cultural, structural, interpersonal, and intrapersonal levels interact, thereby creating and maintaining racialized pain experiences and outcomes. As a result, intervention at multiple levels is needed to target the compounding injustices experienced by minoritized individuals. EQUIPD was developed with these levels in mind. EQUIPD begins at the intrapersonal and interpersonal levels, while laying the groundwork for moving into the structural level (i.e., clinic and healthcare system) as we make plans for system-wide implementation to change clinical practice.

Figure 1



The intervention itself is guided by the Chronic Care Model (Figure 2), which emphasizes productive interactions between patients and providers within the larger context of the health system and community. Of particular relevance is collaborative management, which takes place when patients and providers have productive relationships, well-articulated goals, and shared understandings of their roles.[100] With collaborative care, patients and providers work together through sharing information and decisions, to find treatments best aligned with patients' needs and goals. This requires an informed, activated patient, who is aware of options, asks questions, and gives information that reflects their priorities.[100, 101] The emphasis on patients' roles in collaborative management is supported by evidence that patients who are informed and engaged are better equipped to participate in treatment decisions,[87, 102] which leads to greater adherence and better patient outcomes.[103] EQUIPD, with its focus on providing patients with tools for optimal NPT use, will help patients with chronic pain and depression to become better informed about NPT options and benefits, align these options with their goals, discuss with providers, and ultimately adhere to a mutually agreed upon NPT plan.

Figure 2



The EQUIPD Intervention. The EQUIPD intervention includes two elements: (1) individual coaching and (2) a decision aid (DA) focused on NPTs for chronic pain.

Coaching.

Timing. The EQUIPD intervention consists of four sessions, lasting about 30-45 minutes, over approximately 12 weeks. Three sessions occur before the patient's next scheduled PCP visit; the final session occurs after the visit. About 3 months (+/- 1 month) before their next scheduled PCP visit, patients will be enrolled, and those randomized to the intervention will be scheduled for their first coaching session. Table 1 summarizes the approximate timing and content of each session. Notably, flexibility is built into the coaching intervention to allow for potential missed sessions to be made up. In addition, coaches will schedule sessions on a more compressed schedule or combine content from sessions with the patient's permission if sessions are missed. Attendance at all sessions will be tracked, and, if warranted, considered in further analysis (e.g., examining a dose effect within the intervention group). *All efforts will be made to cover all content; however, if missing a session or part of a session is unavoidable, it will be documented and considered when examining dose effects within the intervention group.*

Table 1. EQUIPD Intervention Sessions

Session 1 - Orientation (Build empathy, motivation, & look for discrepancies)	**Week 1**
1. Ask patient how pain is problematic in life (i.e., interferes with daily activities and things patient finds important). 2. Understand current treatments and how they help. 3. Identify patient's values and goals related to pain treatment & interference with function (including Section 1 & 2 of Decision Aid)—to build empathy and explore discrepancies between values and current treatments.	
Session 2 - Review Life & Treatment Goals, Patient Values. Discuss Treatment Options and Expectancies (Look for discrepancies, enhance motivation & self-efficacy)	**Week 3**
1. Discuss different treatments, including pharmacological treatments and NPTs. 2. Introduce and begin discussing Section 3 of Decision Aid, which shows side-by-side comparison of 4 NPTs available at Eskenazi (study site). 3. In this context, discuss expectancies for NPTs (e.g., may take longer to work than analgesics). Focus on exploring patients' perspectives (empathy), looking for unmet needs (discrepancy), and helping patient identify ways to align treatment with their values, goals, and preferences (self-efficacy and motivation). 4. Ensure primary care appointment is scheduled.	
Session 3 - Work on Connecting Goals and Values to Treatment Options and Preparing Patients to Discuss Preferences with Primary Care Provider (PCP)	**Week 5**
1. Revisit goals and NPT options. 2. Discuss what options patients are leaning toward and why (Decision Aid Section 4). 3. Prepare patient to discuss NPT preferences with provider (Section 5: Questions for PCP). 4. Practice/role play of provider appointment. 5. Have patients take a photo of the DA.	
PCP Appointment	**Weeks 5-10**
Session 4 - Reinforcement, Motivation, Self-Efficacy, Adherence	**Weeks 10-12**
1. Review patient goals and treatment preferences. 2. Discuss recent PCP visit, including treatment decisions (using Section 6 of Decision Aid). 3. Provide motivation and encouragement to stick with NPT plan, including reminding patient that NPTs may take more time. OR 4. If NPT was not chosen, revisit goals, values, current treatments, barriers and discrepancies between current treatment and values and goals.	

Content. EQUIPD coaching is manualized and has been iteratively refined with local pilot funding. In these sessions, coaches elicit goals and priorities; discuss specific NPT options, including what is expected of patients; help patients align these options with their goals/priorities; and ultimately prepare patients for decision-making and long-term adherence. By eliciting and discussing what is important to patients, coaches can tailor the content and approach for each patient, allowing for variations in pain management goals, preferences, the impact of depression on pain and pain management, and sociocultural factors. The EQUIPD intervention uses a motivational interviewing (MI) approach in recognition that patients likely experience ambivalence about modifying their current treatment plan.[104] MI techniques are associated with better treatment adherence among patients with chronic pain and reduced use of a variety of substances.[105-107] This approach may be especially beneficial for patients suffering from comorbid depression, given that they may be more ambivalent about modifying their treatment plan and may require additional motivation and encouragement to adhere to a new plan.[68] Specifically, coaches will (1) express empathy; (2) foster patient self-efficacy; (3) explore resistance to change; (4) discover discrepancies between patients' current treatment plan and their stated values, goals, and preferences; (5) using the DA, help patients identify their goals and values and compare how different NPTs align with these goals/values; (6) using the DA, prepare the patient to discuss NPT preferences in the upcoming PCP visit (including role play); and, after the visit, (7) debrief about the PCP appointment and discuss treatment decisions; and (8) provide motivation and encouragement to adhere to the NPT plan, including

reminding patients that NPTs often take time to work. If an NPT was not chosen, the coach revisits goals, values, current treatments, and barriers to NPT use, and encourages patients to continue these conversations with their PCP. This encouragement may be particularly effective for these patients, given that evidence shows that patients who receive recommendations for behavioral approaches to chronic pain are more likely to be interested in trying these approaches.[34]

The DA is integrated into the first three coaching sessions in preparation for their primary care visit. After Session 3, the patient will attend their scheduled primary care visit. In addition to the preparation through coaching, we will also use the following strategies to encourage patients to bring and use their DA: (1) a research assistant will attempt to call patients the day before their visit to remind them to bring their DA (including a copy for the PCP) to the visit; and (2) in Session 3, coaches will ask patients to take a photo with their phones of the entire DA, as a backup, since they would be unlikely to attend the visit without their phone. After this visit, Session 4 will take place. In this session, the coach reviews patient goals and treatment preferences, and discusses what occurred during the patient's appointment. The coach will also provide motivation and encouragement to stick with the NPT plan or encourage patients to continue considering NPTs if one was not chosen in their PCP visit.

Delivery. Consistent with many of our other studies with patients with pain, all sessions will be delivered by phone. Consented patients deemed eligible and assigned to the intervention group will receive two copies of the DA (one to give to their PCP) after they complete the baseline assessments. Consented patients deemed eligible and assigned to the wait-list control group will receive the DA after the final assessment at 6 months. See section 2.0, Aim 1.3 for more information.

Table 2. EQUIPD Decision Aid

Decision Aid Section	Content
1. What is Important to You	Guides patients through important reasons (goals) related to improving their pain (e.g., better sleep, ability to work).
2. What Matters Most to You about Choosing a Treatment?	Patients answer questions about their priorities in choosing a treatment (e.g., how flexible their schedules are, whether they prefer to work on their own, with a provider, or in a group) to further help them align treatment(s) with their goals and lifestyles.
3. Get the Facts	Side-by-side comparison of 4 NPTs available at Eskenazi Health, the study site (walking, chiropractic treatment, physical therapy, and cognitive-behavioral therapy) to see potential pros and cons, and what is expected of them for each treatment.
4. Where are You Leaning Now?	Lists all 4 NPTs, with spaces for additional treatments patients may write in, and asks patients to indicate on a continuum whether they are leaning toward, against, or are undecided on each treatment. Space is included after each treatment for them to note reasons for their inclinations.
5. What Questions Do You Have for Your Doctor ?	Provides space for questions related to each treatment option (plus space for additional treatments) that they can bring to their visit.
6. Making the Decision/Plan with Your Doctor	Provides space for patients to write down the specific treatment plan decided upon, including when, where, how long, and how often they will engage in the treatment, and plans for follow-up.

Decision Aid (DA). According to the International Patient Decision Aids Standards (IPDAS) Collaboration, DAs are evidence-based tools that prepare patients to make informed, values-based decisions with their providers.[54] According to IPDAS, DAs (1) explicitly state the decision to be considered; (2) provide evidence-based information about treatment options; and (3) help patients to recognize the values-sensitive nature of the decision to help them align their values

with treatments being considered.[54] The EQUIPD DA accomplishes this in 6 sections (Table 2) and is administered in a simple paper-and-pencil format with the coach.

DA Content and Development. Our DA was developed in consultation with research experts in chronic pain and treatment decision-making, clinical experts in chronic pain (including our grant Co-Is), and patients. In addition, we consulted systematic reviews and evidence-based practice guidelines. While numerous NPTs exist, it is not possible to include all potential options. Consequently, we focused on NPTs with high-quality evidence of safety and effectiveness that are readily available (at the study site in particular). We also sought to include a variety of options. For example, we chose both provider-delivered (e.g., chiropractic) and self-delivered (e.g., walking) approaches to accommodate different patient preferences. We also included more traditional NPT approaches (physical therapy) and psychological approaches (cognitive-behavioral therapy) to accommodate a variety of preferences. We did not include some evidence-based complementary and integrative health therapies, such as acupuncture and yoga, as they are not yet widely available at Eskenazi Health (study site), but they can easily be added as availability changes.

Moreover, choices do not have to be confined to the options on the DA. The purpose of a DA is not to limit options, but to facilitate discussions about treatments that are grounded in patients' goals and values, helping "clinicians and patients come to quality decisions…and taking into account the potential trade-offs" of different options—even if some of these options are not included on the DA.[56] That is why there is space on the DA for patient questions and consideration of other NPT options. Also of note, the DA is flexible. Treatment options can be modified according to (1) emerging evidence and (2) the needs/resources of individual health systems (in an implementation scenario), without changing the overall structure of the DA. This is important because it is likely that evidence will change as research on NPTs continues, and access to NPTs continues to expand.

Supporting Data. Coaching: Thus far, through local pilot funding, we have iteratively developed and refined the coaching manual. We also have good evidence of adherence to coaching sessions, based on our COOPERATE study. Although COOPERATE's coaching content was different, the study was conducted with 250 Black patients with chronic pain (almost half of whom had at least moderate depression) using 6 telephone-delivered coaching sessions. 85% of patients attended the majority of sessions, providing preliminary evidence that such coaching is feasible and acceptable. Aim 1.3 will facilitate further testing of this new coaching model for Black patients with comorbid depression.

Decision Aid: We have 3 aspects of preliminary data from patients for the DA. The first involved obtaining and incorporating feedback from a 12-member Patient Advisory Board, half of whom are from minoritized groups. In the next, we pilot tested the revised DA with 12 Black patients, eliciting additional feedback and making changes as appropriate. Lastly, we conducted a larger pilot study (N=30, 21 of whom are Black) at the study site (Eskenazi). In this sample, 91% indicated that the EQUIPD DA made them think more about using one of the listed NPTs; 93% said they were likely or very likely to talk about one of the NPTs with their doctor; and 89% thought the DA would be helpful for other people with pain. Qualitatively, patients said: "This is a very good tool to identify and refine goals and give the patient vocabulary to speak to their doctor." "It gives the patient power. It's empowering." "It gives you a plan for discussing chronic pain treatment with your doctor." "This [decision aid] gives you hope—and actual solutions." This preliminary work demonstrates high patient enthusiasm for the DA, indicating feasibility of use and acceptability of content/format. Our next step, which will be accomplished in Aim 1.2, is to elicit PCPs' perspectives on the DA, including feasibility and acceptability of use in clinic appointments and adaptation where needed before the pilot RCT.

PLANNING (Phase 1, Years 1-2). In preparation for a future fully powered clinical trial (phase 2), we have three specific aims. Each aim and associated activities are described below.

2.0 Specific Aims, Study Design, Recruitment, Eligibility

AIM 1.1: Establish an engagement panel comprised of Black patients with lived experiences of chronic pain and depression to provide consultation . The objective of our engagement plan is to create a partnership between our team and patients with lived experiences of racialized pain treatment and depressive symptoms. This will ensure that our research is relevant to the needs of these individuals and will maximize the likelihood of positive outcomes. This panel will be formed during the beginning of the project, with plans to meet approximately quarterly .

Recruitment. We will work with our consultant, Dr. Robles (or delegate(s)), who is the clinic chief at one of the Eskenazi Primary Care Clinics, to identify Black Eskenazi Primary Care patients with chronic pain and depressive symptoms to serve on this panel for our research team to recruit. Dr. Robles will facilitate recommendations from primary care clinicians throughout the health system. We have used a similar approach in prior studies. Eskenazi primary care patients who previously participated in a pain study with Dr. Matthias or other faculty research personnel may also be contacted for recruitment. We aim to recruit up to 6 patients (up to 12 throughout the study to allow for replacements in case of withdrawals) to partner with us as stakeholders throughout our project.

Engagement Panel Meetings. Members of the research team will meet with Patient Engagement Panel members up to 4 times annually for a total of up to 8 meetings during this study. Meetings may be held in person, by phone, or virtually depending on group preference and pandemic protocols and will last up to 90 minutes each. Meetings may be recorded (audio only if by phone or in person; audio and video if virtually). Recordings will only be used internally by research team members for those who missed meetings or to help draft notes from the meetings. Meeting materials may be sent to participants by mail or email. Participants may be contacted about scheduling meetings and for reminders of meetings by phone (including texts), email, and/or mail. If patients withdraw (actively or passively), they may be replaced during the study as needed.

Eligibility Criteria for Engagement Panel Patient Participants.

Eligible patients must (verified by self-report):

- be at least 18 years old,
- have chronic pain,
- have depressive symptoms,
- identify as Black, and
- be willing and able to participate in Engagement Panel meetings.

Compensation. Patient panel members will be paid $30 for each meeting attended for a potential total of $240.

Collaboration with the Panel. We will elicit the panel's input on the study's decision aid and the feedback obtained from PCPs on the decision aid (Aim 1.2), including advising on proposed modifications. For our pilot RCT (Aim 1.3), we will consult with the panel on (1) recruitment strategies, including advertising materials, mode of contact (e.g., mail, email), and language describing the study; (2) data collection materials, including appropriateness of questionnaire items and length; (3) intervention materials (e.g., welcome material, decision aid); and (4) potential future modifications for the follow-up fully powered trial.

AIM 1.2: Elicit primary care providers' (PCPs) perspectives on the EQUIPD decision aid content and structure to optimize its use in PCP appointments. We will recruit up to 15 PCPs to obtain their opinions on the DA. This sample size is consistent with published recommendations on qualitative sampling for a relatively homogeneous group (PCPs),[108] as well as our team's experience. In these one-time interviews, we will use a semi-structured interview

protocol for individual interviews or focus groups to elicit feedback on the DA, including content, structure, and use in clinic visits. Individual interviews or focus groups may be completed by phone, virtually, or in person and will be recorded. We expect the interview or focus group to last up to 30 minutes. We will conduct a rapid qualitative analysis with interview/focus group data to facilitate timely revisions in preparation for the pilot trial.[109] Toward this end, the analytic team (comprised of research team members) will review each interview or focus group transcript and enter notes into a data matrix. The matrix columns will correspond to interview questions and elements of the DA. Each column will be comprised of summary points from each interview. We will seek input from our patient advisory panel during this process, particularly as we finalize the DA.

Recruitment. We will work with our consultant, Dr. Robles (or delegate(s)), who is the clinic chief at one of the Eskenazi Primary Care Clinics, to identify potential participants for our research team to recruit.

Eligibility Criteria for PCP Qualitative Interview Participants.

Eligible PCPs must:

- be a Primary Care Provider (prescriber), and
- work in an Eskenazi Health Primary Care Clinic.

Compensation. Participating PCPs be paid $150 for participating in an interview or focus group.

AIM 1.3 Conduct a 2-arm pilot randomized controlled trial (RCT; N=40) to test and refine data extraction, recruitment, intervention delivery, and data collection protocols.

Overview of Study Design. This 2-arm pilot trial will aim to enroll up to 40 Black patients with comorbid chronic musculoskeletal pain and depression in primary care from an urban safety-net health system (Eskenazi) with the end goal of at least 30 patients completing the trial. After the baseline assessment, patients randomized to the intervention will be asked to participate in 4 coaching sessions over approximately 12 weeks. See Coaching Section and Table 1. Sessions will use Motivational Interviewing principles to foster openness to NPTs and self-efficacy by helping patients identify their goals and priorities, understand their NPT options, prepare them to discuss and choose options with their primary care providers (PCPs), and reinforce these choices to foster maintenance of these changes (Table 1). DA contents will be integrated into these sessions (Table 2), which will facilitate discussion of these options with their PCP. Ideally, the first 3 sessions will take place prior to the patient's next scheduled PCP visit with the final session occurring after this PCP visit. Assessments will be conducted at baseline, 3 months (i.e., after completing the final coaching session), and 6 months. Coaching session and PCP visit attendance will be tracked; participants will not be withdrawn for non-attendance and missing either is not considered to be a protocol deviation. Participants may be contacted about scheduling/completing assessments and/or coaching sessions and for reminders by phone (including texts), email, and/or mail.

Wait-List Control Group. Patients randomized to wait-list control will receive usual care (in addition to study assessments at baseline, 3 months, and 6 months). After completing the final assessment, they will then be given the DA along with a 20-minute coaching session to walk them through it (patients may decline the DA and/or coaching session or schedule for a future time). We are using this approach so that all patients have an opportunity to benefit from participation.

Coach Training. Coaches have at least a Bachelor's degree in psychology or related field. Training will involve didactics, demonstrations, and role-plays. All intervention and control sessions will be audio-recorded with participants' permission, and a random subset reviewed for fidelity and quality control. During individual and group supervision, adherence scores and fidelity will be discussed.

Intervention Fidelity. We will use treatment fidelity strategies consistent with the NIH Behavior Change Consortium recommendations,[110] which include (1) using standardized

intervention protocols and training; (2) monitoring audio-recorded sessions; (3) using coach adherence checklists to track protocol deviations; and (4) holding regular meetings to address problems or concerns. Although there are no clear guidelines on the optimal level of adherence, 80% integrity typically constitutes high fidelity.[111-114] Thus, we will set a minimum threshold of 80% on the coach adherence checklists used to evaluate the audio-recorded sessions (where adherence is the ratio of the number of required topics discussed to the total number of session topics). Ongoing corrective feedback will be provided, as needed, during supervision to maintain fidelity.

Participant Recruitment. Similar to our other studies at Eskenazi, including Dr. Matthias' NIDA-funded R21, eligible patients will be identified by Regenstrief Institute's Data Core, which has agreements with Eskenazi to access patient data for research. Eskenazi PCPs may also refer patients who may be eligible to contact the study team or may provide the study team with patient referrals. Patients will be mailed or emailed a letter explaining the study, followed by a phone call approximately one week later.

Eligibility Criteria for Patient Pilot RCT .

Eligible patients must:

- have musculoskeletal pain in the low back, cervical spine, or extremities (hip, knee, shoulder) for ≥3 months,
- have at least moderate pain intensity and interference with function, defined by a score ≥4 (possible range: 0-10) on the PEG, a 3-item measure of pain intensity, interference with enjoyment of life, and interference with general activity,[115]
- have at least mild depression, defined as PHQ-8 score ≥5,
- identify as Black,
- have consistent access to a telephone,
- indicate openness to new pain treatments, and
- have a scheduled appointment with their PCP in the next approximate 2-4 months

Patients are excluded:

- if previously participated in Dr. Matthias' past pilot study (IRB #12885) or participation as a Patient Engagement Panel member for this project (Aim 1.1),
- if medical records indicate severe medical conditions likely precluding participation (e.g., NY Heart Association Class III or IV heart failure), or
- if the eligibility screener reveals (1) active suicidal ideation, or (2) severe hearing/speech or cognitive impairment.

Feasibility of Recruitment. According to a data pull by Regenstrief Data Core, Eskenazi has approximately 6,500 patients with chronic musculoskeletal pain (identified by ICD codes from our prior work), over half of whom (>4,000) are Black. Given that 30-50% of chronic pain is accompanied by depressive symptoms,[5] we have a pool of 1,200-2,000 potential participants.

Participant Compensation. Participants will be paid $30 for each assessment completed (baseline, 3 and 6 months), for a possible total of $90.

3.0 Measures

Measures are patient-reported, widely used in pain studies, and brief, creating low burden. They are also consistent with IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) recommendations[116] for key outcome domains in chronic pain trials. The baseline assessment will also gather socio-demographic data and review the patient's history, particularly current and past pain treatments. Baseline assessments will be conducted prior to randomization. Outcomes will be assessed at baseline, approximately 3 months (intermediate effects) and approximately 6 months (primary endpoint). Six months is our primary endpoint because NPTs typically take time to work.[1, 13] Based on our prior studies, we

estimate the screening and baseline assessments to take about 1 hour and 3 and 6 month assessments to take about 45 minutes.

Pain Interference (Primary Outcome) will be measured with the Brief Pain Inventory (BPI) Interference Scale, which is recommended for pain studies[116] and has been validated in primary care.[117] The pain interference score averages seven ratings, 0 (does not interfere) to 10 (interferes completely), of interference with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. The BPI is highly responsive to change in clinical trials[118] and has strong internal consistency (Cronbach's $\alpha = 0.77$).[117]

Satisfaction with the coaching sessions and coach will be measured by asking two satisfaction questions during the 3-month assessment (coaching group only).

Pain Self-Efficacy will be measured using the Pain Self-Efficacy Questionnaire (PSEQ). The PSEQ is a 10-item questionnaire developed to assess the confidence people with ongoing pain have in performing activities while in pain.

Pain Intensity will be measured with the Brief Pain Inventory (BPI) Intensity Scale which has 4 items with ratings from 0 (no pain) to 10 (pain as bad as you can imagine).

Depression (Secondary Outcome) will be measured with the PHQ-8,[119] a widely-used, validated 8-item measure of depression severity. Notably, improvements in pain are associated with similar improvements in depression.[6]

Anxiety (Secondary Outcome) will be measured with the GAD-7,[120] which has demonstrated good reliability and validity.

Pain catastrophizing (Secondary Outcome) will be measured with the Pain Catastrophizing Scale, a 13-item scale that assesses catastrophizing—a cognitive-emotional factor that predicts poor treatment response. Validation studies support its criterion, concurrent, and discriminant validity.[121]

Patient engagement (Secondary Outcome) will be measured with the 12-item Altarum Consumer Engagement (ACE) Measure,[122] which has 3 subscales: 1) commitment to manage one's health, 2) informed choice, and 3) confidence to participate in treatment decisions. Items are assessed on a 5-point Likert scale. The ACE is internally consistent and has demonstrated convergent, predictive, and criterion validity.

NPT Use (Secondary Outcome). We will use the NSCAP (Use of Nonpharmacological and Self-Care Approaches) to assess NPT use. This measure was developed by the NIH/DoD/VA Pain Management Collaboratory, comprised of national experts on NPTs and pain; two EQUIPD Co-Is (Taylor and Burgess) are members. The NSCAP asks about 9 NPT modalities, including the 4 that are in our DA, and assesses details of use such as frequency, location/source of service, and patients' judgments of effectiveness. Space is also provided for other NPTs that are used but not listed. The number of modalities for which patients answer "yes" will be summed for descriptive purposes.

Tobacco, alcohol, and drug use, as well as prescription medication misuse in the last year will be assessed using the 4-item screening tool, Tobacco, Alcohol, Prescription medications, and other Substance (TAPS) measure.

Communication self-efficacy (Secondary Outcome) will be measured with the Perceived Efficacy in Patient-Physician Interactions Scale (PEPPI-5), a 5-item scale that measures patients' self-efficacy in obtaining medical information and getting their most important health concern discussed in a clinic visit.

Shared decision making (Secondary Outcome) will be measured with CollaboRATE, a 3-item measure assessing provider effort from the patient's perspective to engage in shared-decision making during a recent appointment.

Working Alliance (Secondary Outcome). The Working Alliance Inventory (WAI) Client Short Form assesses patient-provider agreement on treatment goals, collaboration to achieve these goals, and degree of emotional bond (liking and trust) between patients and providers. The WAI

has shown high reliability (α > .90 for WAI total) and demonstrated convergent, discriminant, concurrent, and predictive validity.[139, 140,]

Perceived Discrimination. We will measure perceived discrimination in healthcare settings with the 7-item "Perceived Discrimination in Healthcare" Scale.[42] Participants are asked, "When getting healthcare, how often do the following things happen to you because of your race or color?" Sample items include "You are treated with less respect than other people," and "You feel like a doctor or nurse is not listening to what you were saying." Response categories are Never, Rarely, Sometimes, Most of the Time, and Always. This measure has shown good reliability (Cronbach's α=.89).[141]

Physical functioning will be assessed with the PROMIS Physical Function Short Form 6b which assesses universal physical functioning with a 6-item, self-report scale.

Sleep disturbance will be measured with the PROMIS Sleep Disturbance Short Form and sleep duration will be measured by asking about the number of hours and minutes of actual sleep in the last month.

Patient-reported impression of change will be measured using the Patient Global Impression of Change (PGIC). This one-item measure reflects a patient's perception of change after the start of an intervention.

Opioid use will be assessed for enrolled patients taking prescribed opioids. Regenstrief Institute's Data Core will extract opioid prescriptions from patients' medical records, and daily doses will be described as morphine-milligram equivalent (MME), calculated with the Centers for Disease Control and Prevention's conversion tables.[142] Average daily doses will be calculated within 30-day windows. For each opioid prescribed within each window, the dose in MME will be multiplied by the number of pills dispensed, then divided by the number of days supplied. The average daily dose for each window will be the sum of the daily doses for all opioids dispensed during the window.

4.0 Data Analysis Plan

Data Analysis for Pilot RCT. Descriptive statistics such as proportions and 95% CIs will be estimated to assess milestones. Only descriptive statistics (N, mean, SD, median, minimum, and maximum or frequency and percent) will be estimated by study group and timepoint. This will allow us to test coding of instruments.

5.0 Study Calendar

	Screening	Baseline	Coaching Sessions 1-3 over approximately 5 weeks	Coaching Session 4 at approximately 10-12 weeks	3 Month Visit^	6 Month Visit^
Eligibility Checklist	X					
Informed Consent and Authorization	X					
Contact Information	X					
Demographics		X				
BPI (Interference + Intensity Scales)		X			X	X
Satisfaction^^					X	
PSEQ		X			X	X
PHQ-8		X			X	X
GAD-7		X			X	X

Pain Catastrophizing Scale		X			X	X
ACE Measure		X			X	X
NSCAP		X			X	X
TAPS		X			X	X
WAI		X			X	X
PEPPI-5		X			X	X
CollaboRATE		X			X	X
Perceived Discrimination in Healthcare		X				
PROMIS Physical Function Short Form		X			X	X
PROMIS Sleep Disturbance Short Form + Sleep Duration		X			X	X
PGIC					X	X
Intervention*			X	X		

***For participants randomized to the intervention. Ideally, PCP visit (non-research) to occur between coaching sessions 3 and 4.**
^Three-month assessments may occur at 10 weeks – 4 months so long as it is after coaching session 4. Six-month assessments may occur at 5-7 months (+/- 1 month).
^^For participants randomized to the intervention (coaching group).

6.0 Reportable Events

We do not anticipate more than minimal risk to subjects who participate in this study and adverse events will not be systematically collected from participants. If a research team member becomes aware of any adverse events possibly related to study procedures, they will be assessed and reported to the Indiana University (IU) IRB according to the IU Standard Operating Procedures for Research Involving Human Subjects and to the study sponsor as required. Any unanticipated problems involving risk to participants or others will also be reported according to the IU Standard Operating Procedures for Research Involving Human Subjects.

Suicidal Ideation. Participants will be screened for thoughts of suicidal ideation during assessment of eligibility to participate in the study by asking, “Over the last two weeks, have you thought that you would be better off dead or that you want to hurt yourself in some way?” If the participant responds with yes, the assessment continues with the P4 Suicidal Ideation Screener to assess risk level.

- Based on the participant’s responses to this interview, they are characterized as: low to minimal suicidal risk or possible suicidal risk.
    - For possible suicide risk, the RA will provide the potential participant the Suicide Prevention Lifeline phone number as well as other relevant phone numbers (e.g., Suicide and Crisis Lifeline, Eskenazi Mental Health Emergency Line) and then will discuss with one of our two investigators who are licensed clinical psychologists (Hirsh, Rand) who will contact the subject and/or facilitate follow-up with their primary care or mental health provider as appropriate.
        - Such a participant, per exclusion criteria, would then be ineligible for study participation.
    - For low to minimal suicidal risk, participants are likely eligible to participate.

Study coaches will have regular contact with enrolled subjects during the active (intervention) phase of the study. The PI and 2 co-investigators (Hirsh and Rand) will meet approximately monthly with study coaches during this time and will discuss any problems or concerns that arise and how to address them—this will include continued training to implement safety protocols as necessary. If any immediate concerns arise during the coaching sessions, coaches will contact the PI along with Dr. Hirsh and/or Dr. Rand, who will be available to address any instances of worsening mental health or suicidality. In addition, RAs will be in contact with subjects for screening/baseline, 3-, and 6-month assessments and will report concerns to the project manager and/or PI. If safety concerns arise (e.g., mention of self-harm or suicidality), Dr. Hirsh and/or Rand will be consulted and will contact the subject and/or facilitate follow-up with their primary care or mental health provider as appropriate. All personnel will be trained in study suicide assessment and referral protocols.

7.0 Data Safety Monitoring

We will use an Independent Safety Monitor (ISM), defined as a physician, nurse, or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues. This role will be filled by *Dr. Matthew Bair, M.D., M.S.,* who is a Professor of Medicine at Indiana University School of Medicine and Research Scientist at the Roudebush VA Medical Center. He is a primary care physician, general internist, and pain researcher who has led multiple clinical trials ranging from opioid management to use of nonpharmacological pain strategies

Monitoring Schedule: Investigators will conduct continuous review of data and subject safety. Approximate quarterly review meetings with the PI, Project Manager (PM), grant co-Investigators as available and appropriate, and ISM will take place during the pilot RCT while subjects are active in the intervention. Meeting summaries will be documented with notes and will include a review of data, number of subjects enrolled, and number of subjects who have completed the study.

Requirements/conformance with informed consent documents: In preparation for these quarterly review meetings, the PM or delegate will randomly select study identification codes for approximately 5% of enrolled subjects to review. This review will include examining consent documentation for completion and accuracy, as well as ensuring all study materials are properly and securely stored (see data monitoring plan below).

8.0 Study Withdrawal/Discontinuation

Participants may withdraw from the study at any time and may communicate their intent to withdraw to the study team either verbally (in person, over the phone) or in writing. An attempt may be made to obtain their permission to complete any remaining assessments. Once the study team has been informed by the participant that they wish to withdraw (either just from the intervention or from the study entirely), a note will be made in the participant's study record. If the participant chooses to withdraw from the study entirely, no further data will be collected. All data collected from the participant prior to their withdrawal from the study may continue to be used and stored by the study team.

9.0 Data Management and Confidentiality

All documentation will be stored on a secure university server, on Regenstrief's secure network drive, or locked file cabinets behind locked doors. All electronic databases housing subject data will be password-protected with access limited to approved study personnel only. Identifying information will be separated from all data provided by subjects used in analysis through a

unique subject identification code assigned by study personnel with the linking file only accessible to research team members.

All data entry will be done by trained personnel. Electronic databases will be constructed to include forms for data entry that mirror paper or computer-based questionnaires and have restricted field ranges and values to prevent errors as much as possible. In addition, quality of data entry will be monitored by the PM, who will attempt to ensure complete and accurate data is entered while addressing any potential interview or data entry problems promptly. The study statistician or delegate will periodically generate reports for the entire dataset to identify outliers, missing data, or other potential problems. All data will be imported into statistical analysis package (e.g., SAS, SPSS) data sets for analysis. Analyses will include only summaries of data; personal identifiers will be omitted.

A data manager and/or delegate will create and maintain all databases. The data manager, PM, and RAs, supervised by the PI, will be responsible for data management. Each subject will be assigned a unique study ID number, and all data will be entered into a database only accessible to research team members, using these unique ID numbers.

Primary data will be collected primarily by phone, directly entered and stored electronically in REDCap and/or statistical analysis software packages. If needed, data may also be recorded on paper (either by research staff using who interview participants or by a research participant who receives a paper copy of the data collection form by mail and sends back in a prepaid envelope) and then entered into REDCap and/or statistical analysis software packages. Enrolled participants may also complete REDCap surveys (invitation only, using unique links) for 3 and/or-6-month data. The storage locations will be backed up automatically on a frequent and regular basis. Manual back-up copies may be made of data collection events (e.g., PDF of completed REDCap survey) and stored on a secure university server or Regentrief's secure network drive. Other data sources may include paper data (recorded by research personnel when talking to a subject on the phone), audio/video recordings, and data extracted from medical records that will be stored using the study ID numbers in files on a secure university server or Regenstrief's secure network drive. For qualitative data, transcribed interviews and/or focus groups will be checked for accuracy, de-identified, and may be entered into Atlas.ti or other appropriate qualitative data analysis program.

10.0 Follow-up and Record Retention

This study will last approximately 2 years. Records will be retained according to all applicable laws and regulations.

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