Study Title: Developing SUPPORT, A community-driven, recovery-oriented system of care

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Developing SUPPORT, a Community-Driven, Recovery-Oriented System of Care

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1.0 Background

The National Survey on Drug Use and Health (NUSDUH) identified 21.6 million individuals as having a substance use disorder in 2013, yet only 11 percent of those identified as needing specialty treatment received it.[1] For those who do receive treatment, their experiences are less than optimal. In 2011, 32 percent of adults dropped out of treatment or were terminated for failure to comply with program rules.[2] Additionally, half of those who complete treatment will relapse within 6 months of discharge.[3] These numbers demonstrate the current treatment system does not promote sustainable recovery for a large number of individuals with substance use disorders. The proposed R34 addresses this gap through development and pilot testing of Substance Use Programming for Person-Oriented Recovery (SUPPORT), a community-driven recovery-oriented approach to substance abuse care. We propose to model SUPPORT, on Indiana's Access to Recovery (ATR) program, which was closed due to lack of federal support despite local evaluation results demonstrating improvement in client recovery outcomes.

The concept of recovery has received increasing attention in the mental health and addiction fields over the past two decades. While the meaning of recovery varies in the scientific literature, definitions guiding current mental health and addiction treatment policies agree that it is a unique, holistic (i.e., encompassing the entirety of a person's life including self-care, social relationships, housing, employment, transportation, clinical treatment, physical health, etc.), person-centered process. However, the implementation of recovery-oriented care for addictions lags because of a tendency to equate recovery with a single outcome, abstinence.[4–6] Currently, the most advocated road to recovery relies on an acute treatment model in which abstinence is the only outcome of consequence and clients are often punished for substance use through restriction of privileges or administrative discharge, rather than being supported through and learning from relapse.[7–10]

The principles of recovery, as defined in current policy, are backed by research demonstrating recovery from substance use disorders can happen outside of treatment and encompasses more than abstinence.[11–13] Indeed, the first large-scale study seeking to understand the recovery experience from the client perspective demonstrated clients' definitions of recovery were focused more on the process than the attainment of abstinence, and some who continue to use still considered themselves to be in recovery.[14] Additional research suggests individuals with substance use disorders have different recovery trajectories, and recovery is often not attributed to formal treatment or involvement in 12-step programming.[10,15,16] Moreover, studies illustrate that individuals in treatment need to develop recovery capital, that is, the internal and external assets that can be used to initiate and sustain recovery.[17,18] Too many, treatment approaches emphasize the modification of clients' behavior, thoughts, and feelings and ignore interactions between the external environment and the individual that affect treatment and recovery outcomes and increase the potential for relapse.[18–21] Finally, current addiction treatments largely overlook the chronic nature of the disease by focusing on short-term therapeutic interventions, delivered in fixed amounts and durations with limited follow-up after discharge, relying on peer-based, "self-help" as a form of "aftercare".[22–25]

To promote sustainable improvements in clients' lives, treatment for drug and alcohol use disorders must do a better job integrating recovery principles.[19,26] A likely solution is the movement from an acute care treatment model to a recovery-oriented system of care (ROSC) that offers a choice of services and strengthens both internal and external aspects of recovery capital over a prolonged duration of time.[19,24,27] A ROSC approach provides client-focused, strength-based addiction care through a network of comprehensive treatment and recovery supports,[23,28,29] which make long-term recovery more likely.[20,25] Support services often include non-clinical services (e.g., peer mentoring, support groups, employment assistance, housing services)[17,30] aimed at developing recovery capital through a holistic approach that considers the individual, family, and community.[17,25,30,31] Support services can be driven by peers or professionals and offer a solution to the lack of chronic care models by supporting self-management and

sustainable treatment.[27] By merging recovery support with client choice, a ROSC facilitates reduced substance use and abstinence through individualized treatment plans that address clients' developmental stages of recovery and systematic needs.[29] Ultimately, this approach serves as a system-level solution within a community or state that aims to help clients not only achieve abstinence but to make significant progress in other areas of life,[32] as the RSOC model is well-suited to develop sustainable supports and life-long skills that are transferable to natural settings and promote personal development. [23,24]

Access to Recovery:

Access to Recovery (ATR) is a ROSC approach developed by the Substance Abuse and Mental Health Services Administration (SAMHSA). ATR supports flexible, comprehensive, and client-centered recovery services.[33–35] The intervention expands substance use services beyond traditional treatment, includes faith- and community-based providers, stresses individualized client goals, and utilizes voucher funding as a mechanism clients use to choose services. The ATR model fosters sustainable recovery by encouraging clients to find meaning and purpose to their life, regain citizenship, and create a valued role for themselves.[36–38] Since 2004, SAMHSA has awarded more than $200 million through 68 ATR grants to 32 states and 7 tribal entities.[39] Despite substantial national investment, there is a dearth of research on ATR. Indeed, we identified only four empirical peer-reviewed publications related to ATR programming. One was purely descriptive.[34] The second compared outcomes between clients receiving different treatments as part of the ATR program.[40] Two studies, both from Washington State, compared outcomes of ATR clients with those of a matched group of substance users; findings suggest ATR improved treatment retention and completion, increased employment,[12] and resulted in moderate Medicaid savings for ATR clients.[41]

Indiana received ATR funding from October 2007 through December 2014. Indiana's 11 county program focused on four target groups: (1) women who are pregnant or who have small children; (2) military personnel and their families; (3) methamphetamine users; and (4) felony offenders who are reentering society. The primary goal of the Indiana program was to provide a continuum of support services to bridge the gap between clinical and social needs. A recovery consultant worked with each ATR client to develop a recovery plan based on the client's personal goals. Client's received services for approximately 6 months (services could be extended if needed), and each client had $1,400 in vouchers to access an array of support services from a network of faith- and community-based providers certified to accept ATR vouchers. The program supported clients, rather than administratively discharging them for substance use. Our local program evaluation found clients and providers felt the program was beneficial, and that clients involved in the program improved on a number of outcomes (e.g., frequency of substance use, abstinence, housing status, employment, income, anxiety, and involvement in the criminal justice system).[42,43] (These evaluation results are described in greater detail in Section C1) Despite positive results, Indiana's ATR program and most other ATR renewal applications were denied due to significant budget cuts that reflected a lack of investment in research documenting program impacts.[44,45]

The loss of ATR significantly weakened the treatment infrastructure in Indiana's 11 participating counties. Recognizing this, Indiana's Division of Mental Health and Addiction (DMHA) provided start-up funds to the Central Indiana Recovery Services (CIRS) Coalition (working from Public Advocates in Community Re-entry (PACE) in Indianapolis, IN) in December of 2014 to develop SUPPORT as a community-driven alternative to ATR. The CIRS partnership includes treatment providers, clients, advocates, and academic researchers. **The initial design of SUPPORT refines Indiana's ATR program**, using the network of certified **faith- and community-based organizations** to provide recovery-oriented treatment and services that are coordinated by a **recovery consultant** and accessed through a **voucher-based system**. Figure 1 presents a model that demonstrates how SUPPORT will affect outcomes. By increasing options available to clients through its expanded infrastructure and flexible

services, the program improves client's sense of agency (i.e., control) over their recovery. Increased agency improves motivation to participate in treatment and supportive services, as well as other aspects of recovery capital (e.g., social support and self-efficacy). Improved social capital reduces barriers to recovery and leads to improved recovery outcomes. The model also asserts that improved recovery capital and services support the individual through a relapse (should one happen) and reflects process-based definitions central to current recovery policy.[46,47]

While CIRS ultimately plans to provide the SUPPORT program for anyone with a substance use disorder, partners chose to focus on returning inmates with a substance use disorder during the initial implementation because of the significant need for recovery services within this population. In the United States over half of all inmates meet criteria for drug dependence and nearly three quarters report using drugs regularly prior to incarceration.[48–50] However, few inmates will receive intensive substance abuse treatment while incarcerated.[49,51–53] Moreover, nearly all inmates are eventually released back into the community,[50,54] and drug-involved offenders are twice as likely to recidivate, suggesting that many returning inmates may be rearrested because of their inability to refrain from substance abuse.[52,55–57] Though it is clear that several influences converge to determine the outcomes of addiction treatment, there is significant evidence to confirm that mainstream addiction models face limitations in design and fail to provide treatment options that support sustained recovery management, particularly for those reentering the community following incarceration.[18,58–60] In addition to the fact that many inmates in the United States have a substance use disorder and do not receive services, criminal offenders were the largest group enrolled in Indiana's ATR program, comprising approximately 71 percent of clients served over the program's life.[61]

2.0 Rationale and Specific Aims

SUPPORT (Substance Use Programming for Person-Oriented Treatment) is a complex intervention that will require interaction between multiple individuals (e.g., providers, case managers, landlords), organizations (e.g., government funders, nonprofit service providers, property management) and systems (e.g., housing, medical, mental health, substance abuse) to be successful. Due to this complexity, we have chosen a learning-focused developmental evaluation as the overall design for the project. Developmental evaluation approaches are appropriate in the case of complex interventions that need additional refinements before they can be formatively assessed and when scalability is a future goal. It is a utilization-focused approach (i.e., carried out with the end user in mind) that facilitates learning through detailed documentation of the interventions development coupled with rapid response to facilitate strategic decision-making. Learning evaluation is a complementary approach, which utilizes continuous data collection and rapid-response cycles to facilitate continuous quality improvement of a developing intervention. We will conduct a pilot test to understand the effect of the intervention among a small sample of participants (n=100). The primary research question of this research is: **Does the SUPPORT program lead to changes in client recovery outcomes?** We will utilize qualitative and quantitative pilot data to determine what effect SUPPORT has on clients in relation to a comparison group, as well as how the program affects any observed changes. We expect the program will have a positive effect on client recovery outcomes and we will be able to identify specific program elements and processes driving these outcomes.

3.0 Inclusion/Exclusion Criteria

We will recruit 100 participants to be randomly enrolled in either the SUPPORT pilot study or support services as usual (n=50; n=50). To be eligible for the study, individuals must have (1) applied for and been determined as eligible for support services at PACE, (2) be over the age 18 (3) with a substance use disorder. Any individual that is not a PACE client, over the age of 18, or does not have a substance abuse disorder will not be included in the study.

4.0 Enrollment/Randomization

Once PACE determines eligibility, an IU Research Assistant (RA) will provide the initial invitation to participate in the study. At the initial meeting, the RA will explain the study in detail, verbally go over the information provided on the informed consent in full detail, and invite the individual to participate in the study. The RA will be instructed to go over the informed consent and authorization form for HIPPA compliance in full detail and answer any questions. Once all questions have been answered, if the client still agrees to participate, the client will sign the forms prior to beginning any data collection. The client will be provided a copy of the informed consent statement and authorization form and instructed to contact the PI, Dennis Watson, should they have any later concerns or questions.

Once the participant has signed the ICS, he or she will be randomly assigned to SUPPORT or treatment as usual. This process will be repeated until 100 clients are enrolled in the study (50 SUPPORT; 50Treatment as usual).

5.0 Study Procedures

We will conduct the pilot at Public Advocates in Community Re-Entry (PACE), a nonprofit agency in Marion County that provides services to individuals with felony convictions in Marion County Indiana. PACE specializes in the re-entry population and has much experience delivering support services to individuals with substance use disorders. We will recruit a total of 100 clients for participation in the pilot, half of this sample will be randomly assigned to SUPPORT and half to treatment as usual at PACE.

Over a period of 12 months, in addition to regular PACE services, SUPPORT clients (n=50) will be offered support service with a PACE recovery coach. The recovery coach will guide the SUPPORT client through their recovery, offering guidance and support, while coordinating their treatment services and optimizing their recovery coach. The SUPPORT program will provide SUPPORT clients with $1,000 worth of vouchers to cover the cost of additional flexible support services over the 12 months of program enrollment, which will be personalized to fit the needs of the client. These cost vouchers will cover similar support services as the previous Access to Recovery (ATR) program, such as housing (permanent, transitional), employment services (training, placement, readiness), substance use treatment, transportation, childcare, educational or vocational services, or aftercare planning. The costs of each service is determined by the service provider. Clients will NOT be responsible for keeping track of their vouchers, but rather, his/her assigned recovery coach will track all voucher funding/spending. Further, the recovery coach will assist the client in choosing appropriate services and coordinating/monitoring service completion.

Clients in the treatment as usual group will receive all regular treatment provided by PACE but will have reduced choices in services compared to SUPPORT clients. They will not receive additional vouchers to access additional, flexible support services such as transportation and housing and will only receive standard case management, which is more prescriptive and less intensive than the recovery consultant services provided through SUPPORT.

All PACE clients who are over the age of 18, have a SUD, are no longer incarcerated (in a prison, jail, or work release facility), and are unable to access the previously mentioned Recovery Works program, will be eligible for study participation. For both parolees and probationers the risk of recidivism is highest in the first year of release; therefore, we will be connecting with clients during the initial months following releases. We will also be excluding sex offenders from the pilot, as they face greater barriers to community integration and experience higher levels of supervision while on parole, which have the potential to confound results during a small-scale pilot. Once a potential client is released from incarceration and enrolled at PACE, if eligible, a research assistant will 1) read the work release screening tool to ensure they have been recently released from prison/jail/work release BUT are no longer on work release and then, 2) inform them of the opportunity to participate in the pilot study and describe the SUPPORT program services. If the client agrees to participate in the pilot, they will sign a consent form and be randomly assigned to either SUPPORT or a treatment as usual condition. If a participant in either the SUPPORT or treatment as usual group is re-incarcerated during the study period, we will not engage them while under correctional supervision to collect data and we will replace them with a new participant. However, if a participant is re-incarcerated but released back into the community during the study period, and reengages with PACE, they will continue to be a part of the study and we will continue to collect data and offer them SUPPORT services. In short, for the purposes of this pilot, we will not be collecting data from clients while incarcerated.

Quantitative Data:

We will collect both quantitative and qualitative data. PACE will hire and assign two recovery coaches to provide SUPPORT services for the pilot.

An Indiana University graduate student research assistant will be responsible for reading the screening questionnaire and then if eligible, 1) going over the statement of informed consent and Authorization form and have willing participants provide their signature, 2) conduct an initial interview with all clients after they have provided informed consent (to be included at the beginning of the electronic data collection) and have been assigned to the SUPPORT or comparison group, and 3) collect electronic data using REDCap system at the designated time points. Graduate research assistants will collect data through a computer assisted personal interview (CAPI) (i.e., individual interviews assisted by computer technology.) Research assistants (RA) will conduct interviews in a private room, away from other individuals so that others may not overhear what is discussed. Each RA will have a tablet computer through which they will access the REDCap system. The RA will read all questions from the electronic system to the participant and allow them to answer. "Don't know" and "refuse" options are provided for all questions to that clients can opt out of answering.

CAPI interviews will be conducted with all clients (SUPPORT and non-SUPPORT) at baseline and 6 and 12 months to understand change in outcomes overtime. Research assistants will also conduct a CAPI interview at 15 months with SUPPORT clients only to understand retention of treatment effects three months post discharge. Based on our previous experience conducting CAPI interviews, we expect this process to take between 60 and 90 minutes.

CAPI Data collection measures include 3 tools: the GPRA, the Recovery Measures, and the Social Network tool. The GPRA includes demographic and background information on all clients including: date of birth, gender, race, ethnicity, sexual orientation, housing history, education, employment history, drug or alcohol use, past involvement in addiction recovery and treatment, social support, family and living conditions, incomes, arrest history, and history of violence or trauma (We will use the GPRA tool uploaded in the attachments). The recovery measures tool will collect a number of measures, including (1) agency/self-determination, (2) recovery capital (i.e. treatment motivation, social support/networks, and self-efficacy), and (3) recovery-related outcomes (frequency of substance use and abstinence, incremental progress towards recovery, quality of life, recidivism, and administrative data on housing status, education, employment, income, physical and mental health status, and attendance at self-report self-help groups.) (Attachment: Recovery Measures Questionnaire).

The final component of the CAPI is the structured social network interviews. Social support is a proven influential factor on recovery. Having relationships and social networks that provide support, friendship, love, and hope through the process of recovery improves outcomes. The recovery coaches that work in the SUPPORT program will work with the clients to utilize their recovery support services to strengthen the individual's place in the community as a productive community member, family member, and worker, and, ideally, improve the quality of clients' interpersonal relationships and likelihood of positive recovery outcomes. This study will measure social support as a recovery-related outcome to see if the program is able to positively impact the social support in clients' lives over the course of the project. During these interviews, the client will be asked for the first names and last initial of people who provide certain types of social support in his/her life. (Attachment: HMSNBl)

*All computer assisted interviewing will be completed at baseline, 6 months, and 12 months. SUPPORT clients will also complete this interview at 15 months to understand long-term effects. **Qualitative Data:**

IU researchers will also collect qualitative data from *only* the experimental group (i.e. SUPPORT clients) through semi-structured interviews conducted after the completion of all quantitative data (15 months). The purpose of the interviews is to develop an understanding of client's treatment experience and how the SUPPORT program may have assisted them in overcoming barriers to recovery. These interviews are expected to take between 45 and 60 minutes. Guiding questions for the interview include: "Describe what you liked/did not like about the SUPPORT program (probe: client-centeredness, self-determination)."; "How was your relationship with your recover consultant?"; "Overall, how has the program helped you in your recovery? (probe: motivation; social capital; quality of life; elimination of barriers)"; "Are there specific things the program helped you with that you would not have been able to do on your own?"; "How did the program help you not return to jail (for those who did not recidivate)/How could the program have assisted your better so you would not have returned to jail (for those who did recidivate)?"; "If you experienced a relapse in the program, how did the program help you through that?"; "If you could change anything about SUPPORT, what would it be? Why?" (Attachment: Qualitative Interview Questions)

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

To protect participant confidentiality and ensure participant safety, the Principal Investigator, Dr. Watson, will oversee the conduct of the study. Subject withdrawals and any complaints will be monitored by either the PI or the program manager to ensure that study procedures have not resulted in unanticipated

distress or unintended outcomes to participants. Dr. Watson will review inclusion/exclusion criteria for each participant, and verify accuracy and completeness of data collection and safety reports. The program manager will enter and clean the survey data using SPSS for Windows, latest edition. During data collection periods, data will be monitored on a bi-weekly basis to ensure study confidentiality and data quality. If an adverse event were to occur, monitoring frequency would increase to weekly in order to ensure study safety. We will only be monitoring data related to confidentiality and quality. We are not exposing individual to any treatment that would require pre-planned statistical analysis to identify negative events in the data. We will inform the IRB of any adverse issues that occur during interviews, or if we notice procedures are causing undo stress on participants. *Any adverse events or unanticipated problems that may occur will be reported to the IRB within 24 hours.*

7.0 Study Withdrawal/Discontinuation

The subject will be informed that they can remove themselves from the study at any time. They will also be informed that they are under no obligation to participate in future interviews we may contact them for. The subjects' data will be deleted from REDCap and we will shred the paper copy with their contact information within 72 hours of their indicating that they would like to be removed from the study.

8.0 Statistical Analysis Plan

The pilot sample size has sufficient power to detect a minimum 10-day difference in the number of days of illicit drug use between subjects in the SUPPORT program and those in the usual condition after 1-year of SUPPORT programming. This assumption is based on evaluation results that demonstrated an average 7-day decrease in illicit drug use after 6 months of ATR programming. In addition, the pilot data showed a standard deviation of 8.4 days at baseline. To be conservative, we assume that the standard deviation of days of illicit drug use at baseline is 9. Based on these assumptions and the two-sample t test, our sample size of 30 subjects per group achieves at least 80% at the 5% alpha level.[118,119]

To evaluate the effect of SUPPORT on client recovery outcomes such as the clients' agency/self-determination, treatment motivation, self-efficacy, substance use frequency, incremental progress toward recovery, quality of life, and other recovery-related outcomes collected through administrative data, we will use the mixed effects model with measures at follow-up visits as the dependent variable. The clustering effect of repeated measures within a subject will be accommodated using a subject-specific random effect and the baseline outcome measure will be adjusted as a covariate in the model. Also included in the model are time of measurement and treatment group, as well as their interaction to allow differential longitudinal patterns for subjects receiving the SUPPORT program and those receiving usual condition. Effect of the SUPPORT program relative to usual conditional will be estimated based on the model. We choose to use the mixed effects model because of its flexibility in handling repeated measures and missing data. We will perform sensitivity analysis to examine the extent to which results are affected by missing data. Analysis based on complete cases, last observation carried forward (implying no change over time), and mean imputation will be performed. We will compare results based on these models to the mixed effects model results.

Our analysis of social network data will focus on the overall characteristics of the network (e.g., density and centrality), the quality of different relationships in the network.[120] We will carry out the first

step of this analysis in Ucinet,[121] a software package for the analysis of social network data.[122] In a second step, we will compare outcomes for each of the network variables for the two groups.

Regarding recidivism, we will first conduct paired-tests to look at changes in the number of days clients spent incarcerated prior to study enrollment to any incarceration time post enrollment. For this analysis we will examine 6-month and 12-month pre-post analysis for both the treatment and control group. Second, using Fisher's exact test and between group t-tests to consider whether there are differences in the likelihood of any criminal recidivism between the treatment and control groups. Comparisons will also be examined based on any differences that may exist in client choices and outcomes (e.g., services clients use, quality of life measures, recovery outcomes, substance use frequency, etc.). Therefore, we will not only examine the effect of treatment on recidivism but also other potentially important differences that might exist among the sample. Finally, we will estimate event history models. Using repeated measures of various intermediate and collateral outcomes, we will consider the impact of participation in the program and of treatment characteristics on the likelihood of and length of time to recidivism.

We will utilize the same qualitative coding approach and method for determining saturation as described for Aim 1 focus groups.[91,92,95] This analysis will also inform the development of final fidelity guidelines for model replication, as it will provide us with a deeper understanding of the components and processes of SUPPORT driving observed outcomes. In a final stage of the analysis, we will mix quantitative results and qualitative findings to provide a better overall understanding of the SUPPORT program. As a final step in the analysis, we will triangulate qualitative findings and quantitative results to enhance their validity.[91,123]

9.0 Privacy/Confidentiality Issues

To ensure clients are able to obtain all necessary resources, if a research assistant is notified that a client would like additional help, the RA will be informed to approach a member of the front desk staff, who would ensure the client is seen by an appropriate PACE staff member to have their issues addressed. PACE has a multitude of programs and services that are offered to all PACE clients regularly, and any PACE staff members would be able to direct the client to the resources to address the barriers.

Loss of confidentiality could negatively impact subjects' relationship with PACE. Additionally, we are asking a number of questions about criminal behavior that could result in prosecution if confidentiality were broken. Data will be collected using tablet computers and data will be sent to IU over wireless connections, and there is a small risk that data may be intercepted during the transmission process. We will also be collecting detailed information (email address, names of places they go for services, and contact information for family members and/or close friends) to assist us in following up with the subject should they move. There is a possibility that this information could be used to identify someone as a research subject if there is a confidentiality breach.

In order to minimize these risks: All subjects will be informed that their participation, or lack of participation, in the pilot study will in no way affect their relationship with the PACE organization or employees; If they choose not to participate in the study, they will receive support services as usual. Interviewers (i.e. PACE recovery coaches) will be fully trained on IRB procedures and the ICS procedures and will not coerce individuals to participate. All CAPI and semi-structured interviews will take place in a private location so that others will not overhear information discussed. We have applied for a Certificate of Confidentiality from National Institutes of Health (NIH).

Regarding possible interception of data during transmission over the wireless network, we will not be recording any names on the interview itself. Interviewers will only record a subject identification number on the electronic form. Additionally, we are collecting data using the REDCap (Research Electronic Data Capture) database system. The servers hosting REDCap are administered and supported by Indiana University's University Information Technology Services (UITS) and are physically located in IU's secured and environmentally structured data center on the IUPUI campus. To comply with HIPAA guidelines, physical, administrative, and technical safeguards and on ongoing risk management framework have been implemented and documented to ensure the security and protection of the study data within the data center, the servers, and the database. The only information linking participants' names with the answers provided during the interview will be a unique identification number. PACE will be instructed to use their unique, client identification number. The list of names and ID numbers will be stored on the secure, password protected and HIPPAA compliant Center for Health Policy server that only the research team has access to, in order for response monitoring, data entering and cleaning, and interview scheduling.

Because the research team is collecting contact information to follow-up subjects at future time points, procedures designed to protect the confidentiality and privacy of subjects will be closely monitored. Staff access to study files and databases will also be monitored.

10.0 Follow-up and Record Retention

The study will last three years (April 1st, 2016 through April, 2019) from the beginning of subject recruitment through data analysis and reporting. Following completion of the study, all study documents will be stored for 7 years. All paper study documents (i.e. informed consents, and participant contact information) will be physically destroyed. All electronic files will be permanently deleted.

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