SUNDARI FOUNDATION, INC.
POLICIES FOR GOOD CLINICAL PRACTICE IN SOCIAL AND BEHAVIORAL RESEARCH
September 12, 2021
Updated January 2023
Updated August 2023

The Sundari Foundation, Inc. ("Foundation") hereby adopts these Policies for Good Clinical Practice in Social and Behavioral Research ("Policies") for all social and behavioral research studies conducted at or by the Lotus House Women's Shelter ("Lotus House") in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes ("Research"). As with all policies, the Foundation's President, Executive Director, Director and Associate General Counsel ("Executive Team") will review the Research Policies annually based on the experiences and learnings of the Lotus House team members responsible for and conducting the Research, program participant feedback, advice of Research consultants and advisors, and update them as needed for continuous improvement.

I. INTRODUCTION

As the largest women's shelter in the country with extensive knowledge and experience in the field of social and behavioral services, the Foundation recognizes that it is uniquely positioned as a community-based organization to lead service-driven research in collaboration with academic partners that advance our overall mission of ending and preventing homelessness. Through service driven research, we have the opportunity first and foremost to deepen our understanding of the needs of our program participants, tailor services to address those needs, advance the quality of our services to heal and strengthen sheltered children and families, and address the impacts of pervasive, historic and current, gender-based violence and racial, ethnic, health, education and social/economic disparities. We recognize that our work has broad implications for women and children experiencing homelessness across our nation, for women and children in homeless shelters, safe havens, domestic violence shelters, runaway youth centers and transitional housing. We further recognize the importance of our service driven research for solutions to heal, empower and uplift children and families in marginalized communities across our country, struggling with the impacts of poverty, gender-based violence, and racial, ethnic, health, education and social/economic inequities. We are committed to developing practical, scalable solutions to address their needs and sharing what we learn to inform public and social policies and stakeholders at all levels. We do not undertake Research for the sake of purely academic or scientific knowledge, but to advance the human dignity, health and wellbeing of women, youth and children everywhere for generations to come so that they may blossom into who they are meant to be.

II. FOUNDATIONAL PRINCIPLES

To provide a framework for high quality Research and participant safety, the Foundation is committed to social and behavior research best practices, based on the International Conference Harmonization (ICH) guidelines, including the following foundational principles:

Principle 1: Research should be conducted with ethical principles that come from the Declaration of Helsinki and the Foundations standards of care, protocols and procedures, including the Research and Evaluation Plans, IRB Protocols and Clinical Protocols, described below and otherwise in the Foundation's policies and procedures.

Principle 2: Risks, benefits and alternative procedures need to be weighed prior to designing and beginning Research, including if possible focus groups with past and prospective research program participants.

Principle 3: The rights, safety and welfare of the research program participants override the interests of the study, society and science. High quality enriched services supporting our sheltered program participants must be at the core of all research. The advancement of science and/or social and public policy is never the most important factor in research; therefore, our research team must never sacrifice the interests and rights of study program participants to ensure completion of a study or otherwise in the delivery of services. In short, clinical needs will always be paramount.

Principle 4: Proposed and actual Research should be based on sound scientific data.

Principle 5: Research should be described in a clear and detailed protocol, with a written research and evaluation plan.

Principle 6: Research should be conducted in accordance with the protocol that has received prior approval by the Institutional Review Board ("External IRB") of the Foundation's academic collaborators and consultants, as well as the Institutional Review Board established internally by the Foundation ("Internal IRB").

Principle 7: Medical and health care within the context of Research should be the responsibility of the Foundation's qualified health care providers, including by way of example trained mental health counselors, social workers, marriage and family counselors, and child and family therapists.

Principle 8: Each individual on the Lotus House Research team should be qualified by education, training and experience to perform their designated study responsibilities.

Principle 9: Freely given informed consent should be obtained from every program participant prior to their participation in the Research, which must be subsequent to IRB approval. That said, the Foundation is committed to providing enriched, high quality

services to program participants, regular monitoring and data analysis for continuous quality improvement, irrespective of conducting Research.

Principle 10: All trial (amd regular program services) information should be recorded, handled, and stored in a way that allows accurate reporting, interpretation and verification, in accordance with the Foundation's HIPAA Manual and other standards of care.

Principle 11: The confidentiality of program participants' records and their privacy should be protected in accordance with all applicable federal and local regulation, the Foundation's HIPAA Manual and the written consents and agreements of the participants.

Principle 12: Systems with procedures that assure quality of every aspect of the Research should be considered and implemented in accordance with the applicable Research and Evaluation Plan for the study, described below.

III. RESEARCH PROTOCOLS

A. **Grant Proposal/Research and Evaluation Plan.** As part of the grant application process for a Research Project, the Executive Team, Research Team and applicable Lotus House services team, will prepare a written draft research and evaluation plan summarizing the project, purpose, methods and procedures to be followed in the Research project from start to finish, staffing plan, budget and narrative, and such additional information as may be helpful or required by prospective funders ("Research and Evaluation Plan"). If grant funding is approved and a contract with the prime funding agency executed and delivered, the Research and Evaluation Plan will guide the Lotus House Team to completion of the Research project, in accordance with the grant funding requirements and these Policies, and serve as the basis for the IRB Protocol and Clinical Protocol described below. Typically, the preparation of the Research and Evaluation Plan is a multi-disciplinary effort by and amongst various Lotus House teams and its consultants and advisors, including academic collaborators. The Research and Evaluation Plan will be submitted for approval initially to the internal institutional review board of the Foundation ("Internal IRB"), which shall make a general determination as to whether or not review and approval is aligned with the Foundation's overall mission, research policies and principles and determine further whether or not review and approval is required by an external institutional review board.

B. **Establishment of Internal Institutional Review Board.** Effective January 2023, the Foundation will establish an internal institutional review board consisting of not less than three (3) members of the Board, including the President and at least two members of the Board with expertise in research, behavioral health,

education and child care, plus at least two (2) alumna of the Lotus House program. The President may appoint additional persons with expertise to serve on the Internal Review Board. Currently, the Internal IRB includes: Constance Collins, President with expertise in shelter operations and serving women and children; Zafreen Jaffery, Board Member with expertise in behavioral health research; Gladys Montes, Board member with expertise in early child care and education; Rai Johnson, MSW, CPE, Lotus House Wellness Director with expertise in mental health and wellness, and alumna; and Sharonee Delevante, Lotus House Operations Director, with expertise in shelter operations and serving women and children. The Internal IRB shall review all proposed Research and Evaluation Plans to determine whether they are in alignment with the Foundation's overall mission, research policies and principles and determine further, whether or not review and approval is required by an external institutional review board. The Internal IRB shall also review quarterly reports, which may be the same as are provided to foundations funding the research, and in general monitor overall progress. All papers, reports, and presentations, including submissions for presentation at public conferences, are subject to the review and approval of the Internal IRB.

C. **IRB Protocol.** Each and every Research project will be preceded by submission to and approval by both the Internal IRB and if required, the Institutional Review Board ("External IRB") of our respective academic collaborator or consultant ("University") of a written protocol, detailing the critical elements of a Research project ("IRB Protocol"), or a determination by the Internal IRB and President that no IRB is required for the type of research being conducted. In academic/community based organization collaborations, the University will prepare the IRB Protocol for the Foundation's review, feedback and approval in as much as they will have specific requirements for approval. The IRB Protocol will include the research objectives, detailed methods (participant eligibility, study procedures, and data analysis), quality control and assurance, ethics/projection of human subjects, data handling and record keeping, background and significance in light of potential risks to participants, and will emphasize research ethics and participant safety. Upon approval of the IRB application by both the External IRB and Internal IRB, the Foundation will issue an official letter of support for the Research project to be included with the IRB Protocol submission. Note, all amendments to the IRB Protocol must be submitted for approval to the University's IRB. Participant recruitment cannot begin until both External IRB approval if required and Internal IRB approval are received. When awaiting approval, develop the Clinical Protocol, gather supplies and train the team carrying out the work.

D. **Standard Operating Procedures and Clinical Protocols.** Prior to commencing any Research Project, the Foundation's Research team, in collaboration with the applicable services team, will prepare the official "Clinical Protocol," a detailed manual governing the clinical operations, protocols, policies, and standard operating procedures for carrying out the Research project in accordance with

the Research and Evaluation Plan and approved IRB Protocol from start to finish, which will be the Lotus House Team's guide to completing the project. The Clinical Protocol will include standard operating procedures compiled into a "how to" manual ("SOPs"), including the purpose of the study, methods and procedures (methods and instructions for recruitment (inclusion and exclusion criteria) and retention strategies, interviews, standard interviews and methods), clarification of terminology if needed, required equipment and supplies, credentials and training required. The Clinical Protocol will also include SOPs for the following:

a. a data safety, management and monitoring plan in accordance with the Foundation's HIPAA Manual, with special assurances for data integrity, collection, who will have access to data, data sharing, preservation and analysis, breach, and safety of participants;
b. a detailed staffing plan (including credentials and training) and summary and assignment of duties;
c. a plan to consistently record and track deviations from protocols when methods are not followed or in unanticipated circumstances and a plan to record adverse events, in both cases with possible IRB notification (define adverse events for purposes of the study), protocols for addressing deviations and adverse events, reporting protocols, actions taken and ways to minimize future deviations, including for continuous learning, and possible IRB notifications and protocol amendments;
d. a plan for quality control and assurance, staff training and treatment fidelity, to ensure consistent treatment, tracking data to its source, who collected and when and regular analysis of treatment data, assuring accuracy and completeness of data, treatment fidelity checks, regular research and study team meetings, ongoing monitoring and auditing, systematic controls, regular analysis, third party statistical analysis, accountability, misconduct prevention (establish appropriate systems; discuss issues and solutions at staff meetings; implement quality improvement systems, such as secondary data review and/or double data entry, source final and aggregate data review to monitor and catch errors); and reporting protocols, and enforcement;
e. provisions in the plan for cultural, ethnic and racial sensitivity and humility in means and methods, participant recruitment, engagement, and feedback strategies;
f. a regular data analysis and evaluation plan; and
g. a consort where appropriate, a table demonstrating how participants move through the study, when and why dropout is occurring, and whose data remains in the final set; it is often used to evaluate the scientific quality of a study.

The Research Plan, IRB Protocol and Clinical Protocol, including the SOPs, will be maintained on a shared drive for ready access by the Lotus House Research Team.

IV. IMPLEMENTATION AND MONITORING

The Research Plan, IRB Protocol and Clinical Protocol (including all SOPs) will guide the Foundation's conduct of high quality, service driven research to assure delivery of services for sheltered women and children with fidelity and at the same time, accurately and completely assess, record, review, and analyze outcomes for continuous improvement and further dissemination. The Research Team as a whole is responsible for ensuring that the detailed procedures and protocols for the study are adhered to at all times and properly monitored for quality assurance and to prevent and identify errors and potential misconduct, as well as timely, complete and accurate data management, tracking and reporting. Regular meetings of the Research Team will facilitate open discussion and communication of issues and concerns. The Foundation's Principal Investigator shall be responsible for investigating any adverse events or misconduct and making any required reports with the University Co-Principal Investigator to the Internal IRB and External IRB, as well as filing any amendments to the IRB Protocol.

V. DISSEMINATION AND CLOSE OUT

All grant reporting shall be performed by the Research Team in collaboration with the Community Outreach and Grant Management Team, subject to the review and approval of the Foundation's Principal Investigator, Director, Executive Director and President of the Board.

Additional dissemination of results will be made in accordance with the Research Plan for each study, in collaboration with the applicable University Co-Principal Investigator as applicable for scientific and academic papers, and subject to the review and approval of the Foundation's Internal IRB, Principal Investigator, Director, Executive Director, and President of the Board.