### A. SPECIFIC AIMS

Oklahoma's Maternal, Infant, Early Childhood Home Visitation (MIECHV) Expansion project has two primary branches of evaluation, the *internal* evaluation conducted by the Oklahoma State Dept. of Health (OSDH) and the *external* evaluation conducted by the OU Health Sciences Center, Center on Child Abuse and Neglect (CCAN). This current proposal describes the external evaluation which uses a mixedmethod (quantitative/qualitative) approach to inform and evaluate change in five specific targeted areas identified for improvement:

- 1) *Systems Coordination*: Evaluate the impact of existing and developing coordination between EBHV programs and other support services.
- 2) *Program Marketing*: Inform, develop, and evaluate the outreach efforts of MIECHV-funded marketing.
- 3) *Client Enrollment and Retention*: Inform, develop, and evaluate new methods for engagement and retention of clients in EBHV services.
- 4) *Service Need*: Evaluate the overall need for child and family services within each community.
- 5) *HV Effectiveness and Improvement*: Establish a quality improvement and control system and evaluate effectiveness of the home visitation and early childhood services continuum.

These five targeted aims of the evaluation intersect with all four of the national MIECHV areas of relevance. The data obtained and evaluated will inform program planning and implementation (aims 1, 2, 3, 4, & 5), will evaluate effectiveness of planned strategies that are intended to enhance and sustain implementation (aims 1, 2, 3, & 5), will evaluate the capacity to support and monitor quality of scaled up evidence-based (EB) home visitation service continuum (aim 1), and will assess the effectiveness of home visitation on key outcomes that overlap with the national MIECHV benchmarks and constructs (aim 5).

### B. SIGNIFICANCE OF THE PROPOSED STUDY

**B1.** Background. On March 23<sup>rd</sup>, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010. The Act authorized the Health Resources and Service Administration (HRSA) and the Administration for Children and Families (ACF) to jointly administer the MIECHV Grants. In June 2010, Governor Brad Henry designated the OSDH to serve as the lead agency for all MEICHV grants and applications for the first round of MIECHV grants were submitted shortly thereafter. Grants that summer were awarded to all 56 states and territories. The original MIECHV Grant was designed to 1) to strengthen and improve the programs and activities carried out under Title V; 2) to improve coordination of services for at-risk communities; and 3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities. The long-term goal was a coordinated system of early childhood home visiting in every state that has the capacity and commitment to provide infrastructure and supports to assure high-quality, evidence-based practice.

A second round of *competitive expansion* MIECHV grants were devised with the intent to award additional funding to states that have sufficiently demonstrated the interest and capacity to expand and/or enhance their evidence-based home visiting programs. These grants recognize states that have already made significant progress towards implementing high-quality home visiting programs as part of a comprehensive early childhood system and are ready to take programs to scale. The OSDH applied, with support from CCAN staff (who agreed to act as the independent evaluators of all *competitive* MIECHV *expansion* activities), for this grant in the summer of 2011 and was awarded a grant in the fall of that year.

Over the years, home visiting in Oklahoma has proven successful in supporting at-risk families. However, downturns in the economy and shrinking state revenues have taken their toll on home visiting budgets. Most Oklahoma home visitation programs have had budgets reduced in the early 2000's as well as these past three years. Still, Oklahoma has a proven track record with home visitation and the Oklahoma State Legislature continues to invest in home visiting – even when general revenues have declined. OSDH and other local agencies are constantly seeking to improve the quality of home visiting services and now enthusiastically share their knowledge and expertise relating to best practices. CCAN Staff contribute to the field by way of their research and publications and is one of the 17 Federal Evidence-Based Home Visitation Grants awardees.

It is true that Oklahoma is a relatively poor state and has its share of challenges related to the health and well-being of young children and their caregivers. Yet, Oklahoma's home visitation professionals will do their utmost to assure that a Maternal, Infant and Early Childhood Home Visitation (MIECHV) *Expansion* Grant Award would improve the quality and quantity of services offered to families and ultimately improve the lives of many within our state.

**B2.** Expansion Counties. Oklahoma began preparing for the MIECHV Grant in the spring of 2010. The potential to receive federal funds for home visiting became a constant agenda item on the Interagency Child Abuse Task Force (ITF) and the Home Visitation Leadership Advisory Coalition's (HVLAC) meeting agendas. Prior to the actual collecting and analyzing of the needs assessment data, the ITF and HVLAC agreed that the following criteria must be present within an at-risk community in order to expand or initiate home visiting services with MIECHV Grant funds:

- The at-risk community must have at least 10,000 residents.
- The at-risk community must have at least one operating home visiting program.
- Substance Abuse, Domestic Violence and Mental Health services must be available in the at-risk community.
- Smart Start Oklahoma must be present in the at-risk community.
- [During the spring of 2011, the requirement of a Child Guidance Team was added.]

The OSDH Title V Maternal and Child Health Assessment Division, with assistance from the MIECHV Grant Evaluation Advisory Group, conducted the MIECHV needs assessment. They first designated the administrative subdivision of "county" as the geographic area to represent an "at-risk" community. The required MIECHV indicators were then compiled for each of the 77 counties. A county level rate was computed for each of the indicators. Risk indicators held equal weight in the average risk ratio computation. The average risk ratios were ranked to reveal the counties' relative position among all counties within the state.

Of the top ten counties ranked with the highest of needs, two counties did not have populations of 10,000 or more. Their removal from the rankings moved McClain and Tulsa Counties into the top ten for consideration. County data profiles were developed for each of the counties ranked in the top ten. The original MIECHV Grant funding and efforts are dedicated to the counties falling first and second in the county rankings: Kay and Garfield counties. For the MIECHV Expansion Grant, the remaining eight counties were considered. Four of these eight counties met the earlier agreed upon MIECHV Grant criteria: Comanche County, Muskogee County, Oklahoma County, and Tulsa County.

**B3.** EBHV Models. The three evidence-based home visiting models selected for either MIECHV implementation or expansion are:

*Nurse-Family Partnership* known in Oklahoma as Children First, is a voluntary program that serves lowincome, first-time mothers and their children by providing nurse home visiting services during early pregnancy and continuing through the child's first two years of life. The NFP Logic Model lists three program goals. Those goals are:

- To improve maternal health and pregnancy outcomes;
- To improve children's health and guide parents to competent care giving; and
- To improve economic self-sufficiency of families.

*Healthy Families America* is a voluntary program that initiates services prenatally or before a newborn turns three months. The model is designed for over-burdened families with risk factors for child maltreatment. HFA program goals include:

- To systematically reach out to parents to offer resources and support;
- To cultivate the growth of nurturing, responsive, parent-child relationships;
- To promote healthy childhood growth and development; and
- To build the foundations for strong family functioning.

*Parents as Teachers* is a voluntary home visiting program with no set income or risk-factor eligibility requirements. Eligibility is based only on the age of the child. Typically, home visits and group meetings are provide once a month. The PAT model has four primary goals:

- To increase parent knowledge of early childhood development and improve parenting practices;
- To provide early detection of developmental delays and health issues;
- To prevent child abuse and neglect; and
- To increase children's school readiness and school success.

#### **B4.** Logic Model for Change.

The logic model below will be used as a device to guide and organize the external evaluation efforts. All specific aims of the evaluation are embedded within this model. These connections are further elaborated in our *Data Analysis* section (see C6 below).

Assumptions	Inputs/Resources +	Activities	→	Outputs	≁	Short-term Outcomes	→	Long-term Outcomes	
EBHV programs target different outcomes		Revamp referral, intake, triage processes	$\rightarrow$	Central, electronic referral, intake, triage system	<b>→</b>	Interagency MOUs, universal & central referral system	<b>→</b>	↑ efficiency & strengthen match of client to EBHV	Air
Overall MIECHV program outcomes are		EBHV interagency coordination	$\rightarrow$	Est. local EBHV coalitions	$\rightarrow$	Agency meetings, peer-learning	$\rightarrow$	Strengthen client service continuum	1 1
ennanced when program activities are targeted at neediest	OK MIECHV staff & consultants	Dedicate local EBHV ambassadors	+	Est. community connector agencies	→	Interagency MOUs, hire connectors	→	↑ awareness & use of EBHV	
populations	Funding: MIECHV federal agencies	Marketing campaign	$\rightarrow$	Est. professional ad campaigns	$\rightarrow$	Radio, TV, web, print, street ads	<b>→</b>	↑ awareness, appeal, use EBHV	∫ 2
Problem	Counties: Comanche, Muskogee, Oklahoma, Tulsa	Expansion of EBHV	$\rightarrow$	Increase providers, programs, capacity per county	$\rightarrow$	Increase clients served per county	<b>→</b>	Greater impact leads to further state expansion	
Statement EBHV programs have greatest impact in high risk communities	Programs: C1, OCAP, OPAT EBHV models: NFP, HFA, PAT	New EBHV enrollment & retention strategies for clients and staff	<b>→</b>	<ul> <li>↓ staff turnover &amp;</li> <li>↑ professional</li> <li>development;</li> <li>↑ # families served,</li> <li>graduating, &amp;</li> <li>meeting EBHV goals</li> </ul>	<b>→</b>	Establish best practices on EBHV enrollment & retention	$\rightarrow$	<ul> <li>↑ maternal &amp; child health, school readiness, economic self-sufficiency;</li> <li>↓ child injuries, abuse, neglect, ER visits, domestic violence</li> </ul>	Aim 3
	State Collaboration: county agencies, model developers, implementation agencies, Smart Start, Child Guidance, Community Connector	Community Needs Assessment	<b>→</b>	Psycho-social assessment data	<b>→</b>	Survey instrument developed and disseminated to potential EBHV clients	<b>→</b>	Report on service needs for home visitation, developmental delays and autism, child sexual behavior problems, school readiness	Aim 4
	agencies, MIECHV CoP- E Communities Other local supports	Evaluate effectiveness of EBHV	<i>→</i>	Quasi-experimental comparison of MIECHV benchmarks & constructs	<b>→</b>	Baseline benchmark & constructs data col- lection of community comparison group and EBHV clients	<b>→</b>	EBHV effectiveness findings on benchmarks & constructs	Air
		Other system improvements: Staff trainings, fidelity monitoring, quality assurances	<b>→</b>	Q.I. feedback loop to stimulate & inform EBHV system improvements	<b>→</b>	Survey, focus group & qualitative interview data on desired system improvements	$\rightarrow$	Est. Q.I.Q.C. evaluation system; increased workforce competence	J J J

# Figure 1. Oklahoma MIECHV Expansion Program Logic Model

### **B4.** Planned MIECHV Activities.

*Expansion of EBHV.* Evidence-based home visiting models that were chosen for expansion include: Nurse-Family Partnership (NFP); Healthy Families America (HFA); and Parents as Teachers (PAT). Each of these models has been utilized in Oklahoma for over a decade. Additional NFP nurses will be added through county health departments. *Invitations to Bid* will be released so that existing HFA programs have the opportunity to acquire more home visitors or agencies can initiate HFA programs. The Oklahoma Department of Education will establish new contracts or increase existing contracts with school districts to further their reach with the Parents as Teachers programs.

A Central, Electronic Referral, Intake, and Triage System. Through consultation with the New Jersey State Department of Children and Families and the Johns Hopkins MIECHV evaluation personnel, OSDH and CCAN evaluation teams have been planning the creation and implementation phases of a centralized referral, intake, and triage system. The creation of a universal EBHV referral form is nearing completion, and plans to establish Memorandums of Agreement and/or Understanding from community service agencies and a Release of Information form allowing family contact information sharing are underway.

Future planned phases of development include the establishment of an electronic referral and triage system. This data system will be modeled after the New Jersey system and will house a database schema that is flexible, scalable, and thoroughly adaptable to the variety of data scenarios we anticipate capturing. Initial development will center on storage and capture of focal client referral fields (gathered from the universal referral form), an automated triage decisional alert system that translates referral information into new specific agency referrals (a tree-diagram of the triage decisions is a planned outcome of MIECHV evaluation), and basic client contact information, engagement, and recruitment outcome information for tracking purposes. A layered system is envisioned with a database at the bottom layer, a business logic triage decision tool at a middle layer, and a GUI user front-end and reporting system at the top layer.

*Community Connector Agencies.* Smart Start Oklahoma (a public-private entity focused on school readiness) and the Tulsa County Department of Health have received MIECHV-sponsored funds to serve as community "connectors." Because of their expertise in early childhood and community development, they are in a fine position to market the home visiting programs; assist with the triaging of referrals; and facilitate coordination and collaboration between all types of services and programs. The goal is to assure that families participate in the home visiting program, as well as other resources, that best meet their needs. Connectors will assure that home visiting programs are knowledgeable about existing supporting services in their county by routinely hosting network meetings and thereby increase the number of appropriate referrals made to such supporting services by home visitors.

*Local Coalition Between All Home Visiting Programs*. A coalition in Oklahoma County is already underway and will meet routinely to discuss services aspects of each program, possible staffing of difficult cases, and strong focus on transitioning families to other services as program eligibility and demands dictate. Coalition establishment in the other three expansion counties are soon to follow.

A System Marketing Intervention. OSDH and CCAN, in partnership with local a marketing firm, have been planning a series of new marketing strategies that will begin to be implemented in the expansion counties at the end of year 1. These marketing efforts will include public service announcements, commercial television and radio advertisements, and print media.

Furthermore, as an Evidence-Based Home Visitation (EBHV) grantee, CCAN has pulled together a variety of professionals, mostly affiliated with home visiting, to explore and develop efforts to sustain EBHV Grant activities. Just recently, that same group voted to extend it mission beyond the EBHV Grant specifically and include all evidence-based home visiting programs within Oklahoma. The group will now be expanded to include representation from more existing models and other stakeholders. The EBHV Sustainability Group has chosen marketing of home visitation services to be a top priority.

*New Strategies to Increase EBHV Enrollment of Families.* New strategies are currently being developed in partnership with the OSDH internal and CCAN external evaluation teams. These plans will be disseminated routinely throughout the project as new data informs best practices.

*New Strategies to EBHV Retention of Families.* New strategies are currently being developed in partnership with the OSDH internal and CCAN external evaluation teams. These plans will be disseminated routinely throughout the project as new data informs best practices.

*Other Systems Improvements.* Planning committees will continue to convene throughout all years of grant activity to both map out the implementation plans for the innovations above but also develop new ideas based on evaluative measures for other potential system improvements. Preliminary discussions are anticipated to cover management of human resources, interagency coordination efforts and education, and provider training in enhanced client engagement techniques (e.g., motivational interviewing).

**B5.** Preliminary EBHV Evaluation. CCAN has a long history of providing independent evaluation as well as training and technical assistance (T/TA) with state and nonprofit agencies to systematically develop, evaluate, and enhance evidence base programs with field trials examining efficacy, effectiveness, and implementation and dissemination questions. These efforts include examining primary, secondary, and tertiary prevention programs (primarily home visitation programs) targeting prevention of child maltreatment. Some of these efforts most relevant to the current application are described below.

CCAN led a statewide evaluation of Oklahoma family support programs from 1996 to 2000, evaluating 74 separate service programs operated at 28 sites. Pre-intervention and post-intervention data were collected on over 1,600 participants in these programs, and over 150 site visits were made, including accompanying front-line staff on over 95 home visits. The published article<sup>1</sup> describing results of this multisite evaluation was awarded the Pro Humanitate Literary Award for 2002 by the North American Resource Center on Child Welfare.

CCAN recently completed an NIMH funded (Chaffin PI; 5R01MH065667-01A1) statewide siterandomized study of tertiary prevention home visitation programs which experimentally manipulated both the intervention model (the SafeCare model vs. standard social support and case management) and also experimentally manipulates a critical aspect of dissemination and implementation strategy (presence vs. absence of an ongoing trainer/monitor deployed by CCAN to accompany front-line home visitors). We obtained multi-wave outcome data on over 2100 families served within this service system over the past four years. (It is important to note that prior to the initiation of the NIMH study, we collected service and family data from the service agencies on over 4500 families, which included data on from the home visitors on visits, and family risk and protective factors). The scope of this project required tight integration between CCAN (as the coordinating center), the state agency funding the service programs, and the provider agencies to coordinate data collection and develop a workable data collection, monitoring and management strategy. The results of this statewide study and related implementation study using qualitative and quantitative mixed methodology (Aarons PI; R01MH72961) include important implications for work force (such as, significant lower job turnover rates of home visitors trained in SafeCare with ongoing consultation<sup>2</sup>) and child maltreatment outcomes.<sup>3-5</sup>

For this NIMH statewide study, CCAN successfully partnered with service agencies throughout the state for purposes of data collection. We successfully contracted with the service agencies to hire data collectors that were locally based, while CCAN maintained responsibility for training them and providing oversight on their data collection efforts. We met monthly with the data collectors at CCAN in order to get the data from their computers, get the consent forms, and troubleshoot any difficulties they may be encountering. During the 5 years of the study, there were no major difficulties with these arrangements.

CCAN has conducted multiple RCTs examining EBHV for child abuse prevention in high risk families (parent with history of domestic violence, mental illness, and/or substance abuse and child 5 years or younger). In the urban and rural RCT of SafeCare (SC) (funded by OKDHS, CDC R49 CE000449-01, and OJJDP 2006.JP.FX.0067) we (a) successfully recruited families from a variety of referral sources, enrolled, and maintained them in SC services at a rate significantly better than the control condition, (b) collected multiple waves of data on participants regardless of service attrition conducted by independent data collectors with computerized interview administration (c) assessed and maintained excellent fidelity to the SC model, (d) examined the Integrated Theory of Parent Involvement<sup>6</sup> to examine client enrollment and retention factors, (e) matched participant with Oklahoma child welfare data to examine child maltreatment reports, and (e) and examined changes in risk and protective factors as well as child welfare outcomes.<sup>7,8</sup>

Drs. Bard and Silovsky are currently involved with Oklahoma's EBHV grant with ACYF Evidence-Based Child Maltreatment Prevention for High Risk Families: Expanding to Latino Communities, Enhancing Family Violence Prevention, and Sustaining Prevention Programs and the State's MIECHV Competitive Grant. The EBHV grant has three overarching aims: (1) address chronic un-met contextual needs of families served in home visitation programs. To achieve this, we have culturally adapted the SafeCare program to fit the culturally diverse Oklahoma communities and developed a healthy relationship curriculum to address the prevalent Intimate Partner Violence (IPV) reported among almost a third of all families in the Child Welfare System. The preliminary results of our ongoing evaluation show overwhelming acceptance, adapt fidelity in training and satisfaction by families trained in the curriculum, (2) pilot and evaluate the efficacy of appropriate service triage in addressing risk and needs of high risk families. We are using rigorous study designs to address risk as a continuum (using a hybrid regression discontinuity/RCT design) and the variants of service approach and scope to address identified risks (Factorial RCT design) and (3) development of a sustainability infrastructure for the widespread adoption, implementation and sustenance of evidence-based child abuse and neglect prevention programs for families with high risk factors (such as, family violence, substance abuse, and mental illnesses). A committee was established in 2008 and currently leads efforts in planning the investment of Federal, State, local and private funding streams for EBHV programs and promotion of greater coordination of related service delivery systems in order to expand and enhance the existing

services. This committee recently voted to expand the focus of the committee to include efforts under Oklahoma's MIECHV grant and has the potential for further expansion to include the proposed grant given the critical role housing plays in the overall well-being of children and families.

Also integral to this project, is the empowerment of families served through their participation in an advisory role as a board/committee. The community/family advisory group is a part of the planning committee of the project and their input is regularly sought to guide the implementation of the project activities. The feedback from these families has been critical to the successes of this grant and would greatly benefit the proposed housing grant as well.

Thus, the CCAN team has been a long track record of successful (a) engagement of urban and rural field agencies in evaluation and research, including agencies currently providing Healthy Families (OCAP) services, (b) collection of data with independent data collectors as well as from field staff including service providers, (c) retention of families in longitudinal field research, (d) establishment of data sharing agreements with OSDH, OKDHS, and OHCA, (e) collaboration with state agencies, nonprofit agencies, and legislative staff, (f) conducting mixed methods and implementation research, (g) successful compliance with cross-site data requirements, and (h) dissemination of findings in reputable peer-reviewed journals.

### C. RESEARCH METHODS AND DESIGN

<u>**C1.**</u> Evaluation Overview.</u> The proposed study will use a mixed-method (quantitative/qualitative) approach to inform and evaluate change on the five targeted aims identified. The evaluation methods used are uniquely designed to assess the epidemiology of disadvantaged early childhood populations in each of the four counties, identity system innovations of potential beneficial impact, and assess effectiveness of implemented system level changes. Data collected for evaluation will cross all four MIECHV areas of relevance, will be obtained from a diverse set of sources, and will provide rich, informative guidance about strengths and weaknesses of home visitation and comprehensive early childhood systems operations. Subaims of each the targeted areas are listed below.

- 1) Evaluate coordination between home visitation programs and other support services.
  - a. Reduction in duplication of services for any particular client
  - b. Develop timeline and analytic covariates that chronicle major program events
    - i. Record successful establishment of a centralized referral/triage system
      - ii. Assess frequency of home visitation coalition meetings
      - iii. Record the successful establishment of Connectors in each county
      - iv. Record frequency of *Connector* initiated network meetings
      - v. Record number of Memorandums of Agreement and/or Understanding between local services
  - c. Evaluate the frequency of referrals coming into EBHV agencies
    - i. Evaluate pre and post changes attributable to triage and connector agency establishments
- 2) Evaluate outreach effort of MIECHV-funded marketing strategies
  - a. Survey large sector of eligible population for knowledge, use, and appeal of EBHV services
  - b. Identify marketing successes/failures among client focus group participant responses

- 3) Evaluate engagement and retention of clients in EBHV services
  - a. Continually evaluate the flow of clients served per county
  - b. Identify reasons for low engagement in services
  - c. Examine provider barriers to program implementation with families that do not engage
  - d. Evaluate effectiveness of new engagement enhancement strategies
  - e. Identify reasons for attrition from services
  - f. Evaluate effectiveness of new retention strategies
- 4) Evaluate overall need for child and family services among disadvantaged early childhood populations within each community
  - a. Epidemiologic assessment of home visitation services need
  - b. Epidemiologic assessment of developmental delays
    - i. Includes psychometric evaluation of screening instruments for Autism
  - c. Epidemiologic assessment of child sexual behavior problems
  - d. Epidemiologic assessment of child abuse and neglect potential
    - i. Includes psychometric evaluation of new abuse & neglect predictive measures
- 5) Establish a quality improvement and control system and evaluate effectiveness of the home visitation and early childhood services continuum
  - a. Compare EBHV and Community for targeted MIECHV benchmarks and constructs from EBHV clients
  - b. Identify system improvements and necessary quality controls through client focus groups, staff and leadership qualitative interviews, and expert systems consultations
  - c. Implement and evaluate system of quality improvements and controls

#### C2. Data Sources

The majority of the project's information comes from three sources: 1) agency records, 2) qualitative interviews, and a 3) longitudinal community survey.

*Agency Records.* The same data collection plan devised in the 2011 Oklahoma formula MIECHV award SIR will be extended to the four counties proposed. The plan calls for client self-report interviews during actual home visits and select provider entered electronic case-file records. Client self-report data will be collected using paper-pencil forms onsite and later hand-entered into each agency's electronic database. CCAN has had regular meetings with OSDH evaluation team to examine strategies to accurately and routinely collect data via home visitors that (a) meet MIECHV benchmark requirements, (b) meet local and national EBHV requirements, and (c) is efficient and minimized burden to the provider. Data from this source will be used to inform specific aims 1, 3, and 5.

OSDH and the evaluation team will be working with agency IT personnel in the first years of project involvement to ensure data capture methods meet project quality standards and to adapt existing database architecture to handle new fields required for benchmark assessments. These methods will require a monitored query system to extract benchmarked data from agency data systems into designated tabled formats and migration of these data, quarterly, to the OUHSC evaluation site. A data sharing agreement has been established between OSDH and CCAN for exchanging this data.

*Qualitative Interviews.* Data from the focus groups with clients and individual qualitative interviews from providers, supervisors, agency directors, and state EBHV leaders will inform specific aims 2 and 3. Groups will be organized and run throughout the entirety of project funding. Six to nine participants will be selected and recruited by phone for each focus group, and a total of 8 focus groups per county are planned for each of years 2 and 4. Approximately 42 EBHV providers/directors/supervisors will be selected for an individual, one-on-one interview during each of years 2 and 4. We intend to interview one EBHV regional leader from each of the expansion counties in years 2 and 4.

All focus group discussions will be moderated by a skilled facilitator. Groups will be held at locations to be determined in consultation with OSDH, the program supervisors, and state leaders. Each focus group discussion will last for roughly 1 to 1.5 hours and will be audio recorded. Transportation to the meeting place will be provided as well as child care. All home visitor client focus group participants will be reimbursed for time and travel (\$30 shopping gift card). Non-State employee provider and agency participants will be reimbursed for time and travel (\$10 gas and \$20 shopping gift card or \$30 shopping card). Per Oklahoma State law, we are unable to reimburse State employees for study participation.

Community Survey. The survey interview data will inform specific aims 2, 3, 4, and 5. This interview sample will provide data that serve a multifaceted role in the evaluation of system success and inform future enhancement efforts. First, the data will be used to study the epidemiology of client needs in each of the four project counties (Oklahoma, Tulsa, Muskogee, and Comanche). A good understanding of the epidemiology of the problems uniquely facing each county will be required in order for appropriate service innovations to be devised and implemented. Second, the sample provides an unprecedented look at access-to-care issues for disadvantaged child populations. We will be able to assess, for example, breadth and depth of system-level reach among its core consumer populations. The longitudinal nature of this sample will further allow analysis of change in system reach, an aspect key to evaluation of proposed expansion and enhancement efforts. This sample will also be closely examined for evaluation of improvements in all identified problem areas. For example, the size of this sample in each county will allow for self-reported system involvement outcomes to supplement our administrative and focus group data on EBHV awareness, triage success, engagement, retention, continuum of care, and program effectiveness. We believe this aspect of our project significantly enhances the rigor of our evaluation and the value of the data obtained. To further enhance rigor, a randomized encouragement intervention will be used to provide yet another means for assessment of EBHV effectiveness. At the completion of each baseline interview, participants who are randomized to an encouragement condition will receive information about the EBHV options available in their community; and, should the participant agree, he/she will also receive referral assistance by our data collectors (data collectors will phone the local community connector before leaving the home). This type of encouragement design will allow us to draw intent-to-treat inferences about changes related to this low-level form of client recruitment/marketing and also inferences about EBHV effectiveness via instrumental variable analysis. More details on these design aspects are included in the Data Analysis section C6 below.

All enrolled participants will be followed for the duration of the project with scheduled annual longitudinal interviews (expected 2-hour administration) to follow our initial baseline assessment. Data collectors in Tulsa and Oklahoma counties will be hired as full time employees and will be expected to enroll approximately 225 new participants in each project year (including year 1). New data collectors will be hired in those counties on an as-needed basis as longitudinal assessments begin to accumulate. We plan for data accrual in the smaller populated Muskogee and Comanche counties to be half the rate of the other two counties, so only part-time data collectors in these counties will be required in the first few years of the project. Muskogee and Comanche data collectors will gradually increase percent effort of employment each year as the longitudinal assessments and new participant interviews require.

# C3. Participant Recruitment

*EBHV Agency Records.* Data will be collected via usual service outcome procedures involving paperpencil client-report responses during home visitations and routine provider reports on case status and outcomes. Data will be transferred electronically to OSDH and the evaluation team as described above under Data Sources. This data will only be available on clients who were recruited for and clients who enroll in one of the three MIECHV EBHV programs.

Qualitative Interviews: Home Visitation Clients. The proposed study will use purposive sampling procedures to select focus group participant.<sup>9</sup> The participants will be identified from a list of referred families in MIECHV EBHV programs. Home visitor logs will used to divide the parents into two categories: a) those who have successfully engaged in services and b) those that have not successfully engaged in services (failure to enroll as well as service attrition). These groups will be furthered cross-sectioned into high and low at-risk groups and urban and rural residential locales. Six to nine participants will be randomly selected (using a random number generator) for each focus group, and a total of 8 focus groups per county are planned for each of years 2 and 4. Parents will be invited by phone to participate in the study by the qualitative research consultant (Lana Beasley) or a member of the evaluation team.

A potential difficulty in focus group research includes barriers of participants to attend focus groups. Plans to address these barriers include providing (a) gas cards for transportation (\$10), (b) child care during the focus groups as well as children's activities, and (c) reimbursement for time spent in the focus group (\$20 gift cards). Other barriers include participant comfort level in sharing their experiences which will be addressed through (a) holding focus groups at a non-threatening location (community center, church, etc.), (b) grouping participants by program experience (i.e., engaged vs. unengaged), (c) providing refreshments, and (d) discussing importance of confidentiality at the onset of each focus group.

*Qualitative Interviews: Providers and State Leadership.* Home-based provider participants will be identified from a list of current and past HFA, NFP, and PAT employees. Providers from potential referral agencies will be selected randomly from a list of employees identified by each county's SSO office. Both types of provider pools will be stratified by agency urban and rural locales. Approximately 21 HV providers and 21 referral providers will be selected for an individual interview during each of

years 1 and 4. Providers will be invited by phone to participate in the study by Dr. Beasley or a member of the research team. Agency and state leadership informants will be identified through the Sustainable Implementation Committee and Home Visiting Coalition Planning Committee. We intend to interview one leader from each of the expansion counties in years 1 and 4.

A potential difficulty when conducting individual interviews is provider comfort level in sharing their experiences which will be addressed through (a) holding individual interviews at a neutral or private location and (b) discussing that information will not be shared with their current and/or past employer. Another difficulty includes acquiring the proposed number of providers for individual interviews. To address this issue the research team will provide compensation for their time spent in the individual interview (\$30 gift card).

*Community Survey.* In cooperation with the Oklahoma Health Care Authority and the OSDH, a random sample of participants from Medicaid and Women Infant and Children (WIC) records will be selected for longitudinal follow-up throughout project duration. The sampling procedure will involve stratification of participants by criteria germane to each of the three OSDH recognized EBHV programs (the Nurse-Family Partnership model provided by OK's Children First program, the Healthy Families America model provided by the OSDH Office of Child Abuse Prevention (OCAP) Start Right program, and the Oklahoma Parents As Teachers programed offered by the ODE) . Specifically, within each county, we will sample the following Medicaid-enrolled strata: 1) first-time mothers who are either pregnant or have given birth within the last 6 months; 2) women with a first child between 6 and 12 months of age and women who are either expecting or have given birth to a 2<sup>nd</sup> or subsequent child who is less than 12 months of age; and 3) families with a child between the ages of 12 and 36 months of age. Selection probabilities within counties will be equal across each stratum so that pregnant women (a key catchment group for our longitudinal continuum of care aims) are oversampled. Sampling weights will be generated based on population strata size and sampled strata size.

The anticipated sample sizes are 900 per Oklahoma and Tulsa County and 450 per Muskogee and Comanche county (for a grand total of 2,700 participants). Assuming 20% sample attrition per year, we anticipate completing a total of 5,530 interviews (2,700 baseline interviews + 2,830 follow-up interviews).

Recruitment pools will be constructed by evaluation team staff based on monthly queries of eligible participants from Medicaid and WIC data. Data sharing agreements are in place for both of the recruitment data sources. Mailed study advertisements will be sent to all participants selected for recruitment. Respondents will be able to enroll immediately after receiving the study advertisement by actively calling an assigned data collector or by waiting for the advertised recruitment call from data collection staff. All evaluation analyses of this data source will adjust for stratification and unequal sample selection probabilities using complex sampling design software. The population inferences are intended to describe those on Medicaid or WIC who qualify for at least one of the three identified MIECHV EBHV programs. We acknowledge that Medicaid and WIC standing does not fully capture all possible EBHV consumers, but we do feel that this is reasonable high-risk catchment population that is likely to reveal significant areas of needed improvement, particularly with regard to marketing and

service engagement strategies. Recruited individuals will be excluded from this data collection effort when conditions prevent the primary caregiver from providing valid self-report data (e.g., severe psychosis, severe mental retardation, etc.).

### C4. Human Subjects

*Involvement of Participants.* Prior to research participant recruitment for the qualitative and quantitative data, approval from relevant Institutional Review Board (IRB) will be obtained. The evaluation team has a long history of successful application for IRB approval with OUHSC, state agencies (including OSHD), and field agencies (when needed). Research-related HIPAA requirements will also be addressed in IRB approval. A Certificate of Confidentiality for the family participant data will be requested. In addition, the following assurances will be adhered to: (a) participation is voluntary and consent can be withdrawn at any time without penalty, (b) clients who do not want to volunteer will not lose access to services, (c) participants will be informed of all foreseeable benefits and risks, (d) mandatory child abuse reporting and duty to warn requirements will be clearly articulated to the parent, and (e) data will be stored on a secure computer and/or locked file cabinet.

The project personnel will contact the prospective participant and arrange a meeting to explain the nature of the research project (the voluntary nature of participation, possible benefits and risks, the informed consent form, conformance with State mandatory reporting law) and solicit the prospective participant's agreement to participate in the study. If the prospective participant meets inclusion criteria and agrees to participate, an appointment for first wave assessment will be scheduled. At each data collection wave, participants in the study will be assessed using questionnaires and interviews via Audio Computer Assisted Self-Interview (ACASI) as described earlier. Participants will be surveyed in a longitudinal design on an annual basis. Each of the occasions will involve face-to-face contact to assist the participants with the computer-administered interview and will be conducted by project data collection staff. Data collectors will take care to conduct the interviews in a safe, private and respectful manner. All data collectors are trained in human research participant protections, participant rights and good practices. Participants will not be required to answer any specific questions and will be free to withdraw from the study at any time without penalty. Participants will be compensated with a \$40 gift certificate to a local shopping establishment (e.g., Wal-Mart) for each wave of data collection.

*Sources of Research Material.* Material obtained from identifiable participants will include questionnaires and interview material, using the instruments described earlier. The interviews will inquire into family's resource needs, parental depression and drug and alcohol use, and child rearing attitudes, relationships, emotional states and similar characteristics related parenting functions as well as the participant's service utilization and satisfaction with services. Observational scales coding home environment and parent-child interactions will be coded by the home visitors. Additional information will be obtained from OKDHS administrative database regarding case characteristics, information about child maltreatment reports, and information about removal of children from the home due to child maltreatment. MIS data obtained from the service agency includes dates of service episodes and any critical incidents.

*Recruitment and Consent.* Recruitment and informed consent will be conducted face-to-face by the onsite study coordinator or by the data collector. Participants will be provided with information about the study and their rights as participants as specified in the consent form. If necessary, the data collector will read the consent form to the participant, and will answer any questions the participant might have at a level the participant can understand. Consent will be documented by signature of the participant and signature of the data collector. The consent form and recruitment and consent procedures will be finalized, and can only be modified, after review by the IRBs. The consent form will provided a full explanation of activities, risks, benefits, voluntary nature of participation, right to withdraw without penalty, contact information for questions or to report problems, and assurances of confidentiality and other participant rights.

*Risks, Benefits and Alternatives to Participation.* Risks due to participation in the research include risk of emotional discomfort related to answering questions about personal matters, risks related to unauthorized access to research information, and mandatory child abuse reporting for anything directly witnessed by data collectors. Benefits are limited to adding to body of knowledge of identification, referral, and child and family outcomes over time.

Process for Minimizing Risk. Participants will be informed that they have the right to discontinue any interview or questionnaire at any time without penalty if they experience emotional discomfort, or for any other reason. Participants will have the right to skip individual questions. Short-term debriefing will be available for any client who reports experiencing distress. Information about clients will be protected and kept confidential at several levels. No data forms, except the consent form, will contain identifying information. These will be stripped from the data forms and stored separately under lock and key. Likewise, identifying information in computer databases will be stored separately from other data tables. Data tables will be stored on a controlled-access server requiring separate login and password, and granting access only to specific accounts. Self-report data collected in the ACASI interviews will not be shared with the service agency, the home visitor, or the state child welfare agency unless the client specifically requests it and the research project is satisfied that the request is legally sufficient, fully informed and voluntary. A Federal Certificate of Confidentiality will be obtained to protect against compelled release of information collected by the research project. Data collectors who observe circumstances that cause reasonable suspicions of abuse or neglect will comply with Oklahoma law on mandated reporting. Clients will be informed of this obligation during the informed consent process.

*Reasonableness of Risks in Relation to Benefits.* The potential benefits of the study for improving services to children and families at high risk for child maltreatment are significant. The findings could potentially have an impact on which services are delivered and their ultimate effectiveness. This could lead to improved outcomes for both parents and children. The risks of the study are limited to discomfort answering questions and risks related to a breach of the project's plan for maintaining confidentiality. Based on our similar studies conducted by the evaluation team, neither of these risks has been realized for any of our subjects to date.

### **C5.** Measured Outcomes and Measurement Schedule

*EBHV Agency Records*. The planned measures from this data source are summarized in Table 1 below. Home based service providers will receive training in data collection and coding the Child Well-being Scale (CWBS) measure, which is an observational scale of conditions in the home. Home visitors will also been trained on the collection and coding of the *ASQ-3 and the ASQ: SE, measures used to* screen children for developmental delays and monitor social-emotional behaviors respectively.

# Table 1. Summary of OSDH Benchmark Measurement Plan

Benchmark Category	Assessment Method	Specific Content	Evaluated Outcome Measure				
IMPROVED MATERNAL AND NEWBORN HEALTH							
Prenatal care	HV Intake forms	Existing items on frequency and start	% women receiving adequate				
		of prenatal visits	prenatal care				
Darantal usa of alsohal, tobassa, ar illisit	HV/ Salf report	Items on frequency and quantity of	% of participating parants				
	interviews	tobacco smoking	% of participating parents				
Preconcention care	HV Intake forms	Self-reported preconception training	% women received Am College of				
		and education that meets ACOG	OB/GYN recommended training				
		quality standards	and education				
Inter-birth intervals	HV Self-report	C1 update form items- extended to	Hazard rate curves for each				
	interviews	Start Right and PAT	cohort				
Screening Postnatal Depressive Symptoms	HV Self-report	Edinburgh Postnatal Depression	% women screened for				
	interviews	Inventory	depressive symptoms				
Breastfeeding	HV Self-report	C1 demographics forms- extended to	% women who initiate				
	interviews	Start Right and PAT	breastfeeding				
Well-child visits	HV Self-report	C1 well-child visit form and Start	% children receiving well-child				
	interviews	Right Health form- extended to PAT	visits per Am Acad of Peds				
			recommendations				
Maternal and child health insurance status	HV Self-report	C1 demographics forms and Start	% women and children who have				
	interviews	Right Health forms- extended to PAT	health insurance				
CHILD INJURIES, CHI	LD MALTREATMENT AND	REDUCTION OF EMERGENCY DEPARTN	IENT VISITS				
Visits for children to the emergency	HV Self-report	ER visit items from weekly visit	% children emergency				
department from all causes	interviews	update forms	department visits from all causes				
Visits for mothers to the emergency	HV Self-report	ER visit items from weekly visit	% mother emergency				
department from all causes	interviews	update forms	department visits from all causes				
Information provided or training of	HV Self-report	C1, Start Right update form items-	% participants who receive				
participants on prevention of child injuries	interviews	extended to PAT	education and training on topics				
			related to preventing child				
			injuries (Family Safety Topics)				

Benchmark Category	Assessment Method	Specific Content	Evaluated Outcome Measure
Reported suspected maltreatment for children in the program (allegations that were screened in but not necessarily substantiated)	Match to OKDHS child maltreatment databases	Screened in reports of child maltreatment from OKDHS	Rate of suspected maltreatment for children participating in the program
Reported substantiated maltreatment (substantiated/ indicated/ alternative response victim) for children in program	Match to OKDHS child maltreatment databases	Substantiated reports of child maltreatment from OKDHS	Rate of substantiated maltreatment reports for children participating in the program
First-time victims of maltreatment for children in the program	Match to OKDHS child maltreatment databases	Screened in first-time reports of child maltreatment from OKDHS	Rate of first-time victimization of children participating in the program
	SCHOOL READINE	ESS AND ACHIEVEMENT	
Parent support for children's learning and development (e.g., having appropriate toys available, talking and reading with their child)	HV Provider report	Items from the Child Well Being Scale	Subscale Scores from the Child Well Being Scale
Parent knowledge of child development and of their child's developmental progress	HV Provider report	Items from the Child Well Being Scale	Subscale scores from the Child Well Being Scale
Parenting behaviors and parent-child relationship (e.g., discipline strategies, play interactions)	HV Provider report	Items from the Child Well Being Scale	Subscale scores from the Child Well Being Scale subscales
Parent emotional well-being or parenting stress	HV Provider report	Items from the Child Well Being Scale	Summary scores from the Child Well Being Scale subscales
Child's communication, language and emergent literacy	HV Self-report interviews	Ages and Stages Questionnaire (ASQ- 3)	% children transitioning from "delayed and need referral" to "on-time"
Child's general cognitive skills	HV Provider report	Ages and Stages Questionnaire (ASQ- 3)	% children transitioning from "delayed and need referral" to "on-time"
Child's positive approaches to learning including attention	HV Provider report	Ages and Stages Questionnaire: Social-Emotional (ASQ:SE)	% children transitioning from "delayed and need referral" to "on-time"

Benchmark Category	Assessment Method	Specific Content	Evaluated Outcome Measure				
Child's social behavior, emotion regulation,	HV Provider report	Ages and Stages Questionnaire:	% children transitioning from				
and emotional well-being		Social-Emotional (ASQ:SE)	"delayed and need referral" to				
			"on-time"				
Child's physical health and development	HV Provider report	Ages and Stages Questionnaire (ASQ-	% children transitioning from				
		3)	"delayed and need referral" to				
			"on-time"				
	DOMES	TIC VIOLENCE					
Screening for domestic violence	HV Self-report	Relationship assessment form -	% participants completing				
	interviews	already done for C1 and Start Right to	assessment form at intake				
		be extended to PAT					
Number of referrals made	HV Provider report	Service Utilization Form-already done	% of referrals made to relevant				
to relevant domestic violence services (e.g.,		for C1 and Start Right to be extended	domestic violence services				
shelters, food, pantries, etc.)		to PAT	among positive DV screens				
Number of families for	HV Self-report	Item assessment establishment of	% of safety plans created among				
which a safety plan was completed	interviews	safety plan	positive DV screens				
FAMILY ECONOMIC SELF-SUFFICIENCY							
Household income and benefits	HV Self-report	New items on the demographics	Aggregated value of household				
	interviews	forms TBD*	income and benefits				
Employment of primary caregiver	HV Self-report	C1-demographics form, Start Right-	Rate of employment at intake				
	interviews	Intake form extended to PAT	and 12 months post-				
			enrollment/birth				
Health insurance status	HV Self-report	C1 demographics forms and Start	% women and children who have				
	interviews	Right Health forms- extended to PAT	health insurance				
COORDINATION AND REFERRALS FOR OTHER COMMUNITY RESOURCES AND SUPPORTS							
Number of families identified for necessary	HV Provider report	Service Utilization forms	% families identified in need of				
services			specific services				
Number of families that required services	HV Provider report	Service Utilization forms	% of families that required				
and received a referral to available			services and received a referral				
community resources			to available community resources				

Benchmark Category	Assessment Method	Specific Content	Evaluated Outcome Measure
MOU's: Number of Memoranda of Understanding or other formal agreements with other social service agencies in the community	State Administrative report	New items TBD*	No. of formal agreements with other social service agencies at the state level or in the communities chosen
Information sharing: Number of agencies that HV has a clear point of contact in the collaborating community agency	HV Provider report	New items TBD*	No. of social services agencies that engage in regular sharing of information with HV
Number of completed referrals (i.e., family accessed referral by HV)	HV Self-report interviews	Service Utilization forms	% families with completed referrals

\* To Be Developed (TBD) in first 18 months of project

*Qualitative Interviews*. Structured interviews will be devised based on topics summarized in the table below, and those developed throughout initial planning meetings. Content analyses will be used to identify core constructs and themes that will be used to inform system-level innovations. These analyses are described elsewhere. The provider interviews will be supplemented by a pencil-and-paper survey based on work by Duggan<sup>10</sup>. Specifically, the survey includes questions regarding how they feel about their training in risk areas, comfort level in communicating risk issues, and ability to recognize and address risk and other issues. Additionally, the survey focuses on determining provider's perception of their ability to assist parents in dealing with risk issues, their effectiveness as a provider, and their perceived success with families.

All focus group meetings and interviews will occur in years 2, and 4 of the project. A total of 32 client participant groups are planned for each of those years. A total of 42 provider participant interviews and 4 state leadership interviews are also planned in those years.

Participant Pool	Topics
HV Clients	
Service Attrition Group	Reasons for drop-out; Perceived treatment impact; Barriers to service; Barriers to implementing change
Service Engaged Group	Perceived treatment impact; Barriers to service; Barriers to implementing change
Agency Personnel	
HV Providers	Barriers to home-based service provisions; "Best Practices" for client engagement and retention; Reasons for client disengagement; Perceived risk assessment ability; Perceived training needs; knowledge of and use of other referral agencies
Providers referring HV	Knowledge of and experience referring to HV services; Perception of HV content and effectiveness; Barriers to providing referrals
State Leadership	Perceived need for HV; Perceived content of HV; Perceived impact of HV on MIECHV Benchmark areas in Oklahoma

Table 2. Focus Group Core Topics

*Community Survey*. A psychometric and health outcomes battery will be used for these participant interviews. The structure of the battery will be modeled after the OUHSC evaluation team's ongoing partnership with ACYF as an EBHV grantee. All project data collectors will be provided with a data collection manual and trained in procedures for obtaining informed consent; uses of audio computer assisted self-interviews (ACASI), and also receive training in research ethics, legal child abuse reporting requirements, managing safety concerns during home visits, cultural sensitivity and cultural competency.

Participant interviews will occur shortly after study enrollment for a baseline assessment and then once annually for longitudinal follow-up assessments. We will use real-time, web-based REDCap interviews for all measures. REDCap items will be presented to participants on a notebook computer screen and simultaneously presented verbally over headphones connected to the computer. The audio component makes it easier for individuals with limited literacy to respond. Tablet-PC's using REDCap software will be used to administer interviews. The interview data will be saved directly onto a file server which is administered by OUHSC IT support. If for some reason the REDCap system is not available, the tablet-PC will run offline REDCap software to conduct the interviews. Answers to the questions are usually completely private unless the participant seeks the data collector's assistance. Data from offline interviews will be downloaded directly from the laptops to a server-based storage warehouse at OUHSC, and then exported for statistical analysis. All electronic data will be kept on access controlled machines, all servers are firewall protected, and server data is remotely backed-up daily. REDCap software will be programmed to reject out-of-range data and perform automatic interview skip patterns. Response data will be stored separately from client identifiers. Client identifiers will only be kept for tracking purposes in separate password protected Microsoft Access databases. Offline REDCap data and tracking databases will be transferred to the evaluation team weekly using the OUHSC Secure File Transfer system which meets FIPS security encryption standards and is HIPAA compliant (http://it.ouhsc.edu/services/SecureFileTransfer.asp).

Data quality indicators will also be collected. These will include the proportion of data collected per wave, response rates, and information on respondent level missing data for a given measure. As part our evaluation requirements, we will complete a data quality progress table that will capture information such as response rates and missing data for the family and child outcomes collected. The data quality information will help alert the program staff to possible technical assistance needs concerning data collection.

Measures currently planned for assessment are listed in the following table and described in the text that follows.

Planned Measures
Demographics Form
Parenting and Child Functioning
Conflict Tactics Scale – Parent-Child Version (CTS-PC)
Ages and Stages questionnaire (ASQ-3)
Ages and Stages Questionnaire: Social Emotional (ASQ-SE)
Family Support and resource measures
Social Provisions Scale (SPS)
Family Resources Scale-Revised (FRS)
Parent risk measures

Table 3. Community Survey Measure
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Brief Child Abuse Potential Inventory (BCAP)
Center for Epidemiology Studies Depression Short-Form (CESD-SF)
Cigarette Use Questionnaire (CUQ)
Alcohol Use Disorders Identification Test (AUDIT)
Drug Abuse Screening Test, 10 item version (DAST-10)
Consideration of Future Consequences (CFC)
Numeracy Scale
Cognitive Reflection Test
Rational/Experiential Multimodal Inventory
Child Abuse and Neglect Prototype Vignettes
Parents Opinion Questionnaire
Home Environment
Home Observation for Measurement of the Environment- Short Form (HOME-SF)
Child Well-Being Scale
Intimate Partner Violence Measures
Acceptance Scale.
Conflict Tactics Scale CTS2S (Victimization & Perpetration)
Conflict and Problem Solving with Others.
Relationship status measure
Service measures
Prenatal Care
Service Utilization-Including Items on Immunization and Injuries/ER visits
Stages of Change Questions on EBHV utilization
EBHV Marketing Questions Via Method of Continued Associations

CPS Involvement
Child Maltreatment Outcomes from DHS Administrative Data Systems
Autism and Development Delay
Communication and Symbolic Behavior Scales-Developmental Profile (CSBS)
The Modified Checklist for Autism in Toddlers (M-CHAT)
Autism Spectrum Rating Scales (ASRS) Short Form (2-5 Years)
Sexual Behavior Problems
Child Behavior Checklist (CBCL) selected sexual behavior questions

*Demographic questionnaire*. The demographic questionnaire has a set of questions developed to capture basic demographic information. Initial versions of the questionnaire were screened by outside consultants to insure their appropriateness for Hispanic and Native American populations, and revisions incorporated. The questionnaire is available in both Spanish and English language versions. An early version of the questionnaire was piloted on 100 parents in similar programs. Items answered inconsistently or indicated by parents to be confusing were corrected. Mean 2-week test-retest correlation was 0.74 for continuous variable items, and Kappa was 0.79 for nominal variables.

# Parenting and Child Functioning

*Conflict Tactics Scale – Parent-Child Version*. (CTS-PC). The CTS-PC is a parent self-report measure of parenting, including harsh and neglectful parenting.<sup>11</sup> It is used to measure the extent to which a parent has carried out acts of psychological and physical maltreatment and neglect of children, regardless of whether the child was injured. The scales of the CTSPC include nonviolent discipline, psychological aggression, physical assault (including questions on discipline/corporal punishment) and neglect, as well as a supplemental scale on sexual abuse. Results of psychometric analysis shows evidence of discriminant and construct validity. Reliability ranges from low to moderate.

*Ages & Stages Questionnaires, Third Edition (ASQ-3).*<sup>12</sup> The ASQ is a reliable, accurate and well-studied tool used to screen children for developmental delays in the first 5 years of life. The questionnaire is parent-completed and includes 17 age appropriate forms, which are used to determine whether a child is on target developmentally or needs further evaluation. The questionnaires are available in both English and Spanish versions. Test-retest reliability was found to be .91 and inter-rather reliability was found to be 0.92. Validity ranged from 0.82-0.88. The ASQ-3 was found to have a sensitivity of 0.86 and a specificity of 0.85.

Ages & Stages Questionnaires<sup>®</sup>: Social-Emotional (ASQ: SE).<sup>13</sup> A Parent-completed, child-monitoring system for social-emotional behaviors and includes 8 age appropriate forms for ages 6-60 months. The

ASQ: SE screens for self-regulation, compliance, communication, adaptive functioning, autonomy, affect and interaction with people. The questionnaires are available in both English and Spanish versions and will be administered by the home visitors. Test-retest reliability was 0.94 and internal consistency ranged from 67% to 91%. Concurrent validity ranged from 0.81 to 0.95. The ASQ-SE was found to have a sensitivity range of 0.71 – 0.85 and specificity range of 0.90 – 0.98.

### Family Support and resource measures

Social Provisions Scale.<sup>14</sup> This measure was designed to capture the degree to which a respondent's social relationships provide various dimensions of social support. The items selected are based on six social provisions: 1) attachment, 2) social integration, 3) reassurance of worth, 4) reliable alliance, 5) guidance, and 6) opportunity for nurturance identified by Weiss (1974). The Social Provisions Scale was chosen because of its theoretical base, good psychometric properties, low reading-level comprehension, and brevity. Total internal consistency reliability is excellent ( $\alpha = 0.93$ ). Total scale alpha reliabilities are excellent when considered by caregiver race ( $\alpha = 0.91$  to 0.95) and study site ( $\alpha = 0.90$  to 0.93).

*Family Resources Scale-Revised.* The FRS<sup>15</sup> is a 30-item self-report scale designed to measure the adequacy of resources in households with young children. The FRS is a reliable and valid tool to assess perceived adequacy of resources among economically diverse families. It assesses resources across six conceptually cohesive dimensions of: 1) basic needs, 2) housing and utilities, 3) social needs/ self-care, 4) child care, 5) extra resources and 6) benefits. Internal consistency is acceptably high to strong. Test-retest reliability and concurrent validity results have been in the moderate range.

### Parent risk measures

*Brief Child Abuse Potential Inventory (Brief-CAPI).* The Child Abuse Potential Inventory<sup>16</sup> is a widely used 160-item agree/disagree format parent self-report questionnaire developed to estimate abuse risk. This standard version is too lengthy for longitudinal interviewing, so we propose to use the short-form version of Ondersma and colleagues.<sup>17</sup> The Brief CAP (or BCAP) reduces the length of the measure from 160 items to 24 items, and correlates 0.96 with the full CAP Abuse Scale in both development and cross-validation samples, and taps domains of distress, social isolation, family conflict and rigid parenting attitudes.

*Center for Epidemiology Studies Depression Short-Form (CESD-SF).*<sup>18</sup> This is a Quality of Life (QOL) tool used to measure current depressive symptoms in the general population. Items on the short form contain simple vocabulary in short sentences which can be administered by self-report or interview. The short form with a 4-point response set had good sensitivity and specificity in identifying potential cases of significant depressive symptoms. The CES-D shows excellent internal consistency (coefficient alpha > 0.83) and test-retest correlation (r>0.5).

*Cigarette Usage Questionnaire.* Three items that coincide with EBHV forms used by OSDH EBHV agencies were selected to assess current smoking status and frequency outcomes.

Alcohol Use Disorders Identification Test (AUDIT). The AUDIT was developed by the World Health Organization (WHO, 1989; updated in 1992) as a simple method of screening for excessive drinking and

to assist in brief assessment. The AUDIT consists of 10 self-report questions about recent alcohol use, alcohol dependence symptoms, and alcohol-related problems. Test-retest (0.87 - 0.97) and internal consistency (0.75 - 0.97) estimates are acceptable to high.<sup>19</sup>

*Drug Abuse Screening Test, 10 item version (DAST-10).*<sup>20</sup> This is a 10-item instrument modified to refer to the past 12 months at time of administration; a "yes" or "no" response is requested for each of the 10 questions. The DAST provides a brief, simple, practical but valid approach for identifying individuals who are abusing psychoactive drugs and yields a quantitative index score of the degree of problems related to drug use and misuse. This instrument will be administered in a self-report format. The DAST-10 correlates very highly (r = 0.98) with the longer DAST-20 and has high internal consistency reliability for a brief scale (0.92 for the total sample and 0.74 for a drug-abuse sample).<sup>21</sup>

*Consideration of Future Consequences.* Reworded from Strathman et al.<sup>22</sup> The CFC was designed to assess the extent to which people emphasize short-term or long-term consequences. Higher scores on this scale demonstrate an ability to delay gratification and optimize future long-term outcomes. We are interested in capturing tendencies to act on impulse with strong focus on immediate gratification as a potential predictor of future abuse and neglect reports. Items of this scale were re-worded by study investigators to handle the lower-end of the anticipated reading level of the sampled population.

<u>Numeracy Scale</u>.<sup>23</sup> We have added this measure as a potential predictor of future abuse and neglect reports. We are interested in capturing participant ability to decipher and understand probabilistic and numeric information. We anticipate this measure will moderate psycho-educational treatment effectiveness for those who receive home-visiting services.

*Cognitive Reflection Test.*<sup>24</sup> The CRT is a three item measure of cognitive ability related to decisionmaking characteristics of time preference and risk preference. We are interested in capturing participant ability to suppress immediate emotive thoughts and apply reason to problem-solving tasks as a potential predictor of future abuse and neglect reports.

*Rational/Experiential Multimodal Inventory.*<sup>25</sup> The construction of this test is based on the theory that people process information with two independent, interactive systems: nonverbal (experiential) and verbal (rational). This measure will be used to assess participant ability to think either analytically (rationally) or experientially (more affectively reactive) as a potential predictor of future abuse and neglect reports.

*Child Abuse and Neglect Prototype Vignettes.* We created this measure as a potential predictor of future abuse and neglect reports. It was developed conceptually out of two existing health behavior theories: the *Theory of Planned Behavior*<sup>26,27</sup> and the *Prototype Willingness Model.* <sup>28</sup> The questions for each vignette are intended to capture constructs that overlap with the dual process theories of decision-making that propose two broad classes of choice influence: cognitive and affective. The measured constructs include past behavior, willingness to engage in risky abuse/neglect behavior, perceived benefit of risky actions, social acceptability of risky action, risk perception of harmful consequences of actions, culpability for negative consequences of risky actions, and cognitive appraisal of action judgment quality.

### **Parents Opinion Questionnaire**

*Parent Opinion Questionnaire (POQ).* The POQ<sup>29</sup> assesses parental expectations of child behavior at various developmental states. Higher scores indicate greater levels of unrealistic expectations. The POQ has been recommended for clinical assessment of abusive parents and those at risk of child maltreatment. An analysis by Haskett et al, 2006, showed full scale scores were associated with parental psychopathology, parenting stress, self-reported discipline practices and IQ but were unrelated to observed parenting behavior. Azar and colleagues provided evidence to support the discriminate validity of the POQ among abusive and non-abusive parents with 12 years or less of education (age of children was not reported).<sup>29,30</sup> The POQ has been recommended for clinical assessment of abusive parents and those at risk of child maltreatment.<sup>31-33</sup> Study investigators selected only 16 items of the POQ (those aimed at parents with children 4 years old or younger) for use in this survey. Response scales for these items were also adapted, replacing the usual yes/no responses with a 5-point strongly disagree to strongly agree scale.

### **Home Environment**

Home Observation for Measurement of the Environment- Short Form (HOME-SF). This measure is based on the HOME inventory<sup>34</sup> which is a combination of trained observer ratings and mother's report on the quality of cognitive stimulation and emotional support provided by a child's family. The internal consistency of the total HOME-SF has been reported as 0.56 with estimates of 0.53. and 0.38 for the cognitive and emotional subscales, respectively.<sup>35</sup> Investigators chose to use a subset of the items from the 0-2 year-old and 3-5 year-old versions of the HOME-SF questionnaire.

*Child Well-Being Scales* (CWBS). The CWBS<sup>36</sup> was developed as an observational outcome measure for child welfare services programs. For the present study, the in-home data collectors will provide responses to selected CWBS items that cover observed household sanitation, home safety/child access to hazards, and clothing and hygiene.

### **Intimate Partner Violence Measures**

Acceptance Scale. This measure was developed by the evaluation team for a separate ongoing project. There are nine questions on this measure each followed by two 4-point response scales. The first response scale assesses their degree of agreement about dating violence while the second scale assesses whether the dating violence was acceptable or not. Acceptance of female perpetrated violence on males (5 items) produced an internal consistency estimate of 0.71 and acceptance of male-perpetrated violence on females (4 items) produced an internal consistency estimate of 0.71 and acceptance of 0.71 0.55. The Acceptance Scale used in the current study supplements the original 9 items with additional psychological control items from the Demographic Health Surveys (http://www.measuredhs.com/).

*Conflict Tactics Scale 2 (CTS2).* The CTS2<sup>37</sup> was developed to assess adult-to-adult conflict and to assess parent-to-child conflict. It includes five subscales measuring negotiation, psychological aggression, physical assault, injury, and sexual coercion. All the scales and subscales had good internal consistency with the exception of the minor injury subscale.<sup>38</sup>

*Conflict and Problem Solving with Others.* No standard measure was found to assess generality of conflict. Study investigators recently developed a new scale of general conflict modeled after the generality of violence questionnaire of Holtzworth-Munroe et al.<sup>39</sup> This new measure is a seventeen item questionnaire that captures how often participants are aggressive directly and indirectly with individuals in their life. There are two categories of people: family, friends/neighbors (informal supports), professional/coworker/service person (formal support). The measure is composed of 12 items from the CTS2 and 5 items from the Richardson Conflict Response Questionnaire (RCRQ).<sup>40</sup> Participants will report frequency of events with each person in the past twelve months.

*Relationship status measure*. We developed this measure to track changes in the primary caregivers' intimate relationships and reasons for change in status. In addition, these questions will allow us to analyze the Conflict Tactics Scale (CTS) across assessment periods in relation to a change in relationship status.

### Service Measures

*Prenatal Care.* Parents access to healthcare, housing, food and other basic services are needed to maximize healthy family functioning. Questions on this measure ask about care and education received during the pregnancy of the youngest child.

*Service Utilization*. We developed this measure to capture participant use of home-visitation and center based services. Additional questions relate to immunization status, child injuries and emergency room visits. We also intend to capture general satisfaction, benefit, and barrier constructs associated with the decision to received and maintain service involvement.

*Stages of Change Questions on EBHV utilization.* This survey consists of seven questions regarding the utilization of a free service offered to participants called parentPRO. Utilization is classified into one of four stages of the Transtheoretical Model of Change<sup>41</sup>: Pre-contemplation/Contemplation, Planning/Preparation, Action, and Maintenance (Re-use of service).

*EBHV Marketing Questions Via Method of Continued Associations.* Decision making research has recognized the effect of imagery influence processes with judgment and choice. The method of continued associations<sup>42</sup> is based on the concept of "word association." This method will be used to assess the community survey participant's associative feelings regarding home visitation services. Slovic, MacGregor, and Peters<sup>43</sup> have used similar methods to elicit public perceptions on prescription medications.

# **CPS Involvement**

*Child Maltreatment Outcomes from DHS Administrative Data Systems*. Future reports of child maltreatment, and related events such as out of home placements of children, are one of the targeted MIECHV outcomes of interest. Matching participants across the evaluation database and the child welfare database will require care because the matches must be made on the basis of general identifiers which may be incomplete or inconsistent. We will use a sequential strategy with both computerized and manual matching components, that includes matching on social security numbers, and then

combinations of name, gender and date of birth, including similar names and spellings. Match sets will subsequently be examined manually, line-by-line, in order to exclude likely false positives, which has been done successfully with previous similarly sized studies. Because the child welfare database also includes unique identifiers for families, any victim or perpetrator matches will be linked back to a family-level identifier, and all reports for that family can be retrieved. Reports will then be aggregated across dates, children and incidents and within types of maltreatment and perpetrator identity. Note also, that extended follow-up for this outcome can be obtained well beyond completion of the study with only minimal effort by simply re-executing the matching and data cleaning algorithms. We will obtain consent from participants for this extended follow-up. A Data Sharing Agreement has already been established between our OUHSC evaluation team and the OKDHS. This agreement will be extended for the life of the project.

# Autism and Development Delay

*Communication and Symbolic Behavior Scales-Developmental Profile (CSBS DP).*<sup>44</sup> The CSBS DP is a checklist of child behaviors completed by the caregiver to identify children who have or are at-risk for developing communication impairment and to monitor changes in a child's communication, expressive speech and symbolic behavior over time. The CSBS DP is an accepted instrument for the early detection of autism spectrum disorders.

*The Modified Checklist for Autism in Toddlers (M-CHAT.*<sup>45</sup> The M-CHAT is validated for screening toddlers between 16 and 30 months of age to assess risk for autism spectrum disorders (ASD). The primary goal of the M-CHAT is to maximize sensitivity. Suggested cutoff scores lead to a sensitivity of 0.87-0.97, specificity of 0.95-0.99, positive predictive value of 0.36-0.80 and negative predictive value of 0.99.

Autism Spectrum Rating Scales (ASRS) Short Form (2-5 Years).<sup>46</sup> The ASRS Short Form contains 15 items. The measure provides a total score which can be used as a screener to determine which children are most likely to require additional evaluation of services for ASD and related issues. Analysis of the measure produced a Cronbach alpha internal consistency coefficient of 0.92 and Pearson's *r* test-retest reliability of 0.90.

# **Sexual Behavior Problems**

*Child Behavior Checklist (CBCL) selected sexual behavior questions.* The caregiver-report Child Behavior Checklist (CBCL)<sup>47</sup> is a brief instrument used to measure problem behaviors and general child competencies. Only the CBCL sexual behavior problem items will be used in the current evaluation.

# C6. Data Analysis

Our planned evaluation targets many aspects of the state's overall approach to EBHV. Here, we isolate each row of the logic model (see section B4), describe how it relates to the five aims, and how we intend to analyze each issue. Many of the rows and subaims share some common patterns, so we first describe the common techniques to make the later descriptions less repetitive.

### Generalities of Qualitative Analyses

Qualitative analyses are conceptualized as providing complementary information that will facilitate interpretation of quantitative analyses as well as provide the basis for refinement of measurement in future studies. Qualitative interviews will be recorded and transcribed. Qualitative analysts will review both *a priori* concepts that emerge from analyses of the quantitative survey data as well as emergent concepts. In each of the domains studied, the primary issues raised by respondents will be identified and coded. A catalog of such points will be developed in each domain and the number of individuals raising each point will be recorded.

Transcription will be conducted by two graduate research assistants. Once an interview is transcribed, the lead focus group researcher will re-listen to each tape while reading the transcript in order to verify that the information provided truly represents the discussion held. If needed, the transcription will be edited. A copy of the final transcript will be given to at least two investigators (graduate students TBH and Beasley) who will code the transcript independently. Coding refers to the process of grouping comments or responses with similar meaning.

Once the coding is completed, the coders will compare their results, reach a consensus regarding the coding scheme, and a codebook will be developed. The graduate students will work together on the same transcripts until inter-rater reliability of at least 80% for primary codes is achieved. The transcripts will be coded in a software program (QSR N\*Vivo) to generate a series of categories arranged in a treelike structure connecting text segments grouped into separate categories or "nodes." These nodes and trees will be used to examine the association between different *a priori* and emergent categories and to identify the existence of new, previously unrecognized categories. The number of times these categories occur together, either as duplicate codes assigned to the same text or as codes assigned to adjacent texts in the same conversation, will be recorded, and specific examples of co-occurrence illustrated with transcript texts.

We will use a double layer design to compare and contrast participant responses in the focus groups.<sup>48</sup> Content analysis will be based on the coded qualitative data, and the results obtained from the analysis will be merged in order to identify important themes and beliefs about factors that influence specific aim outcome areas to include designated a priori topics of: 1) reasons for disconnected care; 2) degree of inter-agency communication within counties; 3) awareness of EBHV and early learning programs; 4) reasons for recruitment nonresponse and program disengagement; 5) degree of inefficiency in system referral process; 6) Perceived impact of EBHV and early learning programs within counties.

### Generalities of Quantitative Analyses

For many quantitative analyses, a generalized estimation equations method (GEE) will be used to describe the relationship between the covariates and the response means in the populations.<sup>49,50</sup> The GEE will allow us to adjust for multilevel dependencies within a person, within an agency, and/or within a neighborhood.<sup>51</sup> Frequently we will use a link function that accommodate a binary or count response variable (that follow a logistic or quasi-Poisson distribution).

Typically, our GEEs will address a longitudinal issue (i.e., "evaluate the frequency of referrals coming into EBHV agencies"), and we will be interested in whether the number increases between years 2 and 3, and whether it again increases between years 3 and 4. This will be assessed with a post hoc contrast available in the R package, geepack.<sup>52</sup> For the agency records data, we will use the client as the lowest level of measurement, and nest clients within their agencies, where agency is a level higher than client. Otherwise, the agency will be considered the lower level of measurement. Furthemore, we may report a united model (and treat county as the highest level), depending on the degree of heterogeneity in county patterns.

Some definitions may help below. A client's value for *annual cohort* will indicate whether they began their participation in either the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, or 4<sup>th</sup> year of the grant. (As a reminder, for both EBHV records and the community survey, there are annual cohorts for years 1, 2, 3, and 4 of the grant.) The value for *time* indicates whether the measurement occurred before or after the deployment of the a specific feature of the study; these features include (a) deployment of the universal referral form, (b) deployment of the electronic referral and triage system, or (c) introduction of connector agencies. Regarding individual people, *clients* refers to those receiving EBHV services, while *participants* refer to the individuals responding to our community survey.

### Analytic Specifics by Aim

Revamp referral, intake, triage processes	Central, electronic referral, intake, triage system	Interagency MOUs, universal & central referral system	<ul> <li>↑ efficiency &amp;</li> <li>→ strengthen match of client to EBHV</li> </ul>
EBHV interagency coordination	Est. local EBHV coalitions	Agency meetings, peer-learning	Strengthen client service continuum
Dedicate local EBHV ambassadors	Est. community connector agencies	Interagency MOUs, hire connectors	↑ awareness & use of EBHV

# Row 1, 2, & 3 (Aim 1) of Logic Model

Three subaims are represented by these rows of the logic model. For subaim **1a** (i.e., "reduction in duplication of services for any particular client"), we will rely primarily on the EBHV agency records. We will examine if the 2<sup>nd</sup> cohort (i.e., those enrolling in EBHV in its second year) indicates more productive and efficient EBHV systems. An *efficient* system will have only a few clients enrolled in multiple services simultaneously (which is related to Subaim **1b**); Level 1 will be a client-level binary variable representing clients enrolled in redundant services; Level 2 will be their agency. A *productive* system will enroll many clients in at least one service; Level 1 will be an agency-level Poisson variable, representing the count of enrolled clients.

For subaim **1b**, basic accounting from ODHS and EBHV agency records will be used to construct a timeline of each county's key MIECHV developments (e.g., "record successful establishment of a centralized referral/triage system"). These timelines will then be used to construct time-dependent analytic covariates that demarcate the before and after occurrence of these key MIECHV-related events. For single-occurrence events, like the establishment of a community connector agency, these covariates

will be binary coded variables where 0 values reflect time before event and 1 values reflect time after event. In the case of recurring events, like the number of connector meetings conducted, these covariates will be constructed as cumulative count indicators.

For **Subaim 1c** (i.e., "evaluate the frequency of referrals coming into EBHV agencies" and "evaluate pre and post changes attributable to triage and connector agency establishments"), the primary outcome of interest is the number of monthly referrals. Many potential predictors will be examined by county, including the annual cohort indicators and the subaim 1b timeline covariates. We will look for an increasing monotonic trend between the predictors and outcome in each county. Level 1 will be an agency-level Poisson variable, representing their count of referred clients. We will assess total referrals and eligible referrals in separate models. We are also interested in exploring whether a time trend still exists in the residuals of our GEE models after controlling for the annual cohorts and constructed covariates. If there are additional intangible (or at least unmeasured) predictive influences, we will expect a to find a residual trend and will then search for possible explanations related to unmonitored events or community dynamics.

# Rows 3 & 4 (Aim 2) of Logic Model



For subaim **2a** (i.e., "survey large sector of eligible population for knowledge, use, and appeal of EBHV services"), we will use the community survey data. Survey items have been constructed to assess free associations with "Home-Visiting" and perceived valence of those associations, prior knowledge of EBHV services, prior usage of EBHV services, and future intent to consider or use EBHV services. Single-level GEE models of baseline survey responses will be used to evaluate marketing effectiveness and reach. The predictors will be the survey participant's annual cohort and county, and the two primary outcomes variables will be: (i) number of first-time survey enrollees reporting awareness of EBHV programs, and (ii) the number of first-time survey enrollees who report they have used EBHV services.

For subaim **2b** (i.e., "identify marketing successes/failures among client focus group participant responses"), we will concentrate on the qualitative data of our client focus groups. The general qualitative analytic strategies outlined above will be utilized to evaluate receptiveness to present and future marketing interventions. This information will be continually fed back into the OSDH marketing planning meetings.

# Row 5 (Aim 3a)



Both agency records and the community survey data sources will be useful for evaluating increased capacity of EBHV services. The agency records will be analyzed in a manner similar to those described for subaim 1c above, simply swapping out the referral count outcome with a clients-served count outcome. We will also analyze a wait-list proportion outcome per agency to evaluate bottle-necks in the system and to identify areas of improvement in each county-wide triage system. Our intention is to directly incorporate (near) real-time information on agency-level capacity back into the triage algorithms that are developed to improve system efficiencies (including reduction of wait-listed participants and wait-list duration). Similar information will be gathered among the subpopulation of clients referred to EBHV who are also participating in our community survey. Monthly contact calls with these participants will produce a second source of data on service receipt and wait-list duration. Summary information on these counts and durations will be presented to OSDH MIECHV staff at every bi-weekly planning meeting.

# Row 6 (Aim 3)

New EBHV enrollment & retention strategies for clients and staff ↓ staff turnover &
 ↑ professional
 development;
 ↑ # families served,
 graduating, &
 meeting EBHV goals

Establish best practices on EBHV enrollment & retention  ↑ maternal & child health, school readiness, economic self-sufficiency;
 ↓ child injuries, abuse, neglect, ER visits, domestic violence

Five subaims are represented by this row of the logic model. Subaims **3b** ("identify reasons for low engagement in services"), **3c** ("examine provider barriers to program implementation with families that do not engage"), and **3e** ("identify reasons for attrition from services") are informed by the qualitative data collected. Conclusions about each subaim (e.g., "identify reasons for low engagement in services," "examine provider barriers to program implementation with families that do not engage," and "identify reasons for attrition from services for attrition from services." indentify reasons for attrition from services.

Subaims **3d** ("effectiveness of new engagement strategies") and **3f** ("effectiveness of new retention strategies") will be informed by the agency record data source. Again, following the design of analyses for 1c above, we will GEE models to evaluate upward trends in client engagement and retention outcomes that coincide with time-varying predictors of county-specific implementations of new engagement and retention strategies.

# Row 7 (Aim 4)



For **Aim 4**, ("evaluate overall need for child and family services among disadvantaged early childhood populations within each community"), the Community Survey is the primary source of data. The repeated measures design allows insight into the longitudinal within-client variability. These prevalence rates will be examined annually (or more frequently if policy evaluation is needed).

There are four outcome variables, each corresponding to a subaim: (4a) general home visitation needs, (4b) developmental delays and autism, (4c) child sexual behavior problems, (4d) child abuse & neglect potential, and (4e) school readiness. There will be an epidemiological assessment of each outcome variable. The numerator of each ratio is the number of children who meet the risk criteria on the screening instruments (embedded in the survey). The denominator will be the number of children in the survey. There will also be two psychometric evaluations conducted for Autism screening instruments of subaim 4b and newly developed maltreatment risk predictors of subaim 4d. These investigations will evaluate and quantify internal reliability, construct validity, concurrent validity, and predictive validity.

Due to the expected heterogeneity between demographic strata, we will use different sample weights depending on the population of interest. When inferring to the Medicaid and WIC population, we will be able to use the actual sampling weights from the stratified sample (recall the participants of the community survey are enumerated and drawn from Medicaid and WIC records; sampling weights will constructed based on these enumerations and draws). If a new research or policy issue arises, we will attempt inferences to other populations (and not just to those enrolled in Medicaid and WIC) by using different post-stratification weights.

# Row 8 (Aim 5)

Evaluate effectiveness of EBHV

Quasi-experimental comparison of MIECHV benchmarks & constructs Baseline benchmark & constructs data collection of community comparison group and EBHV clients

EBHV effectiveness findings on benchmarks & constructs

 $\rightarrow$ 

Quantitative analyses that pertain to this subaim **5a**, diverge somewhat from the generalities stated above, because we plan to implement two analytic approaches to evaluate EBHV effectiveness. In our *Approach A*, program outcomes will be compared across the group of clients who interface with the EBHV service system and the group of community survey participants who do not interface with the EBHV service system prior to their 2<sup>nd</sup> survey administration. In *Approach B*, program outcomes will be compared among two groups of community survey participants who had no exposure to EBHV prior to their baseline interviews- those who receive EBHV services prior to a subsequent survey administration (i.e., prior to a 2<sup>nd</sup>, 3<sup>rd</sup>, or 4<sup>th</sup> interview) and those who do not receive EBHV services for the duration of the participatory period.

For Approach A, we will initially perform a matching procedure to balance out the distribution of key demographics and baseline characteristics of clients in these two non-randomized groups, and this many-to-many matching procedure will stratify on cohort period (i.e., cases- those involved in EBHV- can only be matched to comparisons- community survey participants- who are enrolled in the study within

the same year). For these analytic adjustments, we will rely on the Coarsened Exact Matching procedure<sup>53</sup> using, at a minimum, the following covariates: child age at program/survey enrollment, outcome scores at program/survey enrollment, caregiver gender, caregiver age, child gender, household income, and county of residence. Comparison participants will be excluded whenever adequate matches do not exist. Despite the allowance of many-to-many matches, each EBHV client and each matched community survey participant will be weighted as a single record in this analysis. Once matched groups are constructed, analysis of group differences will proceed using generalized linear models that include main effects for group (EBHV vs. comparison) and cohort (year of enrollment) factors as well as the interaction between these two factors. Dependent variables for these analyses will be annual change scores on all benchmark constructs (see Table 1 in section C5) that are obtained from both data sources. (The community survey incorporates outcomes that can reasonably be compared across groups for all constructs except those involving home-visitor reports, i.e., no Child Well-Being Scale or administrative referral data.) When follow-up data is missing for an individual, the change score will be imputed using group-specific, model-based growth curves. The imputation models will follow standard longitudinal, multiple imputation procedures.<sup>54,55</sup>

For Approach B, we will incorporate the randomized encouragement design variable introduced in section C2 (Data Sources- Community Survey) above. For these analyses, self-report data will be collected monthly (by phone) and annually (at each subsequent in-home interview) from community participants to help devise an intermediate, EBHV service utilization outcome. The method of instrumental variables (see, for example, Angrist, imbens, & Rubin<sup>56</sup>) will be used in this approach to estimate the causal effects of both the encourgagement intervention (an intention-to-treat effect) and the EBHV treatment effect (a complier average causal effect- CACE). For this analysis, we will assume and infer the existence of compliers (those who would seek EBHV treatment when encouraged and avoid EBHV otherwise), always-takers (those who would seek EBHV regardless of encouragement condition), and never-takers (those who would avoid EBHV regardless of encouragement). We will also assume that the proportion of defiers (those seeking EBHV when not encouraged and avoiding EBHV when encouraged) in our sample is approximately zero. The estimation of the encouragement intervention is a simple RCT test of group differences. The CACE for EBHV treatment will involve instrumental variables analysis via structural equation modeling. Approach B will use the same community survey outcomes (and procedures for handling missing data) as those described for Approach A.

# Row 9 (Aim 5)

Other system improvements: Staff trainings, fidelity monitoring, quality assurances

Q.I. feedback loop to stimulate & inform EBHV system improvements Survey, focus group & qualitative interview data on desired system improvements Est. Q.I.Q.C. evaluation system; increased workforce competence

Two subaims are represented by this row of the logic model. For subaim **5b** (i.e., "identify system improvements and necessary quality controls through client focus groups, staff and leadership

qualitative interviews, and expert systems consultations"), interim analyses of rows 1-8 of the logic model will be used to identify possible areas for system-level improvements. (Note that there are no recruitment or study-related stopping rules implemented regarding the interim analyses proposed, and, therefore, no adjustments are needed for the planned final analyses.) A literate programming and dynamic reporting system will be built for each of the subaims addressed within these logic model rows and (near) real-time updates will be available to all local MIECHV partners (OSDH, CCAN, OCHA, OKDHS) daily. These reports will be routinely presented by CCAN evaluators at planning and coordination meetings throughout the duration of the grant. Our intention is that this data will inform and inspire new quality improvement and control initiatives that develop over time. Once new strategies are implemented, these systems improvements/controls will be coded as time-varying predictors of change and future interim analyses will evaluate effectiveness of these changes (subaim **5c**).

### C6. Power Analysis

Power for each analysis will differ depending on the hypothesized contrast and type of modeling procedure used. However, generally speaking, the proposed sample size will permit the following minimal effect size detections across a 2-year community survey cohort comparison (1<sup>st</sup> two years versus last two years) for a Type I error rate of 0.05 and a Type II error rate of 0.20.

		Smaller Counties	Larger Counties	
		(Muskogee & Comanche)	(Oklahoma & Tulsa)	
		N = 112 per year	N = 225 per year	
Proportional Chang	ge	Minimum Proportion	Minimum Proportion	
		Improvement	Improvement	
	0.01	0.08	0.05	
	0.05	0.12	0.08	
Base Rates	0.1	0.14	0.1	
	0.25	0.18	0.13	
	0.5	0.19	0.14	
Mean Difference		Minimum Mean Difference	Minimum Mean Difference	
		in SD Units	in SD Units	
		0.27	0.19	

Table 4. Minimally Detectable Effect Size Estimates for First and Last, 2-Year Cohort Comparisons

For Aim 5, the minimally detectable effect sizes for the difference of differences test across EBHV and comparisons groups will differ by analytic approach and type of treatment effect. For the matching procedure and quasi-experimental analyses of Approach A, we anticipate getting EBHV agency data on roughly 4,000 unique clients. We anticipate matching at least ¼ of these clients to community survey comparison participants. Controlling for model-based cohort and county effects, the design should be able to detect the average treatment effect sizes listed in the Table 5, Approach A column below. For Approach B, we anticipate an 85% longitudinal survey retention rate and a 25% EBHV treatment compliance rate which would produce the minimally detectable CACE effect size estimates found in the last column of Table 5. This evaluation appears to be well-powered for all proposed aims.

		Approach A	Approach B				
Proportional Difference		Minimum Proportion Improvement	Minimum Proportion Improvement				
	0.01	0.03	0.04				
Comparison Rate	0.05	0.05	0.07				
	0.1	0.06	0.08				
	0.25	0.08	0.11				
	0.5	0.09	0.12				
Mean Difference		Minimum Mean Difference	Minimum Mean Difference				
		in Change Score SD Units	in Change Score SD Units				
		0.13	0.17				

Table 4. Aim 5 Minimally Detectable Effect Size Estimates

# D. Project Management

### D1. Timeline

	Year 1				Year 2				Yea	ar 3		Year 4				
Planned Activities	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16
HV Planning Committee Meetings	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Expansion of EBHV	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Smart Start OK Coordination	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
EBHV Sustainability Group	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Child Guidance Coordination System	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Institutional Review Board Approval	Х	Х			Х				Х				Х			
Data System Planning Committee	Х	Х	Х	Х	Х			Х	Х			Х	Х			
County 1 Data System Deployment			Х													
County 2 Data System Deployment					Х											
County 3 Data System Deployment									Х							
County 4 Data System Deployment													Х			
Focus Group Planning Meetings	Х	Х	Х	Х									Х	Х	Х	Х
Recruit Focus Group Participants		Х	Х										Х	Х		
Planned Focus Groups			Х	Х										Х	Х	
Eval Planning Committee Meetings	Х	Х		Х				Х				Х				Х
Eval Team Site Visit with Agency IT	Х	Х														
Eval Team Train HV Data Collection	Х	Х														
Train and Hire Survey Data Collectors		Х	Х					Х	Х							
Recruit Survey Participants		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	
Conduct Survey Sample Interviews			Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Agency Record Data Upload	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Qualitative Data Analysis				Х	Х										Х	Х
Quantitative Survey Data Analysis					Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Quantitative Benchmark Analysis				Х				Х				Х				Х

#### D2. Personnel

#### **Principal Investigator:**

David Bard, PhD, Pediatrics

#### **Co-Investigators:**

Jane Silovsky, PhD, Pediatrics Mark Chaffin, PhD, Pediatrics Debra Hecht, PhD, Pediatrics Lana Beasley, PhD, Pediatrics Will Beasley, PhD, Pediatrics Arthur Owora, MPH, Pediatrics Donna Wells, MEd, Pediatrics La'Chanda Stephens-Totimeh, BA, Pediatrics Carrie Schwab, AA, Pediatrics Gina Carrier, BBA, Pediatrics Thomas Wilson, MPH, Pediatrics

#### D3. Resources

The External Evaluator will be the Center on Child Abuse and Neglect (CCAN) housed within the Department of Pediatrics at the University of Oklahoma Health Sciences Center (OUHSC). CCAN at OUHSC brings significant resources and capacities to this project. The OUHSC is a multi-college campus housing the Colleges of Medicine, Nursing, Public Health, Allied, Health, and Dentistry as well as the Oklahoma Medical Research Foundation. Full library, data analysis, management and professional support services are available on campus. The campus is also equipped with video teleconference technology. The OUHSC computer network is a fully equipped client-server environment with a range of on-line services including e-mail, remote backup, database applications, data analysis applications (SPSS, SAS, LISREL, etc.), document servers, on-line access to library search services, and internet access.

CCAN is a university-based, interdisciplinary center dedicated to the prevention and treatment of child abuse and neglect. CCAN directs research, program administration, clinical services, professional education, program development, and public education in the field of child maltreatment. CCAN has a long-standing history in the community, state, and nation in conducting clinical implementation and dissemination research on the prevention and treatment services for child maltreatment. CCAN team members include established federally funded scientific researchers with extensive publication records, including experience conducting treatment outcome trials in real-world field settings. These include expertise in evaluating EBP uptake at client, provider, organizational and systems levels, use of mixed methods approaches (quantitative/qualitative methods), web-based surveys, automated or computerized interviews, conducting qualitative interviews and focus groups, cross-site data capture, centralized data management and data analysis capabilities ranging from basic to advanced. This includes a wide range of data capture, data storage and data analysis equipment and software, along with years of experience in programming and using these technologies. We have assisted other sites with institutional review board (IRB) application and approval and in fact helped established an IRB in St. Petersburg, Russia.

CCAN has over 60 networked PC's including a database server. Data acquired for this project would be centrally stored on the database server running MySQL Server, allowing for multiple user access and data entry with security control. The server is fault tolerant (dual processors, mirrored drives, uninterrupted power source) and incrementally backed up daily with weekly off-site tape backups that are stored in a fireproof safe. CCAN has an experienced data collection and management team that includes independent data collectors, data managers and analysts with expertise in implementing statewide studies/evaluations. CCAN has the capability to deploy audio-assisted computer self-interviewing, optical mark reader scan forms, and more traditional information collection methodologies, with direct uploading to SQL databases and automated data screening and cleaning.

The strength of the CCAN investigators lies in their capacity to accommodate reasonable scientific rigor within the demands and realities of this fairly unique service context, along with our well established research-practice partnerships with state authorities and frontline service provider agencies. We believe that service quality and client outcomes are best advanced by research that involves the system and front-line service providers as partners in identifying key questions and targets. We also are committed to research that both advances current scientific knowledge and that offers direct benefit to our state agency and provider partners. Finally, our work relies on a translational framework that emphasizes comparative outcomes observed in authentic real-world settings. Although these types of studies necessarily compromise on some aspects of variable control, they offer external validity advantages which we believe outweigh their limitations.

David Bard, Principal Investigator (PI), is a quantitative psychologist and lead evaluator of CCAN's current EBHV grant with Children's Bureau (90CA1764). He has extensive experience and expertise in methodology and statistical analyses to address the complexities of social sciences research. These researchers are frequently invited to present at national and international conferences on research of evidence-based programs in child maltreatment. They serve on the boards of state, national, and international professional organizations in both psychology and child maltreatment. Federal, state, and local grants have funded a variety of studies including treatment outcome studies, program evaluations, and other clinical research as discussed in the following sections.

# E. References

- Chaffin M, Bonner BL, Hill RF. Family preservation and family support programs: Child maltreatment outcomes across client risk levels and program types. *Child Abuse & Neglect*. 2001;25(10):1269-1289.
- **2.** Aarons GA, Sommerfeld DH, Hecht DB, Silovsky JF, Chaffin MJ. The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: Evidence for a protective effect. *Journal of Consulting and Clinical Psychology*. Apr 2009;77(2):270-280.
- **3.** Chaffin M, Bard D, Bigfoot DS, Maher EJ. Is a Structured, Manualized, Evidence-Based Treatment Protocol Culturally Competent and Equivalently Effective Among American Indian Parents in Child Welfare? *Child Maltreatment*. Aug 2012;17(3):242-252.
- Chaffin M, Hecht D, Bard D, Silovsky JF, Beasley WH. A Statewide Trial of the SafeCare Homebased Services Model With Parents in Child Protective Services. *Pediatrics*. Mar 2012;129(3):509-515.
- **5.** Chaffin M, Bard D, Hecht D, Silovsky J. Change trajectories during home-based services with chronic child welfare cases. *Child Maltreatment*. May 2011;16(2):114-125.

- **6.** McCurdy K, Daro D. Parent Involvement in Family Support Programs: An Integrated Theory. *Family Relations.* 2004;50(2):113-121.
- **7.** Damashek A, Doughty D, Ware L, Silovsky J. Predictors of Client Engagement and Attrition in Home-Based Child Maltreatment Prevention Services. *Child Maltreatment*. Feb 2011;16(1):9-20.
- Silovsky JF, Bard D, Chaffin M, et al. Prevention of child maltreatment in high-risk rural families: A randomized clinical trial with child welfare outcomes. *Children and Youth Services Review*. Aug 2011;33(8):1435-1444.
- 9. Morgan DL. *Focus groups as qualitative research.* 2nd ed. London: Sage; 1997.
- **10.** Duggan A, McFarlane E, Fuddy L, et al. Randomized trial of a statewide home visiting program: Impact in preventing child abuse and neglect. *Child Abuse & Neglect*. Jun 2004;28(6):597-622.
- **11.** Straus MA, Hamby SL, Finkelhor D, Moore DW, Runyan D. Identification of child maltreatment with the parent-child Conflict Tactics Scales: Development and psychometric data for a national sample of American parents. *Child Abuse & Neglect.* Apr 1998;22(4):249-270.
- **12.** Squires J, Twombly E, Bricker D, Potter L. *Ages and Stages Questionnaires: Third Edition.* Baltimore, MD: Paul H. Brookes Publishing; 2009.
- **13.** Squires J, Bricker D, Twombly E. *The ASQ: SE User's Guide for the Ages and Stages Questionnaires: Social Emotional*. Baltimore, MD: Paul H. Brookes Publishing; 2003.
- **14.** Cutrona CE, and Russell, D. Social Provisions Scale. 1987.
- **15.** Dunst CJ, Leet HE. Measuring the adequacy of resources in households with young children. *Child: Care, Health and Development.* 1987;13(2):111-125.
- **16.** Milner JS. *The Child Abuse Potential Inventory: Manual.* 2nd ed. Webster, NC: Psytec; 1986.
- **17.** Ondersma SJ, Chaffin MJ, Mullins SM, LeBreton JM. A brief form of the Child Abuse Potential Inventory: Development and validation. *Journal of Clinical Child and Adolescent Psychology*. 2005;34(2):301-311.
- **18.** Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement*. 1977;1(3):385-401.
- **19.** Reinert DF, Allen JP. The Alcohol Use Disorders Identification Test: An Update of Research Findings. *Alcoholism: Clinical and Experimental Research.* 2007;31(2):185-199.
- **20.** Skinner HA. The Drug Abuse Screening Test. *Addictive Behavior*. 1982;7(4):363-371.
- **21.** Yudko E, Lozhkina O, Fouts A. A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. *Journal of Substance Abuse & Treatment.* 2007;32(2):189-198.
- **22.** Strathman A, Gleicher F, Boninger DS, Edwards CS. The consideration of future consequences: Weighing immediate and distant outcomes of behavior. *Journal of Personality and Social Psychology.* 1994;66(4):742-752.
- **23.** Woloshin S, Schwartz LM, Black WC, Welch HG. Women's perceptions of breast cancer risk: How you ask matters. *Medical Decision Making*. 1999;19(3):221-229.
- **24.** Frederick S. Cognitive Reflection and Decision Making. *Journal of Economic Perspectives.* 2005;19(4):25-42.
- **25.** Norris P, Epstein S. An experiential thinking style: Its facets and relations with objective and subjective criterion measures. *Journal of Personality*. 2011;79(5):1043-1079.
- **26.** Ajzen I. From intentions to actions: A theory of planned behavior. In: Beckman JKJ, ed. *Actioncontrol: From cognition to behavior*. Heidelberg: Springer; 1985.
- **27.** Ajzen I. The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes.* Dec 1991;50(2):179-211.
- **28.** Gerrard M, Gibbons FX, Houlihan AE, Stock ML, Pomery EA. A dual-process approach to health risk decision making: The prototype willingness model. *Developmental Review.* 2008;28(1):29-61.

- **29.** Azar ST, Robinson DR, Hekimian E, Twentyman CT. Unrealistic expectations and problem-solving ability in maltreating and comparison mothers. *Journal of Consulting and Clinical Psychology*. 1984;52(4):687-691.
- **30.** Azar ST, Rohrbeck CA. Child abuse and unrealistic expectations: Further validation of the Parent Opinion Questionnaire. *Journal of Consulting and Clinical Psychology*. 1986;54(6):867-868.
- **31.** Budd KS. Assessing parenting competence in child protection cases: A clinical practice model. *Clinical Child and Family Psychology Review.* 2001;4(1):1-18.
- **32.** Hansen DJ, Macmillan VM. Behavioral Assessment of Child-Abusive and Neglectful Families: Recent Developments and Current Issues. *Behavior Modification*. Jul 1990;14(3):255-278.
- **33.** Swenson CC, Kolko DJ. Long-term management of the developmental consequences of child physical abuse. In: Reece RM, ed. *Treatment of child abuse: Common ground for mental health, medical, and legal practioners*. Baltimore, MD: The Johns Hopkins University Press; 2002:135-154.
- **34.** Caldwell BM, Bradley RH. *HOME Observation for measurement of the environment.* Little Rock, AR: University of Arkansas; 1984.
- **35.** Baker PC, Mott FL. *NLS child handbook, 1989.* Columbus, OH: Center for Human Resource Research, The Ohio State University; 1989.
- **36.** Magura S, Moses B. *Outcome measures for child welfare services.* Washington, D.C.: Child Welfare League of America;1986.
- **37.** Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The Revised Conflict Tactics Scales (CTS2). *Journal of Family Issues.* May 1, 1996 1996;17(3):283-316.
- **38.** Calvete E, Corral S, Estevez A. Factor structure and validity of the revised Conflict Tactics Scales for Spanish women. *Violence Against Women.* 2007;13(10):1072-1087.
- **39.** Holtzworth-Munroe A, Meehan JC, Herron K, Rehman U, Stuart GL. Testing the Holtzworth-Munroe and Stuart (1994) batterer typology. *Journal of Consulting and Clinical Psychology*. 2000;68(6):1000-1019.
- **40.** Richardson DS, Green LR. Defining direct and indirect aggression: The Richardson Conflict Response Questionnaire. *International Review of Psychology*. 2003;16(3):11-30.
- **41.** Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology.* 1983;51(3):390-395.
- **42.** Szalay LB, Deese J. *Subjective meaning and culture: An assessment through word associations.* Hillsdale, N.J.: Lawrence Erlbaum Associates; 1978.
- **43.** Slovic P, MacGregor DG, Peters E. *Imagery, Affect, and Decision Making.* Eugene, OR: Decision Research;1998.
- **44.** Wetherby AM, Prizant B. *Communication and Symbolic Behavior Scales Developmental Profile-Research Edition.* Chicago, IL: Applied Symbolix; 1998.
- **45.** Robins DL, Fein D, Barton ML, Green JA. The modified checklist for autism in toddlers: An initial study investigating the early detection of autism and pervasive developmental disorders. *Journal of Autism and Developmental Disorders*. 2001;31(2):131-144.
- **46.** Goldstein S, Naglieri JA. *Austims Spectrum Rating Scales (ASRS).* North Tonawanda, NY: MHS; 2009.
- **47.** Achenbach TM. *Manual for Child Behavior Checklist/ 4-18 and 1991 Profile.* Burlington, VT: University of Vermont, Department of Psychiatry;1991.
- **48.** Krueger RA, Casey MA. *Focus Groups. A practical guide for applied research.* 3rd ed. Thousand Oaks, CA: Sage Publications; 2000.
- **49.** Hardin JW, Hilbe JM. *Generalized estimating equations*. Boca Raton: Chapman & Hall/CRC; 2002.
- **50.** Gardiner JC, Luo Z, Roman LA. Fixed effects, random effects and GEE: What are the differences. *Statistics in Medicine*. 2009;28(2):221-239.

- **51.** Hubbard AE, Ahern J, Fleischer NL, et al. To GEE or not to GEE: comparing population average and mixed models for estimating the associations between neighborhood risk factors and health. *Epidemiology.* 2010;21(4):467-474.
- **52.** Halekoh U, Højsgaard S, Yan J. The R package geepack for generalized estimating equations. *Journal of Statistical Software.* 2006;15(2):1-11.
- **53.** Iacus SM, King G, Porro G. Software for coarsened exact matching. *Journal of Statistical Software*. 2009;30(9):1-27.
- **54.** Lavori P, Dawson, R., and Shera, D. A multiple imputation strategy for clinical trials with truncation of patient data. *Statistics in Medicine*. 1995;14:1913-1925.
- **55.** Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*. 1996;52(4):1324-1333.
- **56.** Angrist JD, Imbens GW, Rubin DM. Identification of Causal Effects Using Instrumental Variables. *Journal of the American Statistical Association*. 1996;91(434):444-455.