SIM-PLICITY Science and Merit Protocol – 7/20/2017

Staff Only
Project #
PI:
Submission Date(s):

If you need help with this document, contact the Research Subjects Protection Program office at 651-254-4757. Please save a copy of this document to your desktop AND upload it using the icon in the Research Application.

The following **9 headings/sections highlighted in blue** correspond with the criteria used to evaluate your proposal. All the **questions/requests are highlighted in yellow;** they all must be answered providing sufficient detail for a reviewer to determine whether the review criteria have been met.

You must answer each question *or* list the page and paragraph numbers from an attached proposal, making sure that the reference fully answers the question; a combination of both is acceptable. It is helpful if you highlight the area of the proposal you are referencing that relates to the specific question on this form.

****MAIN RESEARCH QUESTIONS, STUDY AIMS, SPECIFIC HYPOTHESES****

1.1 Please clearly state your overall research questions and/or study aims.

The prevalence of childhood obesity has tripled within the last twenty-five years (Skelton et al., 2009). Interventions targeting children are a high priority because children bear the greatest lifetime health risk from overweight and obesity (Ogden et al., 2007; Franks et al., 2010). Health professionals in primary care settings have the potential to reach large numbers of parents and children and address obesity because they have regular interactions with and are influential in the lives of families. Studies show that even brief advice delivered well can have a meaningful impact. To support providers in this important role, the Centers for Disease Control and Prevention collaborated with other health organizations to develop recommendations for assessment, prevention, and treatment of childhood and adolescent overweight and obesity. Despite the 2007 publication of these recommendations and increasing recognition of childhood obesity as a public health problem, rates of provision of obesity-related guidance and counseling remain low (Tanda & Salsberry, 2013), and research indicates that health care providers could use additional education, training, and support related to obesity prevention and treatment. Thus, effective strategies to support pediatric primary care providers in their efforts to intervene against address childhood obesity are needed. Building off the successes achieved in their Phase I study, SIMmersion LLC, in collaboration with Dr. Nancy Sherwood from HealthPartners Institute , Dr. Jayne Fulkerson from the University of Minnesota, and Dr. Michael Fleming from Northwestern University, will expand the Phase I simulation prototype, utilizing feedback provided by a team of independent experts. The innovative computer-based training system with interactive role-play simulations will provide health care providers with much needed experiential opportunities to develop skills in conducting discussions with parents and children about obesity. The product's efficacy will be evaluated in a randomized controlled trial (RCT); 100 pediatric, family practice, and nursing clinicians and trainees at various levels of experience will be recruited to participate. Half of the participants will be randomly assigned to the intervention group during which they will use the newly developed simulation product to develop their skills and half of participants will be randomly assigned to the wait-list control group; the primary outcome is performance in a role play with trained actors at 3 month follow-up.

Primary Aim: Participants randomized to the simulation intervention will have higher ratings on the trained actor role play at 3 month follow-up relative to participants randomized to the wait-list control group.

****1. BACKGROUND & SIGNIFICANCE****

1.2 What is the specific knowledge gap that the project intends to fill? Include a brief review of past research in this area, numbering your citations to relevant literature as well as including them in the reference section #9.1.

Obesity in the United States is at historically high levels and is an important public health problem (Flegal et al., 2010; Ogden et al., 2012a). Although increases in obesity prevalence over the last few decades have been dramatic in all age groups, trends among youth have been particularly alarming (Jolliffe, 2004; Ogden et al., 2006; Ogden et al., 2010; Skelton et al., 2009). Currently, 16.9% of 2- to 19-year-old children are obese, with an additional 15% of youth classified

as overweight (Ogden et al., 2012b). Interventions targeting children are a high priority because children bear the greatest lifetime health risk from overweight and obesity.

Unfortunately, a recent meta-analysis demonstrated that over half of parents underestimate their overweight/obese children's weight status (Lundahl et al., 2014); meaning their motivation for change is likely low as well. There is a critical need to inform parents of overweight and obese youth of obesity's sequelae, but the increase in prevalence of childhood obesity has made population reach an important issue. For most people information provided by their health care professionals has significant credibility, and even brief advice, if it is informed and delivered appropriately, can have a meaningful impact. In a study of overweight and obese adult patients, those who had weight-related communication with their healthcare providers were almost nine times more likely to believe that their weight status is damaging to their health (Durant et al., 2009). Obesity treatment interventions targeted toward children have been shown to be more effective than those for adults (Epstein et al., 1998), but these empirically supported family-based treatment programs typically require frequent intensive in-person visits, limiting their reach. In contrast, pediatric care providers have frequent, albeit brief, interactions with families, putting them in the perfect position to provide guidance and behavioral support for prevention in addition to treatment. Despite the increasing recognition, focus, and research, rates of provision of obesity-related guidance and counseling from primary care providers to parents remain low (Tanda & Salsberry, 2013).

Research also indicates that health care providers could use additional education, training, and support related to effective communication and motivation of patients. The types of communication between providers and patients are important in these brief encounters. Research suggests that just talking with patients about obesity is not sufficient. Rather, how providers talk with patients about obesity during a health care visit is of critical importance. When providers were asked about the primary barriers to preventing childhood obesity, they indicated the lack of parent and child motivation, family sedentary behavior, and poor eating habits in the family (Spivack et al., 2010). Similarly, parents of overweight children frequently mention child and family food preferences, resistance to change, and economic barriers to change (Sonneville et al., 2009). Lack of motivation and unhealthful family habits are likely to be difficult to change and require specific targeted training in order to be effective. The use of motivational interviewing techniques that are patient-centered and engaging has been associated with weight loss in adults (Pollak et al., 2010). The goal of such interactions would be to raise awareness of the issues and activate parental concern and behavior change in a supportive way without causing undue discomfort. But skill acquisition in this area requires more than didactic materials. Brief training limited to "key talking points" may not be enough and could elicit defensiveness among parents. Thus, role-playing or interactive education training methods may be more effective in preparing health care providers for interactions with parents of overweight and obese youth.

To meet this imminent need, we are proposing to evaluate a training system with role-play simulations to train primary care providers to effectively conduct discussions with parents to provide intervention for, and reduce the likelihood of progression to, childhood obesity.

1.3 What preliminary results do you have that support your proposal?

We worked with SIMmersion LLC on a SBIR Phase 1 grant during which we developed an early version of the online simulation. During Phase 1, we obtained initial feedback about the simulation from experts in the field.

1.4 What is the importance of the research to the scientific community?

The proposed training system is significant because it will ensure that the necessary skills are appropriately acquired and maintained by providing trainees with ample opportunities to apply knowledge and build skills while receiving ongoing feedback. Additionally, developing computer-based training package will provide a cost-effective solution that will allow for the broad dissemination across the diverse range of student affairs personnel. By providing an effective training package that has the potential to broaden the number of personnel who receive training, this proposal will ensure that primary care providers acquire evidence-based approaches to provide parents the education and support they need to make healthy lifestyle changes for their families.

****2. APPROACH****

Some questions in this section do not apply to all study designs; please mark Not Applicable as appropriate.

2.1 Describe the study design (e.g., "This is a randomized controlled trial to test the effect of a guided imagery intervention on sleep quality"). Please see this List of Study Designs.

The efficacy of the simulation will be evaluated in a randomized controlled trial (RCT); 100 pediatric, family practice, and nursing clinicians and trainees at various levels of experience will be recruited to participate. Half of the participants will be

randomly assigned to the intervention group during which they will use the newly developed simulation product to develop their skills and half of participants will be randomly assigned to the wait-list control group; the primary outcome is performance in a role play with trained actors at 3 month follow-up.

2.2 How are you identifying eligible subjects or records? (e.g., clinic visit, search of Epic, registry, etc.)

	Not Applicable

We will identify providers through the HealthPartners Medical Group and Park Nicollet clinic system from our internal resources and we will identify nursing students, medical students, and residents through the School of Nursing and the Academic Health Center at the University of Minnesota. Respondents will be screened to identify initial eligibility.

2.3 What is the study population of interest and what are the study inclusion/exclusion criteria?

The subjects for the study are primary care pediatricians, family practice physicians, and nurse practitioners, as well as medical and nursing students and residents. These health care providers will be recruited from clinics within the HealthPartners Medical Group system, the Park Nicollet clinic system, the University of Minnesota pediatrics and family medicine residency program, and the University Of Minnesota School Of Nursing. The study will include equal numbers of male and female subjects, all 21 years of age or older.

Eligible if:

21 years of age or older

A health care provider within the HealthPartners Medical Group system or Park Nicollet clinic system OR a resident in the University of Minnesota pediatrics and family medicine residency program OR a student in the University of Minnesota nurse practitioner program

Willing and able to participate in measurement visits and intervention activities

See pediatric patients greater than or equal to 1/3 of their practice time

Ineligible if:

< 21 years of age
Unable to ensure commitment to study measurement and intervention activities
See pediatric patients less than 1/3 of their practice time

2.4 If you are not using the entire population of interest, what is the method for obtaining a subset or sample of this population?

X	**Not Applicable**

2.5 Will you need to perform "preparation for research" activities prior to consenting subjects for research?

X	**No**
	Yes
	Not Applicable

If you answered yes above, appropriate preparation for research activities prior to consenting subjects must include the following process to determine inclusion/exclusion criteria:

1) Study staff will work with the PI to determine the methods used in identifying potential subjects for the research. For example, this may include creating an Epic Workbench report of patients who are in the hospital and meet minimum criteria for the research.

2) Study staff may access medical records of all potential subjects' identified (i.e., Workbench) to determine eligibility criteria using information that already exists in the medical record. During this process, no identifiable information may be recorded and any documentation made of a potential subject's information that would disqualify them will be destroyed.

If an eligible patient is not being cared for by the PI, study staff must approach the patient's provider to determine if it is appropriate to proceed with the consent process.

3) If additional testing needs to be done to see whether a patient meets criteria for entry into the study, the PI or staff will need to consent the patient first.

4) If the preparation activity confirms a patient is a possible subject, PI/staff approaches the patient to begin the consent process.

2.6 Describe the steps in your recruitment process.

	Not Applicable

1. Recruiting in the following ways: identify provider through the HealthPartners Medical Group and Park Nicollet clinic system from our internal resources. Identify pediatric and family practice residents, medical students and nursing student. We will also be giving presentations about the study at existing meetings for the various groups and interested people at these meetings will then proceed starting at Step 3.

2. Send invitation e-mail to potentially eligible providers, residents and students.

3. Screen for preliminary eligibility.

4. During the initial study visit, candidates will review and sign the consent. After the consent has been signed, the subject will participate in a survey and two role plays with a trained actor.

5. After the initial study visit is complete, the subject will be randomized to either intervention or waitlist control group.

2.7 Describe any interventions that are used in this study.

	Not Applicable

Educational Intervention: The educational intervention will be the online simulation training program. Participants will be taught how to use the simulation during a 20 minute orientation session with a research staff person. We will use a mastery based approach rather than prescribing an absolute number of hours participants need to play. The criteria are as follows: 1) achieving a score of 90% or more on 2 out of the last 3 simulations played or 2) maximum of 8 hours of play, whichever comes first. After the orientation sessions, training sessions will be completed by participants on their own. The research team will confirm remote usage, and contact participants by email and phone to prompt usage as needed. The research team anticipates that the proposed method will accommodate for participant schedules while still ensuring intervention compliance.

Waitlist Control Group: The control group will participate in pre- and post-test assessments of their conversational skills with a trained actor. At the end of the study, the waitlist control group will be allowed to access to the simulation and the study team will provide training to participants upon request.

2.8 Provide a brief, sequential, bullet-point description of the all the data collection activities you will conduct from start to finish (e.g., chart review, patient survey, follow-up visits, data pull from the electronic medical record, etc.) and who will conduct each. Please see our Example of Data Collection Steps.

1. Recruitment strategies including working with HealthPartners and Park Nicollet colleagues and the University of Minnesota contacts in order to identify candidates. Invitation emails will be sent to invite providers, residents and students to participate in the study.
2. The invitation email will include an initial screening survey for eligibility. Those who are eligible will be scheduled for an initial study visit.
3. Candidate will complete the initial baseline measurement visit where they will review and sign the consent, complete a survey, and participate in two role plays with a trained actor.
4. Subjects are randomized to either the intervention or waitlist control group.

5. Subjects randomized to the intervention group will complete one 20-minute session with a study staff member over the phone to learn about and practice with the simulator. Subjects will then practice with the simulator until 2 out of the last 3 simulations they have conducted receive a score greater than or equal to 90 percent OR up to 8 hours of play within the first 10 weeks. Subjects randomized to the control group will not receive any formal training beyond what they normally would receive.
6. All subjects will participate in a follow-up evaluation visit where they will complete a survey and participate in two role plays with a trained actor.
7. The control group will not receive any formal training beyond what they normally would receive during the course of the study. The wait list control group will receive access to the online simulation after the follow-up evaluation visit.

2.9 Provide a timeline for the main study activities. Please see our Example Timeline

	1	2	3	4	5	6	7	8	9	10	11	12
Obtain IRB approval	**x**											
Train standardized patients		**x**										
Recruitment & Baseline Measures			**x**	**x**	**x**	**x**	**x**					
Intervention			**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**		
Post-Test Measures						**x**	**x**	**x**	**x**	**x**		
Analysis & Manuscript Writing											**x**	**x**

2.10 Describe your plans for ensuring data security

All study personnel will have completed the human subjects training. Confidentiality of study data will be ensured by assigning a subject identification number to each participant. All data collected in the study will be identified by an arbitrary and unique subject identification number only. These data will be entered by identification number into a computerized database residing on a user name and password protected file-server to which only the researchers involved in the study will have access. No participant data will be individually identified or released to anyone other than the study investigators without specific written permission from the study participant.

2.11. List the KEY variables that will be collected to support the study aims outlined in item 1.1. KEY variables include those used for:
1) achieving the study aims (outcomes, predictors, potential confounders),
2) identifying the study population (for inclusion/exclusion criteria),
3) describing the study population

Please see an Example of a Completed Table and an Example Data Dictionary.

Variable Name	**Data Source (patient survey, EMR, claims, registry)**	**Purpose (sample identification, description, grouping variable, study endpoint, predictor, covariate)**	**Measurement Scale (binary, continuous)**
Demographic characteristics	Participant survey	Moderator	Continuous
Simulation Score	Based on role play with a standardized patient	Dependent Variable, primary outcome	Continuous
Confidence for addressing obesity with patients	Participant survey	Moderator	Continuous

2.12 Provide operational definitions of any variables listed above that aren't adequately described by the variable name above, and provide a brief background of any validated measurement scales listed above.

The simulation scoring system is tailored for the obesity simulation and is based on the Simmersion team's prior work using a similar standardized patione and scoring approach.(Fleming, M., Olsen, D., Stathes, H., Boteler, L., Grossberg, P., Pfeifer, J. & Skochelak, S. (2009). Virtual reality skills training for health care professionals in alcohol screening and brief intervention. The Journal of the American Board of Family Medicine, 22(4), 387-398).

Each participant will complete two role-plays pre-intervention and two role-plays post-intervention. These will be audio-recorded and labeled only by participant ID. Raters will be blind to condition and any participant identifiers.

2.13 If you are collecting data elements besides those listed in Table 2.10 above, provide a justification for gathering the additional data.

N/A

Reminder: For chart review studies, a data collection form must be uploaded with your application listing variables collected and how they are recorded (chart review studies). Provided are links to two example chart review tools: **Word Chart Review Example** and **Excel Chart Review Example**

****3. ANALYSIS****

3.1 Describe the statistical methods that will be used to address the study aims. For each aim, this will usually include:

- Description of the sample used for the particular analysis
- The variables included in the specific analysis and their role in the analysis
- Numeric summaries computed (e.g., mean, standard deviation, proportion, correlation)
- A summary of data exploration and presentation activities (e.g., generating scatter plots, summary tables)
- Description of statistical tests (e.g., independent samples t-test, Mann-Whitney test), and models constructed (e.g., logistic regression)

Please see our Examples of Statistical Methods.

Describe here:

Note: Please reference the area/pages of an established protocol if you are not writing your own analysis plan.

The attained effectiveness of the developed computer-based training program will be demonstrated through the analysis of relative pre-post changes on measures from the clinical skills assessments with standardized patients, with adjustment for baseline clinical skill assessment level. The clinical skills assessment data will be tested for treatment specific changes in conversational skills. Expected increases in skill levels will correspond to the skills acquisition objectives of the computer-based training simulations. Scores will be assigned to each research subject in the study for both pre-test and post-test sessions. To address the primary study aim regarding the efficacy of the simulation intervention in enhancing conversational skills, the treatment by time interaction will be quantified using a general linear mixed model approach where treatment (Simulation Intervention, Wait List Control) will be a fixed between-subjects effect and time a fixed within-subjects effect. Additional exploratory analyses will be conducted to examine if the patterns of change are the same across individual characteristics within the sample, such as student versus practitioner status, gender, and educational background (nursing, pediatrics, family practice.

Sample size:

3.2 What is the estimated sample size(s) for the primary study analyses (per group for studies with different arms or comparison groups)?

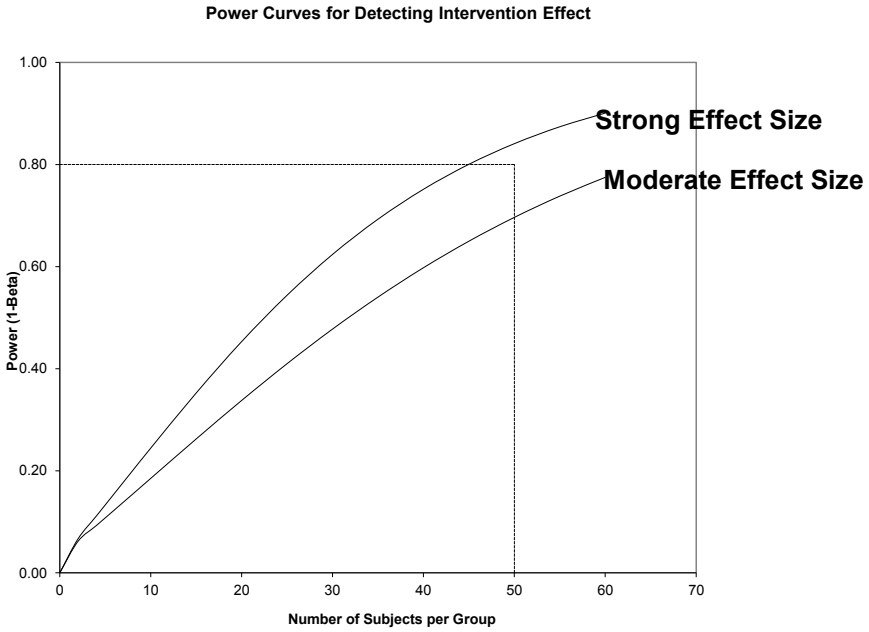
We will be recruiting up to 100 participants, with the goal of enrolling 30 clinicians in practice and 70 clinicians in training. Of the 70 clinicians in training the goal is to enroll 35 medical students/residents and 35 nursing students.

3.3 The sample size selected was (check all that apply):

	Based on data likely to be available during a specific time period (often based on data available in past periods)
X	To conduct one or more specific analyses with adequate statistical power
	To achieve a specified level of precision in one or more key estimates
	Other (explain):

3.4 Explain your choice of the sample size selection you listed above:

Power Calculation to Estimate Sample Size: Sample size calculations for the study are based on the power to detect a significant improvement in scores by the intervention group on the standardized patient assessments. Based on our experience with the NIAAA-funded STTR alcohol and screening simulation (Fleming, 2009), both groups will have mean scores of 150 out of the possible 300 points, with a standard deviation of 50. The control group is expected to show a 0.5(σ) improvement at follow-up due to standard test-retest factors such as familiarity. The intervention group is expected to show moderate (1.0 σ) to strong (1.1 σ) effect. Sample size and power projections are provided in the figure below. The graph represents the power and sample size requirements assuming a moderate (1.0 σ) or strong (1.1 σ) effect size in the intervention group. Assessment of the major hypothesis, assuming moderate efficacy, may be achieved with an effective sample size of 100 total subjects (50 per treatment arm) and statistical power (1-ß) of 0.70. If the intervention has the expected strong effect, we project study power (1-ß) to be between 80% and 85% with a sample size of 100.



3.5 Describe your assumptions concerning data available for analysis (e.g. How many subjects will be randomized, possibly lost to follow-up or a procedure? What do you expect for survey response rates, and how much missing data do you expect?). Include information as it pertains to your study (human or animal).

See above.

Power analysis

NOTE: If you are doing a descriptive study (i.e., aside from computing confidence intervals you are not using statistical tests, inferential statistical testing for group comparisons, or statistical models), please complete 3.6 and skip 3.7-3.8.

If you are conducting statistical tests, using statistical inference to compare groups, or are building statistical models, please skip 3.6 and complete 3.7-3.8. **Please see our Example Power Analysis.**

3.6 Provide a measure of the precision of your estimates for key study endpoints, (e.g., 95% confidence intervals on proportions or means), using actual expected estimates.

See above.

3.7 What level of differences observed in your primary endpoints would be considered clinically or practically significant?

See above.

3.8 What is the power for your primary analysis (and the set of assumptions underlying it: hypothesis addressed, expected pattern of effects with justification for these expectations, analysis used, variables in the analysis, effect sizes, sample sizes, alpha level, one or two-sided test)?

See above.

3.9 What are the limitations of the proposed approach and analysis?

It is possible our assumptions are incorrect and we won't have sufficient power to detect and intervention effect.

3.10 Please name the people who completed the analysis section of this application.

Laura Humm (Simmersion), Dale Olsen (Simmersion), Michael Fleming (Northwestern)

3.11 Please name the people who will summarize data and conduct statistical analysis.

Nancy Sherwood, PhD

****4. RESEARCH TEAM****

List your study team and degrees.	**List what each person will do:** Identify study subjects; Data entry; Chart abstraction; Statistical analysis; Study recruitment; Interview patients; Draft and revise manuscripts	**List each person's experience** Explain each person's previous research experience with the tasks assigned or what other background/experience relates to the task they are assigned.	**Time Estimate** Please estimate the number of hours or % effort each person will spend on the study
Nancy Sherwood, PhD	Oversee all aspects of the project including communicating to the IRB, ensuring methodological design compliance, supervising personnel and completing all data collection and statistical analysis. She will also be responsible for dissemination of study results.	PhD in clinical psychology, extensive experience managing research studies over a 15 year time period.	5% effort
Dani Bredeson, BS	Coordinate recruitment, measurement, intervention, data collection and IRB communication	Four years of experience at the Institute working on recruitment, data collection, quality assurance and study coordination.	30% effort
TBN	Research Specialist	Selected personnel will have experience working on recruitment, data collection and quality assurance	40% effort

****5. DISSEMINATION****

5.1 What are your plans for publication, including target journals?

We will write a primary outcome paper and will consider the following journals: Obesity, Childhood Obesity, American Journal of Preventive Medicine

5.2 What plans do you have to share results or translate results to care delivery at HP or for HP personnel?

We will share the results of the trial with the HealthPartners and Park Nicollet pediatrics and family medicine departments.

****6. ENVIRONMENT****

6.1 Where will the study be conducted? Why is the proposed location appropriate for study?

The study will be conducted at the University of Minnesota Simulation Center for all providers, students and residents, which allows for flexibility and convenience of a centralized location. The Simulation Center also is able to provide trained actors and private space for role play simulations as well as privacy for the informed consent process.

6.2 How will the results of this study impact the health of HealthPartners members and the community? Be specific as to whether and how you see any clinical application as a result of this study.

The simulation tool could be utilized by the HP and PN medical groups.

6.3 Does the treatment strategy (drug or service) proposed in the study commit HP to covering or continuing to provide the treatment or program support after the study is completed?

The treatment strategy does not commit HealthPartners to cover or continue to provide treatment or program support.

****7. OTHER REVIEW****

7.1 Has this study been submitted for other review and/or received approval/rejection previously, including but not limited to: Federal, collaborative agency, previous HealthPartners (rejected), or other funding sources (e.g., nonprofit foundation review)?

	No
X	**Yes** (Provide dates of submission and status of review [approved, pending, or rejected]) The study was submitted to the NIH/CDC and funded by the CDC. The study was funded in 2015, and we have been working on revising the simulation in preparation for the randomized trial.

7.2 Does this study require review by HealthPartners Radiation Safety Officer?

X	**No**
	Yes Please state that you have spoken to the Radiation Safety Office (651-254-3322) and have their support for this study.

If a research protocol is to involve the use of ionizing or non-ionizing radiation, the principal investigator (PI) should contact the Institutional Radiation Safety Officer (RS0) for Regions Hospital and HealthPartners clinics.

Regions Radiation Safety Office: 651-254-3322.
Frank E. Zink, Ph.D., Radiation Safety Officer for X-Ray Use
Yuanlin Peng, Ph.D., Radiation Safety Officer for Radioactive Materials

****8. DATA ACCESS REQUEST****

These questions must be completed if you are accessing HP/Regions data or if you study involves a HealthPartners Institute programmer. You will need to work with an Institute programmer to complete this form. Please contact Ann Werner (952-967-5263) or Teri Defor (952-967-7304) for assistance.

If you are not proposing the access HP/Regions data (e.g. Animal Study), you may check "N/A" below.

8.1 What is the name of the programmer helped you complete this section?

NA

8.2 Will you need to add a programmer to your study team?

X	**No**
	Yes

8.3 Considering your inclusion/exclusion criteria described in 2.3, what specific data will you need?

NA

8.4 What years of data are needed?

NA

8.5 Will any of the study data be shared or transferred to others within HealthPartners?

No

8.6 Will any study data be shared or transferred to others outside of HealthPartners?

	No
	Yes - mark which method you will use to share study data: [X] E-transfer [X] Secure website/portal [ ] Other secure, encrypted method. Describe below.
A de-identified limited dataset will be transferred to study partners after all data is collected for analysis purposes.	

8.7 Data Sources (please mark all known data sources)

Mark (X)	Data Source	Mark (X)	Data Source
	EWIS – Claims Data		Registries (chronic condition, disease)
	RDW (Research Data Mart) – historical medical, dental, state death data		Inpatient Case Management data (i.e., Care Guide, Care Partner)
	Claims/Mumps/Cache		Paper Medical Chart
	EPIC (Electronic Medical Record)		Provider's own source (own patient's chart, provider or department/hospital registry)
	EDR (Electronic Dental Record)		Geriatric department data (i.e., transitional, long term care database)
	EDR Reporting		Data directly from contracted clinics
x	New Subject Survey		VDW (Virtual Data Warehouse)
	MEDIPAC System (Regions Billing System)		Consolidated Network Provider (CPN)
	Physician Services Department Data		Health Behavior Group Data (e.g., 10,000 steps, HRA)
	MN State Death Data		MN State Birth Data
	Misys/Sunquest (Lab production system)		Clarity (Epic Reporting Database)
x	Other (Please describe): role play with trained actor score		

8.8 Exclusion Lists: Institute programmers are required to review and apply the following privacy requirements to study patients and their wishes regarding access to medical record information.

Mark X	Exclusion List
	HealthPartners Institute Exclusion List which excludes persons from all medical research. This should be used for all studies. Applies to all data used internally and externally.
	Gramm-Leach-Biley Opt-Out List: (if known; sometimes this can be determined after a study starts). Applies to identifiable data being sent externally.
	Consent for Treatment-Payment-Operations (TPO) Opt-Out List: (if known; sometimes this can be determined after a study starts). Applies to identifiable data being sent externally.

8.9 Data Elements (Please mark all elements that will be used/ accessed during the study):

Mark (X)	Data Elements
	Name
	Address
	Telephone Number (any)
	Fax Number
	Certificate/license number (i.e., DEA number, professional license number)
	Email address
	Device identifier or serial number
	URL or IP address (web addresses)
	Full face photos, biometric identifiers, or other images
	Health Plan beneficiary number (or family contract number)
	Date of Birth
	Vehicle identification or serial number
	Medical Record number (or any personal record identifier)

8.10 Data Content (Please mark all content areas that apply to your study

Mark (X)	Data Content
	Demographic: age and gender
	Health Plan enrollment information (i.e., dates, coverage)
	Diagnoses - Medical
	Procedures - Medical
	Mortality Data
	Lab Results
	Prescriptions/ Medications
	Dates of Service (treatment)
	Facility or Provider Identifier / Characteristics (e.g., specialty, FTE, Clinic)
	Birth Certificate Data
	Pathology / Tissue Type
	Financial data
	Provider notes

	Vitals – height, weight, BP, etc
	Social history – tobacco use, etc.
	Other Clinical data
	Other: please describe:

******9. REFERENCES******

9.1 Please list below or attach a list of numbered references to support your literature review in section 1 above.

Anderson, SE, Whitaker, RC. Household Routines and Obesity in US Preschool-Aged Children. Pediatrics. 2010;125:420-428.

Berg-Smith, SV. Stevens, Brown KM, Van Horn L, Gernhofer N, Peters E, Greenberg R, Snetselaar L, Ahrens L, Smith K. A brief motivational intervention to improve dietary adherence in adolescents: The dietary intervention study in children (DISC) research group. Health Education Research. 1999;14:399-410.

Boutelle K, Fulkerson JA, Neumark-Sztainer D, Story M. Mothers' perceptions of their adolescents' weight status: are they accurate? Obes Res. 2004;12:1754-7.

Brambilla P, Bedogni G, Buongiovanni C, Brusoni G, Di Mauro G, Di Pietro M, et al. "Mi voglio bene": a pediatrician-based randomized controlled trial for the prevention of obesity in Italian preschool children. Italian journal of pediatrics. 2010;36:55.

Cotton B, Smith A, Hansen I, Davis C, Doyle A, Walsh A. Physician-directed primary care intervention to reduce risk factors for type 2 diabetes in high-risk youth. Am J Med Sci. 2006;332:108-11.

Dalton WT, 3rd, Schetzina KE, Holt N, Fulton-Robinson H, Ho AL, Tudiver F, et al. Parent-Led Activity and Nutrition (PLAN) for healthy living: design and methods. Contemp Clin Trials. 2011;32:882-92.

Dolinsky DH, Armstrong SC, Walter EB, Kemper AR. The effectiveness of a primary care-based pediatric obesity program. Clin Pediatr (Phila). 2012;51:345-53.

Durant NH, Bartman B, Person SD, Collins F, Austin SB. Patient provider communication about the health effects of obesity. Patient Educ Couns. 2009;75: 53-7.

Eliakim A, Friedland O, Kowen G, Wolach B, Nemet D. Parental obesity and higher pre-intervention BMI reduce the likelihood of a multidisciplinary childhood obesity program to succeed--a clinical observation. Journal of pediatric endocrinology & metabolism : JPEM. 2004;17:1055-61.

Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. Pediatrics. 1998;101:554-70.

Ewing LJ, Cluss P, Goldstrohm S, Ulrich R, Colborn K, Cipriani L, et al. Translating an evidence-based intervention for pediatric overweight to a primary care setting. Clin Pediatr (Phila). 2009;48:397-403.

Finkelstein EA, Trogdon JG, Brown DS, Allaire BT, Dellea PS, Kamal-Bahl SJ. The lifetime medical cost burden of overweight and obesity: Implications for obesity prevention. Obesity (Silver Spring). 2008;16(8):1843-1848. doi: 10.1038/oby.2008.290; 10.1038/oby.2008.290.

Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: Payer-and service-specific estimates. Health Aff (Millwood). 2009;28(5):w822-31. doi: 10.1377/hlthaff.28.5.w822; 10.1377/hlthaff.28.5.w822.

Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010;303(3):235-41. Epub 2010 Jan 13.

Fleming, M., Olsen, D., Boteler, L., Stathes, H., Grossberg, P., Pfiefer, J., Schiro, S., Banning, J., & Skochelak, S. (2009). Virtual reality skills training for health care professionals in alcohol screening and brief intervention. Journal of the American Board of Family Medicine, 22(4), 387–398. doi: 10.3122/jabfm.2009.04.080208

Ford BS, McDonald TE, Owens AS, Robinson TN. Primary care interventions to reduce television viewing in African-American children. Am J Prev Med. 2002;22:106-9.

Franks PW, Hanson RL, Knowler WC, Sievers ML, Bennett PH, Looker HC. Childhood obesity, other cardiovascular risk factors, and premature death. N Engl J Med. 2010;362(6):485-93.

Gillis D, Brauner M, Granot E. A community-based behavior modification intervention for childhood obesity. Journal of pediatric endocrinology & metabolism : JPEM. 2007;20:197-203.

Gough JK, Frydenberg AR, Donath SK, Marks MM. Simulated parents: developing paediatric trainees' skills in giving bad news. J Paediatr Child Health. 2009;45:133-138.

Hare ME, Coday M, Williams NA, Richey PA, Tylavsky FA, Bush AJ. Methods and baseline characteristics of a randomized trial treating early childhood obesity: the Positive Lifestyles for Active Youngsters (Team PLAY) trial. Contemp Clin Trials. 2012;33:534-49.

Issenberg SB, McGahie WC, Petrusa ER, Gordon L, Scalese RJ. Features and uses of high-fidelity medical simulations that lead to effective learning: a systematic review. Med Teach. 2005;27(1):10-28.

Jacobson D, Melnyk BM. A primary care healthy choices intervention program for overweight and obese school-age children and their parents. Journal of pediatric health care : official publication of National Association of Pediatric Nurse Associates & Practitioners. 2012;26:126-38.

Jelalian E, Boergers J, Alday CS, Frank R. Survey of physician attitudes and practices related to pediatric obesity. Clin Pediatr (Phila). 2003;42(3):235-45.

Jolliffe D. Extent of overweight among US children and adolescents from 1971 to 2000. Int J Obes Relat Metab Disord. 2004;28(1):4-9.

Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment for childhood obesity compared with routinely given individual counseling. Int J Obes (Lond). 2007.

Korsten-Reck U, Kromeyer-Hauschild K, Wolfarth B, Dickhuth HH, Berg A. Freiburg Intervention Trial for Obese Children (FITOC): results of a clinical observation study. Int J Obes (Lond). 2005;29:356-61.

Kubik MY, Story M, Davey C, Dudovitz B, Zuehlke EU. Providing obesity prevention counseling to children during a primary care clinic visit: results from a pilot study. J Am Diet Assoc. 2008;108:1902-6.

Lundahl A, Kidwell KM, Nelson TD. Parental Underestimates of Child Weight: A Meta-analysis. Pediatrics. 2014 Mar;133(3):e689-703. doi: 10.1542/peds.2013-2690. Epub 2014 Feb 2.

McCallum Z, Wake M, Gerner B, Baur LA, Gibbons K, Gold L, et al. Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity. Int J Obes (Lond). 2007;31:630-6.

Nemet D, Barkan S, Epstein Y, Friedland O, Kowen G, Eliakim A. Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity. Pediatrics. 2005;115:e443-9.

O'Connor TM, Hilmers A, Watson K, Baranowski T, Giardino AP. Feasibility of an obesity intervention for paediatric primary care targeting parenting and children: Helping HAND. Child: care, health and development. 2013;39:141-9.

Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity in the United States, 2009-2010. NCHS Data Brief. 2012 Jan;(82):1-8

Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. JAMA. 2012 Feb 1;307(5):483-90. doi: 10.1001/jama.2012.40. Epub 2012 Jan 17

Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999–2004. JAMA. 2006;295(13):1549-55.

Ogden CL, Yanovski SZ, Carroll MD, Flegal KM. The epidemiology of obesity. Gastroenterology. 2007;132(6):2087-102. Review.

Phelan S, Nallari M, Darroch FE, Wing RR. What do physicians recommend to their overweight and obese

patients? J Am Board Fam Med. 2009;22:115-22.

Pinhas-Hamiel O, Singer S, Pilpel N, Fradkin A, Modan D, Reichman B. Health-related quality of life among children and adolescents: associations with obesity. Int J Obes (Lond). 2006;30(2):267-72.

Pollak KI, Alexander SC, Coffman CJ, Tulsky JA, Lyna P, Dolor RJ, James IE, Namenek Brouwer RJ, Manusov JRE, Østbye T. Physician Communication Techniques and Weight Loss in Adults: Project CHAT. Am J Prev Med. 2010 October; 39(4): 321–328

Poon M-Y, Tarrant M. Obesity: attitudes of undergraduate student nurses and registered nurses. J Clin Nurs. 2009;8:2355-65.

Quattrin T, Roemmich JN, Paluch R, Yu J, Epstein LH, Ecker MA. Efficacy of Family-Based Weight Control Program for Preschool Children in Primary Care. Pediatrics. 2012.

Resnicow, K, Davis R, Rollnick S. Motivational interviewing for pediatric obesity:conceptual issues and evidence review. Journal of the American Dietetic Association. 2006;106:2024-2033

Saelens BE, Sallis JF, Wilfley DE, Patrick K, Cella JA, Buchta R. Behavioral weight control for overweight adolescents initiated in primary care. Obes Res. 2002;10:22-32.

Savoye M, Shaw M, Dziura J, Tamborlane WV, Rose P, Guandalini C, Goldberg-Gell R, Burgert TS, Cali AM, Weiss R, Caprio S.Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. Jama. 2007;297:2697-704.

Schwartz RP, Hamre R, Dietz WH, Wasserman RC, Slora EJ, Myers EF, et al. Office-based motivational interviewing to prevent childhood obesity: a feasibility study. Arch Pediatr Adolesc Med. 2007;161:495-501.

Shaikh U, Nettiksimmons J, Romano P. Pediatric obesity management in rural clinics in California and the role of telehealth in distance education. J Rural Health. 2011;27(3):263-269. doi: 10.1111/j.1748-0361.2010.00335.x; 10.1111/j.1748-0361.2010.00335.x.

Skelton JA, Cook SR, Auinger P, Klein JD, Barlow SE. Prevalence and trends of severe obesity among US children and adolescents. Acad Pediatr. 2009;9(5):322-9. Epub 2009 June 27.

Slusser W, Frankel F, Robison K, Fischer H, Cumberland WG, Neumann C. Pediatric overweight prevention through a parent training program for 2-4 year old Latino children. Child Obes. 2012;8:52-9.

Sonneville KR, La Pelle N, Taveras EM, Gillman MW, Prosser LA. Economic and other barriers to adopting recommendations to prevent childhood obesity: results of a focus group study with parents. BMC Pediatr. 2009 Dec 21;9:81.

Spivack JG, Swietlik M, Alessandrini E, Faith MS. Primary care providers' knowledge, practices, and perceived barriers to the treatment and prevention of childhood obesity. Obesity (Silver Spring). 2010 Jul;18(7):1341-7.

Story MT, Neumark-Stzainer DR, Sherwood NE, Holt K, Sofka D, Trowbridge FL, Barlow SE. Management of child and adolescent obesity: attitudes, barriers, skills, and training needs among health care professionals. Pediatrics. 2002;110(1 Pt 2):210-4.

Tanda R, Salsberry P. The Impact of the 2007 Expert Committee Recommendations on Childhood Obesity Preventive Care in Primary Care Settings in the United States. J Pediatr Health Care. 2013 Jul 4. pii: S0891-5245(13)00196-X. doi: 10.1016/j.pedhc.2013.05.009

Taveras EM, Blackburn K, Gillman MW, Haines J, McDonald J, Price S, et al. First steps for mommy and me: a pilot intervention to improve nutrition and physical activity behaviors of postpartum mothers and their infants. Matern Child Health J. 2011;15:1217-27.

Taveras EM, Gortmaker SL, Hohman KH, Horan CM, Kleinman KP, Mitchell K, et al. Randomized controlled trial to improve primary care to prevent and manage childhood obesity: the High Five for Kids study. Arch Pediatr Adolesc Med. 2011;165:714-22.

Veldhuis L, Struijk MK, Kroeze W, Oenema A, Renders CM, Bulk-Bunschoten AM, et al. 'Be active, eat right', evaluation of an overweight prevention protocol among 5-year-old children: design of a cluster randomised controlled trial. BMC Public Health. 2009;9:177.

Vine M, Hargreaves MB, Briefel RR, Orfield C. Expanding the role of primary care in the prevention and treatment of childhood obesity: a review of clinic- and community-based recommendations and interventions. J Obes. 2013;2013:172035. doi: 10.1155/2013/172035. Epub 2013 Apr 28.

Wake M, Baur LA, Gerner B, Gibbons K, Gold L, Gunn J, et al. Outcomes and costs of primary care surveillance and intervention for overweight or obese children: the LEAP 2 randomised controlled trial. BMJ. 2009;339:b3308.

Wang F, Wild TC, Kipp W, Kuhle S, Veugelers PJ. The influence of childhood obesity on the development of self-esteem. Health Rep. 2009;20(2):21-7.

Weigel C, Kokocinski K, Lederer P, Dotsch J, Rascher W, Knerr I. Childhood obesity: concept, feasibility, and interim results of a local group-based, long-term treatment program. J Nutr Educ Behav. 2008;40:369-73.

Wille N, Erhart M, Petersen C, Ravens-Sieberer U. The impact of overweight and obesity on health-related quality of life in childhood—results from an intervention study. BMC Public Health. 2008 Dec 23;8:421.

Young PC, West SA, Ortiz K, Carlson J. A pilot study to determine the feasibility of the low glycemic index diet as a treatment for overweight children in primary care practice. Ambul Pediatr. 2004;4(1):28-33.