

Promoting Physical Activity in Latinas via Interactive Web-based Technology

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IRB Approved Study Protocol

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PROTOCOL TITLE: Promoting Physical Activity in Latinas via Interactive Web-Based Technology

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1.0 Study Summary

Protocol Information	Description
Study Title	Promoting Physical Activity in Latinas via Interactive Web-Based Technology
Study Design	This is a 24-month randomized controlled trial design comparing two Spanish language, individually tailored Internet-based PA interventions: (1) the original empirically supported, theory-based, Pasos Hacia La Salud Intervention (Original Intervention), and (2) an data-driven enhanced version of Pasos Hacia La Salud (Enhanced Intervention). The Enhanced Intervention incorporates findings and participant feedback from the parent study, which indicated that website use and changes in several theoretical constructs were key to successful PA behavior change. Thus, in addition to all the same content as the original intervention, the Enhanced Intervention provides additional support and resources for increasing and sustaining PA through use of text messages to promote log-ins and activity on the intervention website, additional targeting of theoretical constructs mentioned above, as well as new website features such as adaptive goal setting. We will test the efficacy of the Enhanced Intervention for increasing MVPA compared to the Original Intervention at the end of the active intervention period (6 months), and for maintaining MVPA increases over time (12 and 24-month follow-up).
Primary Objective	To test the efficacy of the Enhanced Intervention for increasing MVPA (moderate to vigorous physical activity).
Secondary Objective(s)	To test the efficacy of the Enhanced Intervention for PA maintenance.

	Evaluate whether the theoretically driven constructs (e.g. self-efficacy, enjoyment, social support) mediate the intervention effect. Explore potential moderators of efficacy including acculturation, health literacy, and BMI. Evaluate the cost effectiveness of delivering the Original vs. the Enhanced Intervention Conduct semi-structured qualitative interviews with mothers of young children (n=30) who participated in our recent superiority RCT, to further understand their intervention experiences.
Research Intervention(s)/ Investigational Agent(s)	
IND/IDE #	N/A
Study Population	Latina women ages 18-65
Sample Size	300
Study Duration for individual participants	24 months
Study Specific Abbreviations/ Definitions	Physical Activity (PA) Moderate to Vigorous Physical Activity (MVPA) Physical Activity Recall (PAR)

2.0 Objectives

2.1 *Describe the purpose, specific aims, or objectives.*

Primary Aims:

Aim 1: To test the efficacy of the Enhanced Intervention for increasing MVPA (moderate to vigorous physical activity).

Aim 2: To test the efficacy of the Enhanced Intervention for PA maintenance.

Additional Questions of Interest:

- Evaluate whether the theoretically driven constructs (e.g. self-efficacy, enjoyment, social support) mediate the intervention effect.
- Explore potential moderators of efficacy including acculturation, health literacy, and BMI.
- Evaluate the cost effectiveness of delivering the Original vs. the Enhanced Intervention
- Conduct semi-structured qualitative interviews with mothers of young children (n=30) who participated in our recent superiority RCT, to further understand their intervention experiences.

2.2 *State the hypotheses to be tested.*

Our hypothesis is that participants randomized to the Enhanced Intervention arm will demonstrate significantly higher accelerometer measured MVPA at 6 months (Aim 1) and at 12, 18, and 24 months (Aim 2) compared to participants in the Original Intervention arm.

3.0 Background

3.1 *Describe the relevant prior experience and gaps in current knowledge.*

Dr. Marcus (PI) and colleagues have over 25 years' experience developing and testing empirically supported individually tailored print and web-based PA interventions (e.g., R011HL64342, R01HL69866), as well as adapting these interventions for Latinos (R21NR009864; R01NR011295; R21NR01491). To meet the changing intervention needs and technology preferences of this rapidly growing yet underserved target population, our web-based PA intervention was culturally and linguistically adapted for Latinas (R01CA15994), and successfully implemented with 205 Latinas in the parent study. We also have extensive experience in recruitment and retention of Latinos (Drs. Marcus, Marquez, Benitez, Pekmezi) and using text messaging for promoting behavior change (Drs. Patrick and Marcus).

While PA interventions have shown significant PA increases in Latinas, results are limited to short-term follow-up. Most PA intervention studies with Latinas have not followed participants beyond 12 months. The few that did looked mostly at older adults, people with Type 2 Diabetes, or parent-child pairs, not the general Latina adult population. Additionally, despite the

significant increases in MVPA, participants were on average still well below national PA guidelines, suggesting that a more intensive Internet-based approach is necessary to help sedentary Latinas reach and sustain health-enhancing PA levels.

3.2 Describe any relevant preliminary data.

Findings from our recent culturally and linguistically adapted, print-based PA program for Latinas in the Northeast (R01NR011295) demonstrated significantly greater increases in moderate-to-vigorous physical activity (MVPA) in the Intervention arm than the Wellness arm at both 6 (mean difference=41.36 min/week, SE=7.93, $p<0.01$) and 12 months (mean difference=52 min/week, SE=9.38, $p<.01$). These findings were also corroborated by accelerometer data with $\rho=0.370$, $p<.05$.

Building on the success of this evidence-based print intervention, and the rapid growth of Internet use among Latinos, we conducted formative research with Latinas regarding their Internet use behaviors to develop an Internet-based PA intervention that was tested in the parent study in Southern California (Pasos Hacia La Salud, R01CA159954) for the current proposal. Results of our intervention showed that participants achieved significant PA improvements, increasing from 8.1 min/week of MVPA at baseline to 75.8 min/week of MVPA at 6 months and 70.4 min/week at 12 months.

The Enhanced Intervention incorporates findings and participant feedback from the parent study, which indicated that website use and changes in several theoretical constructs were key to successful PA behavior change. Thus, in addition to all the same content as the original intervention, the Enhanced Intervention provides additional support and resources for increasing and sustaining PA through use of text messages to promote log-ins and activity on the intervention website, additional targeting of theoretical constructs mentioned above, as well as new website features such as adaptive goal setting.

3.3 *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

Latinas exhibit high rates of inactivity and related chronic health conditions (including some cancers, diabetes, stroke, and hypertension). Despite the benefits of PA for enhancing health, reducing illness, disability and early death, Latinas are one of the least active populations in the U.S. Only 38.2% of Latinas in the U.S. meet the national guidelines for aerobic PA (>150 minutes/week of at least moderate intensity aerobic activity), compared to 50.9% of non-Latino White women and 47% of Latino men. Moreover, Latinas report numerous social, environmental, economic, linguistic, and cultural factors that limit their access to PA programs and resources. This calls for innovative strategies to overcome these barriers and help Latinas achieve the health benefits associated with PA and a need for culturally and linguistically adapted physical activity interventions.

This study will strengthen the power and reach of an existing web-based physical activity intervention for Latinas (Pasos Hacia La Salud,

R01CA159954, conducted through the University of California San Diego), by increasing the intervention's efficacy, increasing maintenance of the intervention effects, and incorporating up to date technology.

4.0 Study Endpoints

4.1 *Describe the primary and secondary study endpoints.*

Accelerometer. For the week prior to each assessment, participants will wear an Actigraph GT3X+ accelerometer, which measures movement and intensity of activity and has been validated against heart rate telemetry and total energy expenditure.

7-Day PAR Interview. Provides an estimate of total weekly minutes of PA. The 7-Day PAR has been used across many PA studies and has consistently demonstrated acceptable reliability, internal consistency, and congruent validity with other more objective PA measures along with sensitivity to changes in both moderate and intensive levels of PA. Our team has extensive experience with administering this instrument, which requires annual recertification.

4.2 *Describe any primary or secondary safety endpoints.* N/A

5.0 Study Intervention/Investigational Agent

5.1 *Description: Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Original Intervention Condition: Participants randomized to the Original Intervention condition will receive access to the Spanish language website designed for the original Pasos Hacia La Salud intervention study. At the in-person visit, study staff will guide participants on how to log into the website and use all the features. The website includes: 1) an interactive PA tracking calendar; 2) a discussion forum; 3) exercise videos; and 4) regular updates by peer PA progress. Features will be updated regularly to model the dynamic nature of the internet by providing users with new and engaging content.

At the in-person meeting, study staff will guide participants to set a personalized PA goal, teach participants how to enter the goal into the website and track their activity on the website. Participants will be encouraged by staff to regularly access the website and will receive email prompts to visit the website and complete online surveys. Emails will be sent weekly during month 1, every other week during months 2 and 3, and monthly during months 4-12. New tip sheets will be made available on the website on this same schedule. From months 13-24 participants will have continued access to the website but will not receive additional emails or contacts from the study.

Additional monthly email prompts will direct participants to complete online update surveys. The participant will click on the URL contained in the email, which will send the

participant to the survey link. Upon completing the monthly update surveys, participants will immediately receive an online tailored expert system report based on their responses to the survey. These reports will include information regarding: 1) current stage of motivational readiness for PA; 2) increasing self-efficacy; 3) cognitive and behavioral strategies associated with PA (processes of change); 4) how the participant compares to individuals who are physically active and with national guidelines (normative feedback); 5) how the participant compares to her prior responses (progress feedback); and 5) useful facts about PA, such as health benefits, stretching, and heart rate monitoring. The expert system draws from a bank of over 300 messages addressing different levels of these psychosocial and environmental factors affecting PA. After reading the expert report, the participant will click “next” and receive an online motivation-matched PA manuals which emphasize behavioral strategies for increasing activity levels, such as goal-setting, self-monitoring, problem-solving barriers, increasing social support, and rewarding oneself for meeting PA goals.

In addition to the website and emails, participants will receive 3 brief phone calls (5-15 min each) at 1 week, 1 month, and 9 months to answer questions about using the website and support participants in revising PA goals.

Enhanced Intervention Condition: Participants in the Enhanced Intervention arm will receive all the intervention components of the Original Intervention described above. They will have an in-person session to review website use and receive regular text messages from the study. They will have 3 brief phones with study staff (at the same schedule described for the Original Intervention Condition). They will also receive monthly prompts to complete an online questionnaire, receive a tailored report based on their answers along with a PA manual matching their current level of motivation. However, this group will receive enhanced features which include: text messages to prompt them to access the website, and enhanced website content and features.

The monthly expert system reports for this arm will be enhanced to include added tailored feedback messages on social support and enjoyment. In addition, tip sheets will be posted on the website that provide more in-depth information on these constructs. Additional tip sheets will be posted biweekly during the first six months of the study, monthly during months 7-12, and once during months 14, 16, 18 and 21. Participants will have unlimited access to the website during the 24 months of the study.

Participants will receive two text messages per week during the first six months of the study, followed by once weekly texts during months 7-12, and biweekly texts during months 13-24. Texts will provide brief personalized feedback on participant’s website use, along with reminders to use the tracking features on the website. Participants will have the opportunity to earn non-monetary incentives (e.g., water bottles) and virtual awards (tokens) for regularly logging on to the website and using interactive features (e.g., posting a goal, completing a questionnaire; features associated with greatest PA change in parent study). The virtual tokens will be presented on their home page as a form of reward for participants’ completion of an activity, such as a “Shooting Star Token” for logging on to the website more than 10 times in a week.

The PA tracking feature for the Enhanced Intervention condition will be refined for adaptive goal setting. The Original Intervention emphasizes a relatively static goal of reaching national guidelines for PA. However, the goal setting feature for the Enhanced

Intervention will encourage participants to increase their current PA by approximately 20% each month.

Additional enhancements to other sections of the website include:

- The video section will feature longer instructional videos (10-30 minutes) that teach participants skills necessary to perform PA.
- The discussion board will be used as a platform to facilitate community meet-ups among participants. Study staff will also post a list of free and low cost PA events participants could attend.
- The interactive community board will include a new “check-in” feature that will enable other participants to view their status. Study staff will introduce the group, monitor group conversations, and post a new discussion topic related to social support once weekly during the first 6 months of the study and bi-weekly during months 7-12. Participants will be identified in discussion groups only by self-selected usernames. The community board will remain available to participants to visit during months 12-24.

6.0 Procedures Involved

6.1 Describe and explain the study design.

This is a 24-month randomized controlled trial design comparing two Spanish language, individually tailored Internet-based PA interventions: (1) the original empirically supported, theory-based, Pasos Hacia La Salud Intervention (Original Intervention), and (2) an data-driven enhanced version of Pasos Hacia La Salud (Enhanced Intervention). The Enhanced Intervention incorporates findings and participant feedback from the parent study, which indicated that website use and changes in several theoretical constructs were key to successful PA behavior change. Thus, in addition to all the same content as the original intervention, the Enhanced Intervention provides additional support and resources for increasing and sustaining PA through use of text messages to promote log-ins and activity on the intervention website, additional targeting of theoretical constructs mentioned above, as well as new website features such as adaptive goal setting. We will test the efficacy of the Enhanced Intervention for increasing MVPA compared to the Original Intervention at the end of the active intervention period (6 months), and for maintaining MVPA increases over time (12 and 24-month follow-up). Participants who participated in Pasos study and agreed to be re-contacted for future research activities will be invited to take part in a new study procedure. This study procedure is described below and will require a consent addendum.

6.2 *Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.*

Recruitment:

Recruitment flyers and brochures will be displayed and distributed at community locations around Rhode Island and the surrounding Massachusetts area. We will place flyers in public areas (e.g. grocery

stores, libraries, community centers) with high traffic of Latina women. We will also advertise on local media outlets such as newspapers, radio stations, and web-based outlets such as Craigslist and a local Facebook page. In addition, we will do outreach with Latino community organizations around the state, such as Progreso Latino and Clinica Esperanza.

Telephone Screening:

Participants that contact the team to interested in the study will first complete an eligibility screener by telephone with a staff member. Participants will be screened for factors that may increase risk of injury. Potential participants with medical or psychological problems that could make adherence with the study protocol difficult or dangerous will not be included. Exclusions include history of coronary heart disease, history of myocardial infarction, symptoms of angina, diabetes, stroke, osteoarthritis, osteoporosis, orthopedic problems that would limit activity during the following 24 months, or any other serious medical condition that would make physical activity unsafe (based on the modified Physical Activity Readiness Questionnaire). Other exclusion criteria will include current or planned pregnancy, planning to move from the area within the next two years, current suicidal ideation or psychosis, current clinical depression, hospitalization due to a psychiatric disorder in the past 3 years, BMI above 45 kg/m², and/or taking medication that may impair physical activity tolerance or performance (e.g., beta blockers).

After screening is completed, eligible and interested participants must agree to be randomly assigned to one of the intervention conditions. When individuals do not qualify for the study during the screening process, we will deem them ineligible and store their information in a locked file cabinet at the School of Public Health building. Only designated research staff will have access to this file cabinet. We will store the information collected from ineligible individuals to track reasons for ineligibility and to examine potential differences between eligible and ineligible individuals on other variables (e.g., demographics). In addition, we maintain contact information of ineligible individuals who have given our staff explicit permission to contact them regarding future studies for which they may be eligible to participate.

Orientation Visit:

Following telephone screening for eligibility, interested individuals will be asked to attend an in-person, group orientation session in which a bilingual/bicultural research staff member will provide detailed information about the study. During this session, all questions regarding participation in the study will be answered. All interested participants will then be asked to read and sign a consent form approved by the university's Institutional Review Board. After the informed consent process, all participants will be required to complete a web and text message access test. The individual will also be sent a text message to their personal cellphone. They will be

required to respond to the message. Once the participant has successfully completed both tests, they will be scheduled for a measurement visit.

Measurement Visit:

At this in-person visit, participants will have their measurements taken by bilingual study staff. Their height, weight, waist circumference, blood pressure, and percent body fat will be measured. Additionally, participants will also complete study questionnaires. At the end of the visit, participants will be given a physical activity monitor and detailed instructions to wear it for seven days.

Baseline Assessment/Randomization Visit:

One week after the measurement visit, participants will return for a second in-person visit at the Brown School of Public Health where they will return the activity monitor. Wear time will be checked and if participants did not wear the activity monitor for enough time, they will be asked to re-wear the device for another 7 days and a follow-up visit will be rescheduled. If the participant wore their activity monitor for sufficient time, they will be asked to complete a 10-minute treadmill walk to demonstrate moderate intensity physical activity (3-4 miles per hour). They will also complete a 7-Day Physical Activity Recall (PAR) and additional baseline assessment measures. Participants will then be randomly assigned to one of two conditions: 1) the Enhanced Intervention arm or 2) The Original Intervention arm.

Randomization:

Randomization will be stratified by the baseline Transtheoretical Model (TTM) stage of change to ensure an equal distribution of the different levels of motivational readiness for PA across groups. Group assignment will be determined by a block randomization scheme and assignments will be distributed to participants in sealed envelopes. After randomization, study staff will review study procedures and expectations of participants. To ensure both experienced and non-experienced users can navigate through the website, participants of both groups will receive training in navigating the relevant website during the randomization session.

6, 12, 18, and 24 Month Assessments:

Approximately one week prior to each scheduled follow-up assessment, study staff will mail the participant an activity monitor along with instructions to wear it for 7 days prior to their in-person visit. They will return the device when they come into the office. At each in-person follow up assessment visit, participants will complete anthropometric and blood pressure measurements, and repeat all baseline evaluation measures.

At 12 and 24-month follow-up visits, semi-structured, qualitative interviews will be conducted with a randomly selected subsample of participants.

Interview questions will explore: 1) overall perceptions and satisfaction with the intervention; 2) opinions regarding specific intervention features, particularly the enhancements, 3) suggestions for improving the intervention (how to keep participants logging on to the website and engaged over 24 months), and 4) barriers and facilitators to participating in a clinical trial and staying active over the 2-year project period. Participants will be given the option at 12 and 24 month assessments to complete the qualitative interview in person at the assessment visit, or to complete the interview by phone. This data will be used to inform future dissemination trials should efficacy be demonstrated.

Participants who are not able to come to our office for these assessments will be given the option to complete parts of the measures by phone and/or via the internet.

Additional Study Procedure

Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined. This new study procedure, funded by the Legorreta Cancer Center is focused on conducting semi-structured qualitative interviews with mothers of young children who participated in IRB #1708001868 (Promoting Physical Activity in Latinas via Interactive Web-Based Technology) to further understand their intervention experiences. Participants will be asked to complete an interview via Zoom to learn about their perceptions of physical activity as a health behavior, how they find resources and information about physical activity, and any use of technology for information or engaging in physical activity. If participants are interested in taking part in these new study procedures, they will be required to complete an addendum consent. This mixed methods study involves collecting qualitative data to complement the analysis of our prior collected quantitative data. This interview will take approximately 45 minutes to complete. Participants who are eligible will be notified via email and phone. We have included the email and phone scripts for approval.

6.3 Describe:

- ***Procedures performed to lessen the probability or magnitude of risks.*** Participants will be instructed to alert us of any injuries sustained or any new medical diagnosis while they are enrolled in the study. In the event of an injury requiring immediate assistance, the participant will be instructed to contact their Primary Care Physician, and if necessary, go to the closest emergency center.

For other non-emergency injuries, participants will have a link in the study website, "Have you been injured?" where they can report their diagnosis or injury. This will trigger a call from our study physician or project director depending on the injury or medical condition. The principal investigator along with the study physician will determine if the participant will be put into a medical hold or will have to withdraw from the study.

Injuries that interfere with functioning (i.e., ability to move about or perform activities of daily living) will be considered serious and will be reported as soon as possible to the IRB but within one business day of participant reporting. The participant will be asked to cease activity and obtain physician clearance before continuing within the study. Other soft-tissue injuries that do not meet the definition of serious event will also be monitored and reported to the IRB within 7 days of participant reporting.

- ***The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)***
 - a) 7-Day PAR Interview
 - b) Demographics Form and Brief Acculturation Scale (BrAS)
 - c) Neighborhood Environment Walkability Scale Abbreviated (NEWS-A)
 - d) Perceived Stress Scale
 - e) Center for Epidemiological Studies Depression Scale (CES-D)
 - f) Stages of Change for Physical Activity (SCPA)
 - g) Processes of Change for Physical Activity (POC)
 - h) Self-Efficacy for Physical Activity (SE)
 - i) Social Support for Exercise (SSE)
 - j) Physical Activity Enjoyment Scale (PACES)
 - k) Short Test of Functional Health Literacy in Adults (STOHFLA)
 - l) *Health Expenses Questionnaire*

6.4 What data will be collected during the study and how that data will be obtained. Qualified study staff will collect the following data at baseline, months 6, 12, 18, and 24:

- Demographics and Brief Aculturation Scale- these surveys will be administered and collected at baseline only during the orientation visit.
- Anthropometric Measures- Height and weight, estimated percent of body fat from body impedance measurement, and blood pressure will be collected by qualified trained staff during measurement visit at baseline and all follow-up in person visits.
- 7-Day Physical Activity Recall- in-person survey conducted by trained staff members
- Actigraph- will be given to participant during their baseline measurement visit or will be mailed to the participant for their months 6,12,18 and 24 follow-up visits so that it can be used the week prior to their in-person visit. Once a participant attends the visit a staff member will download the data from the monitor and verify it has valid wear time.
- Psychosocial questionnaires- will be given to participants at baseline during the orientation and mailed to participants along with the actigraph for their month 6,12,18, and 24 follow-up visits.

Participants will be asked to complete all surveys prior to their visits so that staff can collect them.

- Social Cognitive Theory and Transtheoretical Construct Surveys- will be administered and collected at all in-person visits, as well as online each month to generate tailored reports for participants. For Group 2 (Enhanced Intervention) it will be collected at additional time points during 18, 15, 21 months.
- Semi-structured Qualitative Interviews: these will be administered by a qualified research staff during the 24 month follow-up visits.
- Semi-structured qualitative interviews with mothers of young children (n=30). The purpose of this interview is to better understand how to provide useful resources for physical activity promotion to Latina mothers with young children (under 5 years of age). In this discussion we want to hear people's individual opinions and experiences with the Pasos intervention. Interested participants will need to agree to participate via a consent addendum for this new study procedure.

6.5 *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.* No plans for long-term follow-up regarding this study. *We will submit an IRB amendment if there becomes new follow up needs.*

6.6 *For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.* N/A

7.0 Data and Specimen Banking

7.1 *If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.*

Data Storage Location and Access Details

Digital Data: All collected data will be de-identified and coded by a data manager to ensure that all personal identifiable information cannot be connected to the data provided by participants through the surveys and evaluation visits. The data will be backed up and *stored on a secure server* located in Brown University's School of Public Health. This server is protected and requires username and password granted by the university to access the shared network where the files will be saved. There will be restricted access to this data and only our data manager, database manager and statistician will have access to these files.

Physical Data: Paper data will be locked in cabinets. Signed informed consent forms will be kept in a separate locked file cabinet designated for documentation purposes. Any other documents containing participant names will be maintained by the project director and stored in a locked file cabinet separate from study data. Only the project director will have access to these records.

Storage Duration: All subject-identifying information will be destroyed after recruitment and analyses are completed for long-term storage of the data sets.

Strict confidentiality procedures will be in place for circumstances where staff will need access to subject's names. However, once the intervention is completed, staff will no longer have access to that participant data. In addition, some study staff will be able to see subject names and data on incoming messages from people interested in participating. Data will be stored for a minimum of 7 years after completion of the study.

7.2 **List the data to be stored or associated with each specimen.** No specimen data will be collected or stored for this data.

7.3 **Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.** Only authorized personnel, including the study investigators, intervention and evaluation coordinators, and data manager, will have access to data. The study team conducts ongoing monitoring to ensure adherence to these procedures.

8.0 Sharing of Results with Subjects

8.1 **Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.** Study results will be published, and a summary of the results will be available at the <http://www.ClinicalTrials.gov> website, as required by U.S. Law. Additionally, once all the manuscripts have been published with study results, the PI will send all study participants a lay summary of the findings.

9.0 Study Timelines

9.1 **Describe:**

- **The duration of an individual subject's participation in the study.** Each participant will be enrolled in the study for 24 months.
- **The duration anticipated to enroll all study subjects.** Participants will be enrolled on a rolling admission during months 5-32.
- **The estimated date for the investigators to complete this study (complete primary analyses).** The proposed project will last 5 years.

10.0 Inclusion and Exclusion Criteria

10.1 **Describe how individuals will be screened for eligibility.** Participants that contact the team interested in enrolling for the study will first complete an eligibility screener by telephone with a project staff member.

10.2 **Describe the criteria that define who will be included or excluded in your final study sample.** Participants will be screened for factors that may increase risk of injury. Potential participants with medical or psychological problems that could make adherence with the study protocol difficult or dangerous will not be included. Exclusions include:

- History of coronary heart disease, myocardial infarction, symptoms of angina, diabetes, stroke, osteoarthritis, osteoporosis, orthopedic problems that would limit activity during the following 24 months
- Any other serious medical condition that would make physical activity unsafe (based on the modified Physical Activity Readiness Questionnaire).
- Current or planned pregnancy
- Planning to move from the area within the next two years
- Current suicidal ideation or psychosis, clinical depression, or hospitalization due to a psychiatric disorder in the past 3 years,
- BMI above 45 kg/m²
- Taking medication that may impair physical activity tolerance or performance (e.g., beta blockers).

After screening is completed, eligible and interested participants must agree to be randomly assigned to one of the intervention conditions.

Initial eligibility criteria include:

- Participants must be sedentary (defined as engaging in less than 60 min/week of MVPA)
- Women between the ages of 18-65 who self-identify as Hispanic or Latino (or of a group defined as Hispanic/Latino by the Census Bureau)
- Have regular access to a text-message compatible cell phone and to an Internet-connected device through home, work, or their community (e.g., public library, community center, neighbor's house).
- Can read and write fluently in Spanish

Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined in section 6.2. Eligibility criteria thus include being a past participant in IRB #1708001868 (Promoting Physical Activity in Latinas via Interactive Web-Based Technology) and being a mother of a child under the age of 5 years old during the intervention period.

10.3 *Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria.)*

- *Adults unable to consent-* **Exclude**
- *Individuals who are not yet adults (infants, children, teenagers)-* **Exclude**
- *Pregnant women-* **Exclude**
- *Prisoners-* **Exclude**

11.0 Vulnerable Populations

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- This research will not involve individuals who are vulnerable to coercion or undue influence.

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

We aim to recruit and enroll 300 Latina women between the ages of 18-65.

Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined in section 6.2. This new study procedure is focused on conducting semi-structured qualitative interviews with mothers of young children (n=30) who participated in IRB #1708001868 (Promoting Physical Activity in Latinas via Interactive Web-Based Technology).

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.) We aim to consent 700 participants. There are two additional in-person visits after the participant signs a consent form. Accounting for attrition during this process, from 700 consented participants, we aim to be able randomize 300 that will begin the project intervention.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility. We will begin advertising during the first four months of the study and active recruitment will begin in month 5, with a conservatively estimated 10-11 participants recruited per month. We plan to continue recruiting participants through Year 3, month 8.

13.2 First, we will actively recruit through web-based outlets such as Craigslist and local Facebook pages for Latinas. A recruitment and cohort maintenance coordinator will also be responsible for fostering relationships with community contacts and overseeing all recruitment activities which will include use of local media outlets (newspaper, radio, or web-based advertisements), flyers distributed and posted at community events or sites, presentations at community functions or centers, and at clinics. We have partnered with several Latino-serving agencies such as Progreso Latino and Clinica Esperanza. The same bilingual/bicultural staff, who will direct the trial from orientation through final assessment, will be available during local community events hosted by these organizations, providing consistency and a recruitment team well-versed on study requirements.

Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined in section 6.2. Recruitment will be done from our prior pool of study participants, whom we have permission to re-contact (IRB #1708001868: Promoting Physical Activity in Latinas via Interactive Web-Based Technology). Participants who are eligible will be notified via email and phone.

13.3 Describe the source of subjects. We plan to do physical and web-based recruitment in Rhode Island, but our ads will be able to reach the surrounding Massachusetts area. Our subjects will be Latina women who are actively participating or attending community events, are listening to the local radio stations, reading the local newspaper and have access to see our ads online. Referrals from community center liaisons and word of mouth from participants enrolling in the study will also play a role in our recruitment.

13.4 Describe the methods that will be used to identify potential subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility. Recruitment will utilize the same highly successful methods as our previous studies to identify potential subjects. A bilingual and bicultural research assistant who has established rapport with Latino-serving organizations will assist with community outreach and participant recruitment. We will take a multi-pronged approach to recruitment to reach as many Latinas as possible, including those who are less acculturated through the following methods:

- Having all our recruitment materials translated to Spanish by one of qualified bi-lingual research assistant.
- Attending culturally relevant community events
- Displaying flyers and brochures at community locations around Rhode Island and the surrounding Massachusetts area.
- Placing flyers in public areas (e.g. grocery stores, libraries, community centers) with high traffic of Latinas.
- Advertise on local media outlets such as newspapers, radio stations, and web-based outlets such as Craigslist and Facebook

13.5 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.) We will have an IRB approved flyers, brochures and scripts that will be used for web-based, local media outlets and community-based recruitment events.

13.6 Describe the amount and timing of any payments to subjects. We will reimburse their travel cost, \$10, and childcare cost, \$7-10 per hour, anytime they attend an in-person visit at our office. They will receive a \$10 incentive for completing monthly questionnaires for the first 12 months, Group 2 will have additional questionnaires that they will be compensated for in months 15,18 and

21. Group 2 will receive \$5 monthly during while they participate in the study to help with the data usage and text message related costs. All participants will receive a \$25 incentive for completing their follow-up visits at 6,12, 18 and 24 months. All participants can receive a \$50 bonus incentive for completing all follow-up visits in-person at months 6, 12, 18, 24.

Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined in section 6.2. This interview will take approximately 45 minutes to complete, and participants will receive \$50 for their time.

14.0 Withdrawal of Subjects

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. The following circumstances could lead to participant withdrawal from the study without their consent: participants report pregnancy post randomization, participants report a medical diagnosis post-randomization that would make them ineligible, or participants refuse to follow instructions provided by the study personnel.

Additionally, the Principal Investigator may remove anyone from the study without their consent if she feels it is in the participant's best interest or the best interest of the study.

14.2 Describe any procedures for orderly termination.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

All the withdrawal incidents in this list will be reported to the IRB and NIH during our yearly progress report.

After a participant verbally expresses that they want to withdraw from our study, our staff will update the participant's status in our database to either Full Drop- Quit or Partial Drop-Assessment only, depending on the specific circumstance. This will allow our system to remove this participant's ID from appearing in our reports. Our interventionist will also close out the participant's account in our study website. If the participant is a partial withdrawal but agrees to continue with data collection only, they will only be contacted to schedule their 6,12, 18 and 24 follow-up evaluation visits.

15.0 Risks to Subjects

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Possible risks to participating in the study include complications associated with moderate intensity exercise training (e.g., orthopedic injury). Participants may find exercise uncomfortable and may experience sprains, other soft tissue injuries, or bone injuries.

- **Minimization:** Although the likelihood is low, our research team has well-established procedures for monitoring and responding to adverse events resulting from moderate intensity physical activity. All participants will be given an instruction sheet at the start of the study that details what to do for common exercise related injuries. This will include the name and contact information for the study team. In the event of an injury requiring immediate assistance, the participant will be instructed to contact their Primary Care Physician, and if necessary, go to the closest emergency center. Participants will be instructed to report their non-emergency injury through the website as soon as possible so that staff is notified of their sustained injury.

Another possible risk to participation in this study is the loss of confidentiality.

- **Minimization:** Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping all data in locked file drawers. All information obtained from participants will be accessible only to research staff. All texting between participants will be relayed through the study server, so individual telephone numbers will not be shared.

15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. No unforeseeable risks.

15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. No unforeseeable risks to embryo or fetus should the subject be or become pregnant.

15.4 If applicable, describe risks to others who are not subjects. No risk to others who are not subjects.

16.0 Potential Benefits to Subjects

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits Participants may increase their health knowledge and become motivated to exercise more. The broader anticipated benefits correspond to the fact that the results will be used to further understand the unique factors related to promoting physical activity adoption and maintenance among Latinas.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. There may not be any direct benefits for the participants in this study.

17.0 Data Management and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Preliminary Analyses. As a preliminary step, we will assess potential between-group differences in baseline characteristics (demographics, activity level, psychosocial constructs) using graphical methods, non-parametric and parametric tests as appropriate (e.g., Wilcoxin rank-sum test for skewed data, t-tests for normally distributed continuous data & chi-squared tests for categorical data). Any variables not balanced by randomization will be controlled for as

covariates in subsequent analyses. In addition, website use will be summarized (e.g., number of logins per month, average time spent on each website) and compared between-groups using chi-squared tests (binary measures) and t-tests (continuous measures).

Primary Aims. Consistent with our Primary Aims, we will examine the effects of the Enhanced vs. the Original Intervention on our primary outcome: objectively measured MVPA over 24 months. To avoid the effect of outliers, we will apply a normalizing transformation (if necessary) to the outcome ($Y_{i,j}$ =MVPA for participant i at follow-up j) prior to analysis. A single linear mixed effects regression model will be used to simultaneously estimate the intervention effects on outcome ($i=1,2,\dots,300$, $j=1,2,3,4$ where j indexes follow-ups at months 6,12,18,24) with a subject-specific intercept included to account for within-subject correlation in the outcome over time. Data are nested such that weekly MVPA is nested within month within participant and standard errors must be corrected for such a design consideration. We will control for baseline value of the outcome and potential confounders of the treatment effect (including any variables not equally distributed by randomization). Mixed effects models use a likelihood-based approach to estimation and therefore make use of all available data (intent-to-treat sample) without directly imputing missing values. A similar series of regression models will be used to assess between-group differences in the secondary measure (self-reported MVPA).

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Data will be de-identified and coded by a data manager. All subject-identifying information will be destroyed after recruitment and analyses are completed for long-term storage of the data sets. It will be stored on a secure server at Brown University's School of Public Health, which requires a university username and password for access. The servers are backed up regularly, climate controlled, and access is highly restricted to only approved individuals. Only the data manager, database manager, and statistician will have access to the computerized study data. All the data for this project will be handled according to Brown University Policy, Federal guidelines, National Health Institute's policies, and Rhode Island laws regarding confidentiality.

17.3 Describe any procedures that will be used for quality control of collected data. Assessments and staff delivered intervention components will be audio recorded and evaluated for quality control to ensure adherence to the research protocol and consistency. Research staff will audit 10% of all data entered to our databased system and we will enter 100% audit of the 7-day PAR, which is our primary measure.

17.4 Describe how data or specimens will be handled study-wide:

- **What information will be included in that data or associated with the specimens?** Data will be collected using validated measures and will include both objective and self-reported PA measurements. We will collect data on key biological variables such as BMI, percent body fat, age, and pre-existing health conditions to determine if any of these factors moderate the intervention efficacy. Collected data will be de-

identified and coded by a data manager to ensure that all personal identifiable information cannot be connected to the data provided by participants through the surveys.

- ***Where and how data or specimens will be stored?*** All de-identified, coded data will then be backed up and stored onto a secure, password protected shared network at the Brown School of Public Health.
- ***How long the data or specimens will be stored?*** Only de-identified data will be stored long term for future analysis and study comparability research.
- ***Who will have access to the data or specimens?*** Only the principal investigator, data manager, database manager and statistician will have access to these files.
- ***Who is responsible for receipt or transmission of the data or specimens?*** The data manager is responsible for the receipt or transmission of data from this study.
- ***How data or specimens will be transported?*** Data for this study will not be transported, it will be stored in a secured and password protected shared network at Brown University School of Public Health.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects.

18.1 N/A. Describe:

- ***The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.***
- ***What data are reviewed, including safety data, untoward events, and efficacy data.***
- ***How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).***
- ***The frequency of data collection, including when safety data collection starts.***
- ***Who will review the data.***
- ***The frequency or periodicity of review of cumulative data.***
- ***The statistical tests for analyzing the safety data to determine whether harm is occurring.***
- ***Any conditions that trigger an immediate suspension of the research.***

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

To help us protect participant privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify an individual in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify the participant.

Additionally, if a participant decides to join the project, they may quit at any time. If they do not want to answer a certain survey question, they do not have to. If they decide not to participate, there will be no penalty. It will not affect their relationship with Brown University or the organization from which they were recruited.

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures. Participants will be asked to attend an orientation where a qualified research staff, who is also experienced in all our study procedures, will be present to provide a detailed explanation of study measures and answer any questions individuals might have. Participants will also be encouraged to call the study staff if they ever have any questions pertaining to the intervention, visits, or any surveys they are filling out throughout the study.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects. Participant contact information will be kept separate from eligibility and evaluation data. Research team will be permitted to access contact information for the sole purpose of scheduling follow-up visits, re-contacting participants who have reached out with a question, or contacting participants with questions regarding missing survey data.

20.0 Compensation for Research-Related Injury

20.1 N/A- *If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.*

20.2 N/A- *Provide a copy of contract language, if any, relevant to compensation for research-related injury.*

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research. Participants will be responsible for covering any personal costs related to exercise, such as purchasing workout clothes or shoes and gym memberships. However, we will provide information on various free exercise options, including local parks and community centers that may offer free exercise facilities and resources.

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

- ***Where will the consent process take place.*** During the orientation visit, after a qualified bi-lingual and bi-cultural staff has explained all the study procedures and measures, we will ask participants to read and sign a consent form approved by the university's Institutional Review Board.
- ***Any waiting period available between informing the prospective subject and obtaining the consent.*** If a participant decides they need more time to read and sign the consent form, we will grant them a one-month period to do so. If they choose to proceed with participation after this period, we will need to re-screen them and start the enrollment process from the beginning.
- ***Any process to ensure ongoing consent.*** We will maintain open lines of communication with participants and review instructions for ActiGraph wear and use, as well as expectations for follow-up visits. Our interventionists will have periodic check-in calls with participants not only to assist them with their physical activity goals but also to answer any questions that may have arisen during their participation. We will also respect participants' decisions to withdraw from the study at any time or to decline having their sessions recorded or answering certain survey questions.
- ***Consent Addendum.*** *Participants who gave their permission to be re-contacted for future research activities will be invited to take part in new study procedures as outlined. This new study procedure is focused on conducting semi-structured qualitative interviews with mothers of young children (n=30) who participated in IRB #1708001868 (Promoting Physical Activity in Latinas via Interactive Web-Based Technology) to further understand their intervention experiences. Participants who are eligible will be notified via email and phone. If they are interested in participating in this additional study procedure, they will be asked to click the link on the consent addendum confirming they have read and understood the information presented and are agreeing to volunteer as a research participant for this additional study procedure.*
- ***Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:***
 - The role of the individuals listed in the application as being involved in the consent process.***
 - The time that will be devoted to the consent discussion.***
 - Steps that will be taken to minimize the possibility of coercion or undue influence.***
 - Steps that will be taken to ensure the subject's understanding.***

Non-English Speaking Subjects

- ***Indicate what language(s) other than English are understood by prospective subjects or representatives.*** Spanish language
- ***If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the***

language that will be used by those obtaining consent. All study documents will be translated into Spanish by a qualified bicultural and bilingual staff member. Our research assistants and interventionists are also bicultural and bilingual and have experience administering study procedures entirely in Spanish. They will conduct the orientation sessions and obtain consent from participants in Spanish as well.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- N/A

Subjects who are not yet adults (infants, children, teenagers)

- N/A

Cognitively Impaired Adults

- N/A

Adults Unable to Consent

- N/A

Humanitarian Use Device (HUD)

- N/A

23.0 Process to Document Consent in Writing

Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing. For this study, we will follow written documentation of consent. Participants will attend an in-person orientation where all details of the study will be thoroughly explained, and they will have the opportunity to ask questions and receive answers from qualified research staff in their native Spanish language. Participants will be given two paper copies of the consent form; they will be asked to read, sign, and date both forms. Our research staff will also sign and date the forms as witnesses to confirm that the informed consent process has been completed and that participants agree to continue with the study. The research assistant will collect one copy of the consent form, and the participant will keep the second copy for their records. If a participant decides not to participate after the informed consent process, no further action will be taken.

Consent Addendum for additional study procedures: To obtain informed consent for the additional study procedure, study staff will explain all the procedure and requirements, and they will also answer any questions participants may have prior

to agreeing to participate. Participants that are interested in participating will complete the informed consent process. Throughout the informed consent process participants will be reminded that participation in this study is voluntary and can be ended at any point throughout the study. The informed consent will be obtained in Spanish. The consent form will be translated from English to Spanish by our staff member, Esther Solis-Becerra who is a native Spanish speaker and certified medical interpreter. She has extensive experience translating research materials for our prior studies such as print-based materials, recruitment flyers, informed consents, qualitative interviews, telephone screeners, etc. Each participant will receive a personal email or individualized link via text message, whichever mode of delivery they deem easier/preferred, that takes them to the Qualtrics online consent form. After reading and clicking the link to sign the informed consent form the participant will have the option to download and save a PDF copy of the signed consent form. Participants who are not able to save the form or would like a physical copy will be mailed a hard copy of their signed consent form.

- 23.1 ***N/A-If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.***

Additional study procedure: We are requesting a waiver of written documentation of consent for the follow-up interview portion as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context.

- 23.2 ***(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.)*** Consent will be documented in writing and IRB approved consent form will be submitted.

24.0 Setting

- 24.1 *Describe the sites or locations where your research team will conduct the research.*

- ***Identify where your research team will identify and recruit potential subjects.*** Our research team will recruit potential subjects at cultural community events, as well as through web-based platforms and local radio, newspaper, and flyering in predominantly Latino communities in Rhode Island and the surrounding Massachusetts area.
- ***Identify where research procedures will be performed.*** Research procedures will all be performed at the Brown School of Public Health, Center for Health Equity William's Research Laboratory.
- ***Describe the composition and involvement of any community advisory board.*** N/A

- ***For research conducted outside of the organization and its affiliates describe:***
 - a) ***Site-specific regulations or customs affecting the research for research outside the organization.***
 - b) ***Local scientific and ethical review structure outside the organization.***

25.0 Resources Available

25.1 *Describe the resources available to conduct the research: For example, as appropriate:*

- ***Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*** Rhode Island has the fastest-growing Latino population. We estimate that we will conservatively recruit approximately 10-11 participants per month on average, and based on previous experiences recruiting at community events, we have had up to 100 sign-ups in one day. This will help us reach our recruitment goals.
- ***Describe the time that you will devote to conducting and completing the research.*** The proposed research project will last 5 years.
- ***Describe your facilities.*** At the Brown University School of Public Health we have access to a physical activity research lab equipped with a BIA machine, blood pressure machines, stadiometer, weights, and treadmills that will be available for us to use for this research study.
- ***Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of the human research.*** We have a list compiled for mental health resources, physical activity and health resources as well as a study physician and psychologist.
- ***Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*** All research staff and investigators have completed the rigorous CITI training course and are recertified every three years. All persons assisting with the research have been trained and have sufficient knowledge of the study.