



The Learning Garden Pilot Program Evaluation and Recommendation Study

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Introduction

The Institutional Review Board (IRB) of the University of Colorado is responsible for the review of all human subject research when conducted by the university's faculty, staff, students or other affiliates and agents. The primary goal is to ensure human subjects are:

1. Treated with dignity
2. Adequately protected from risk of harm
3. Provided informed consent so they may voluntarily and knowledgeably participate in research

The following document is the IRB submission for The Kitchen Community Learning Garden Evaluation and Recommendation Study.

PROTOCOL #:

(Use Protocol Manager on the COMIRB Website)



COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
CAMPUS BOX F-490 TELEPHONE: 303-724-1055 Fax: 303-724-0990

Project Title: The Learning Garden Pilot Program Evaluation and Recommendation Study

Principal Investigator: Lois Brink

Abstract

Garden/outdoor education programs can help teachers increase student performance and positive attitudes towards the scientific process and their environment (Blair, 2009; Ozer, 2007). However, there are several common obstacles to their widespread implementation: 1) lack of physical garden/outdoor space (Ozer, 2007; Blair, 2009), 2) lack of curriculum integration, and 3) lack of teacher development and training. The Learning Garden project is an innovative solution to all of these obstacles.

The Kitchen [community] (TKC) is a family of restaurants and a 501c3 nonprofit organization that creates community through food. TKC has leveraged its 7 years' experience supporting school gardens in Colorado to create **The Learning Garden** - an experiential learning environment designed as an extension of the school playground. Learning Garden is an interactive school vegetable garden, using prefabricated raised planters that are easy for a community and school to install and maintain. Children will engage the Learning Garden during free time – before or after school or during lunch and recess. Teachers will engage the Learning Garden by incorporating the physical garden into their daily lesson plans and other curricular activities. TKC will provide teacher development and training through a digital platform.

TKC, in partnership with OpenLands, an Illinois not-for-profit corporation, is currently launching a six-school pilot program within the Chicago Public School District. Five of these schools are either K-8 or middle school and they will be the focus of the study. After this pilot year TKC plans to scale the Learning Garden program nationally. It is the intent of the Learning Garden to: 1) increase children's exposure to a garden environment by 20%; 2) increase children's awareness of fresh fruits and vegetables by 20%; 3) increase children's consumption of fresh fruits and vegetables by one serving a week; 4) foster and increase positive types of children's play; and, 5) show a positive correlation between outdoor learning environments and increased science and literacy scores.

The Methods by which TKC will deliver this product are:

1. Physical presence of built environment
2. Method of installation – community participation
3. Experiential learning
4. Digital platform for teacher technical assistance
5. Literacy and Science Lessons Plans

Literature Review

School gardening programs have become increasingly popular as a tool used in promoting healthy eating habits among children⁽⁷⁾. Concurrently, research has shown that improving eating habits causes a reduction in obesity⁽⁸⁾. These gardens, primarily planted on school grounds, also have the potential for increasing community awareness on the importance of healthy eating choices⁽²⁾. The end result is that school gardens (particularly in low income neighborhoods) ultimately increase food literacy and access, increase healthy eating habits while promoting and encouraging community engagement. The Kitchen Community Learning Garden Pilot Project (TKCLG) will provide a unique, engaging and accessible integrated program and environment. The University of Colorado in partnership with The Kitchen Community will implement and research the effectiveness of TKCLG in 6 local Chicago Public Schools. It is our hypothesis that this particular environmental addition to the existing schoolyard will significantly increase children's exposure to a garden environment, increase awareness of fresh fruits and vegetables and increase children's consumption of fresh fruits and vegetables.

A study conducted by Morgan, et al.⁽³⁾ concluded that school gardens can have a positive impact on student's willingness to taste vegetables and their vegetable taste rating. It is this willingness that contributes to a greater awareness of fresh fruits and vegetables that facilitates an improvement in overall eating habits. The study went on to present findings that support garden implementation as a promising tool to improve knowledge within a health promoting school and community framework. Since knowledge as well as accessibility and preferences are important predictors of dietary intake among children⁽³⁾, this strategy is a framework for success. This framework is further supported by a study conducted by Parmer, et al.⁽⁴⁾ who found that gardens, as a component of nutrition education, can increase fruit and vegetable knowledge and cause healthy eating behavioral changes among children. This supports efforts to incorporate hands on gardening into the school day.

In support of the federally mandated school wellness policies, Ratcliffe, et al.⁽⁶⁾ showed that school gardens are an appealing intervention strategy for carrying out wellness driven policy goals. The reasons stated were that gardens were relatively inexpensive, promote academic achievement and health, and support positive youth development. The study also showed that simply increasing fruit and vegetable options available to students was not as effective as implementing activities with increased hands on gardening experiences.

Finally, location and environment is a powerful factor in promoting enjoyment of an activity. In a study conducted by Hale, et al.⁽¹⁾, they investigated the tactile, emotional and value driven responses to the gardening experience and how these experiences influence health. They found that both the physical and social qualities of participation in gardening support positive health related behaviors. This finding, when applied to a child's playground environment, could have significant implications on not only the physical process of gardening, but also the social interactions associated with the garden. Referring back to a classic study, Parten⁽⁵⁾ investigated the social value of various activities, games and toys. From her conclusions, the models of basic types of play were formed and have been adapted to include: 1) Solitary play, 2) Onlooker play, 3) Parallel play, 4) Creative/Dramatic play, 5) Co-operative play. These play types are critical in analyzing the social components for the garden environment for children.

Benefits

It is the intent of The Kitchen Community Learning Garden Pilot Project (TKCLG) to: 1) increase children's exposure to a garden environment 2) increase children's awareness of fresh fruits and vegetables and, 3) increase children's consumption of fresh fruits and vegetables. This will be accomplished through the creation of an interactive vegetable garden, a Learning Garden, using

prefabricated raised planters that are easy for a community and school to install and maintain. Children will have the opportunity to engage with the garden during free time, before or after school or during recess, pending permission from supervisors.

Not only will the gardens provide a new, interactive, and exciting addition to the existing school yard environment, but the research behind the potential behavior change could be valuable to school administrators, teachers, wellness coordinators and parents as well. With healthy eating habits and active living objectives identified as high-priority actions to reduce childhood obesity, the research could provide the information needed for funding initiatives, policy change, and community engagement in and around the school environment.

Only when children are exposed to a food item, can they then request it as a part of their meals. By exposing children to fresh fruits and vegetables grown in a garden, they are getting an education about where food comes from and how to grow it themselves. Providing students with the opportunity to experience a garden will not only equip them with a skill to fulfill one of life's necessities, it will also allow them to share that interest and information with their families and friends. This greatly expands the reach and impact beyond the borders of the school yard. When children request fresh fruits and vegetables from their parents, the family's exposure to healthy foods increases and that exposure could have a positive impact on the family's diet.

Introducing children to healthy food options through gardens is developmentally beneficial as well. While children are in these interactive gardens, experiencing the natural cycle of plants and ultimately feeding themselves, they are filled with a sense of pride and ownership. They learn responsibility and are exposed to a healthy way to spend their time. The research aims to capture the relationship between children and food and what behavioral changes surface because of it. This research will support these benefits to students exposed to the Learning Gardens.

Research Methodology

The research question at hand is whether or not this unique garden environment has a positive impact on healthy behaviors in elementary school children and test scores. The Learning Garden evaluation and recommendation study will: 1) evaluate and determine to what degree changes in behavioral patterns and academic performance (outcomes 1- 5 above) are associated with the new built environment, teacher technical support and lesson plans; and, 2) make recommendations for refinement and improvement for local and national implementation. Recommendations for improvement for each method of delivery will be addressed.

Methods:

TKCLG will use three types of evaluation methods to evaluate behavior change as a result of exposure to the new built environment: direct observation, surveys and focus group meetings.

Direct observations will target the elementary students in 5 schools. Those schools include:

1. Burr
2. Lavizzo
3. Miles Davis Magnet
4. Irma C. Ruiz
5. U-C Woodson

Evaluation tools to be used will include:

1. **Direct observation** – Two data collection periods – one immediately after the planters have been installed and one prior to the fall harvest. Using these two periods we can evaluate the effects of the built environment with and without plants. This will be useful information regarding the spatial arrangement of the planters, sitting areas, gateway and trellis (where applicable). One control area will be identified at each schoolyard. Initially, the first observation period was to be the control area. However, after touring the schoolyards we have determined there is sufficient unimproved play area for concurrent control area/Learning Garden observation during both observation periods allowing for a more robust evaluation of play.
 - a. Two data collection periods – unimproved condition (control area) / recently installed garden in late spring 2012 and unimproved condition / pre-harvest garden in early fall 2012.
 - b. Mobile GIS technology will be used, consisting of open source software run on an Android tablet, to document the locations and types of play of children in the Learning Garden/control areas. This will allow for higher-level detail and spatial analysis in order to determine the effectiveness of individual garden components and their relationship to types of play:
 - i. Solitary Play
 - ii. Onlooker Play
 - iii. Parallel Play
 - iv. Manipulative Play
 - v. Creative/Dramatic Play
 - c. Each school will have four 15-minute observation periods at the following times:
 - i. Before school
 - ii. During recess
 - iii. After school
 - iv. Weekends

2. School/Community survey

- a. Three surveys will be prepared: One for adults, one for elementary-age children (grades 1-5), and one for junior high age children (grades 6 - 8).
- b. The survey will be administered twice. Once at the beginning of the project (mid April – end of May) and once again in November 2012 after the final harvest is complete. The minimum target will be a response rate of 10%.
- c. Hard copy survey: The survey will be administered hard copy to elementary/middle school children at the five schools. CCCD will work with TKC, Open Lands and school principals to develop a schedule for May and November. Surveys will be administered during the school day and in between site observation.
- d. Generate a template for test-score data analysis (quantifying survey responses) and collect pre and post surveys and conduct data analysis as well as data interpretation of said surveys.
- e. Gather and organize public access data on pre and post student achievement scores (ISAT) in science and literacy, aided by CPS, for 4th and 7th grade students participating in the Learning Garden pilot program. In addition, pre and post student achievement data in science and literacy from CPS Common Core quarterly testing will be gathered and organized for 4th and 7th grade students participating in the Learning Garden pilot program.
 - i. Adult Web-based Survey: The survey will be converted to a web-based survey and hosted on a website and translated and published in Spanish at a separate address.
 - ii. Data from surveys and student achievement will be analyzed using SPSS statistical software to establish correlation between variables, and to determine if a positive correlation exists between outdoor learning environments (Learning Garden pilot program) and student achievement (in science and literacy).
 - iii. Weekly updates will be provided. For the final product, data will be exported to a .csv file to create charts, tables and wordles. This will include merging the paper data with the online data.

3. Focus group meetings

- a. Six focus group meetings and one principal interview will be conducted at each school – 3 pre and 3 post with teachers, students and wellness coordinators/parents. The focus groups will:
 - i. Go beyond the survey in providing rich, insightful data
 - ii. Provide for participant interaction that draws out varying perspectives
 - iii. Allow for expanded discussion around specific issues
 - iv. Result in quick turnaround from implementation to findings
- b. Each group will consist of 6-10 participants with a study certified moderator.
- c. The moderator will guide discussion about the Learning Garden and healthy eating to provide insight into attitudes towards and consumption of fresh fruits and vegetables. Discussions and/or answers are recorded during the session and later analyzed for common themes. The focus groups allow the research team to explore and understand attitudes, opinions, feelings and behaviors of staff, family, community members and students as they participate in the garden process and experience.
- d. Results will be compiled in combination with the baseline data of the school/community profile and will also be analyzed in the context of quantitative findings of the survey and direct observation.
- e. Microsoft Access and Excel will be the main format for the storage of data. Any data collection done using a paper method will be assigned a study identification number that can only be identified as a child or adult survey and referenced back to the school. Paper copies will be placed in secure storage at the University of Colorado-Downtown Campus. No other private information will be gathered. Data will be stored on a HIPAA compliant, password protected server at the University of Colorado Denver - Downtown Campus. The entire system is backed up nightly.
- f. All participants will be required to sign a consent and/or assent form that has been approved by the Colorado Multiple Institutional Review Board (COMIRB). This approval is pending.
- g. The specific timeline will be negotiated with the principals of each school to be as minimally invasive as possible.

4. Student achievement analysis

- a. Two options exist for this analysis. The student achievement scores on state assessments (ISAT) are given annually in March or the CPS Common Core quarterly testing (10/17-10/25, 1/11-1/20, 4/9-4/17, 5/29-6/6). Given the timing of the Learning Garden evaluation and the need for testing in the spring and fall, our recommendation is to use the CPS Common Core quarterly testing. However, final determination will be made in collaboration with TKC and CPS. Data on student achievement will be obtained from the school administration. However we recommend a contract extension to April 2013 to allow for the option to gather ISAT data).
- b. With the national emphasis on STEM¹ advancement (e.g. Obama's *Race to the Top* initiative), scientific literacy (National Research Council, 1996) and the frequent inclusion of environmental education in science subjects, we will focus solely on science and writing scores as an indicator of student achievement for this study.
- c. The target population will be 4th and 7th graders at a minimum of two of the pilot schools. Lavizzo and Ruiz.
- d. Test data will be analyzed using Excel. We will scale the data to obtain scores for test responses on a 0-100 scale. Pearson's product moment correlation, r , was calculated to determine if positive or negative correlations existed between Learning Garden (survey data) and student achievement in science. It is important to point out that a high r -value does not imply that learning gardens cause students to attain better test scores. (In this case, student achievement in science may be a result of socio-economic status, teacher-student ratios, size of transient student population, and other variables influencing learning.) However, r -values help determine if learning gardens are associated with student achievement in science (Ary et al., 2002) and literacy, and it is this relationship that our evaluation attempts to explore.

¹ STEM refers to Science, Technology, Engineering and Mathematics

Researcher Status

Primary Investigators:

Lois Brink, MLA
Professor
Director – Colorado Center for Community Development
University of Colorado-Denver

Support Faculty:

Bryan Wee, PhD
Assistant Professor
Geography and Environmental Sciences

Primary Partners:

Kimbal Musk
Founder - The Kitchen Community

Travis Robinson
Managing Director – The Kitchen Community

Peter Vitale
The Kitchen Community

Jaime Zaplatosch
Openlands – Education Director

References

1. Hale, J., Knapp, C., Marshall, J., Sancar, F., Litt, J. (2011). Connecting food environments and health through the relational nature of aesthetics: gaining insight through the community gardening experience. *Social Science and Medicine*, (72), 1853-1863.
2. Heim, S.H., Bauer, K.W., Stang, J., & Ireland, M.I. (2011). Can a community-based intervention improve the home food environment? parental perspectives of the influence of the delicious and nutritious garden. *Journal of Nutrition and Behavior*, 43(1), 130-134.
3. Morgan, P, Warren, J, Lubans, D, Saunders, K, & Collins, C. (2010). The impact of nutrition education with and without a school garden on knowledge, vegetable intake and preferences and quality of school life among primary-school students. *Public Health Nutrition*, 13(11), 1931-1940.
4. Parmer, S, Salisbury-Glennon, J, Shannon, D, & Struemptlet, B. (2009). School gardens: an experiential learning approach for a nutrition education program to increase fruit and vegetable knowledge, preference, and consumption among second-grade students. *Society for nutrition education*, 41(3), 212-217.
5. Parten, M. B. (1933) Social participation among pre-school children. *Journal of Abnormal and Social Psychology*, (27), 430-440.

6. Ratcliffe, M.M., Merrigan, K.A., Rogers, B.L., & Goldberg, J.P. (2011). The effects of school garden experiences on middle school-aged students' knowledge, attitudes, behaviors associated with vegetable consumption. *Health Promotion Practice*, 12(1), 36-43.
7. Robinson-O'Brien, R., Story, M., & Heim, S. (2009). Impact of garden-based youth nutrition intervention programs: a review. *Journal of American Dietetic Association*, (109), 273-280.
8. Zenzen, W., Kridli, S., (2009) Integrative review of school-based childhood obesity prevention programs. *Journal of Pediatric Health Care*, (23), 242-258.

Application for Protocol Review

PROTOCOL #:

(Use Protocol Manager on the COMIRB Website)

Colorado Multiple Institutional Review Board
Campus Box F-490 Telephone: 303-724-1055 Fax: 303-724-0990

Approval Stamp

A. Review Dates

1. Date of Initial Submission: **4-16-12**
2. Version Date: **4-16-12**

B. Project Information

1. Project Title: **Learning Garden Pilot Evaluation and Recommendation Study**
2. Research Area (Disease or Condition to be studied): **Healthy eating and active living**

C. Contact Information

If you are conducting a study on an FDA regulated product requiring the submission of FDA Form 1572, this should include the same person(s) listed on FDA Form 1572, Item 6. Attach additional information as required.

Principal Investigator

Name: **Lois A. Brink** Department: **Architecture and Planning**
Employee # /Student # (or POI #): **103845** Phone #: **303-315-5863**
Rank: **Professor** Cell #: **720-939-5194**
Campus Box or Mailing Address: **126**
Pager #: Fax #: **303-315-5872**
E-Mail Address: **lois.brink@ucdenver.edu**

Mentor (required for students, residents and fellows)

Name: Department:
Employee # (or POI #): Phone #:
Rank: Cell #:
Campus Box or Mailing Address:
Pager #: Fax #:

E-Mail Address:

Co-Investigators (please provide phone # and e-mail address).

Please indicate all VA personnel with "[VA]" after their names.

Name	Phone	E-Mail
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Primary Contact

Name:	Lois Brink	Department:	Architecture and Planning
Employee # (or POI #)	103845	Phone #:	720-939-5194
Rank:	Professor	Cell #:	
Campus Box or Mailing Address:	CB 126		
Pager #:		Fax #:	
E-Mail Address:	Lois.Brink@ucdenver.edu		

List Additional Research Personnel (please provide phone # and e-mail address)

Please indicate all VA personnel with "[VA]" after their names.

Name	Phone	E-Mail
------	-------	--------

Administrator / Manager

Name:	Department:
Title:	Phone #:
Role:	Cell #:
Campus Box or Mailing Address:	
Pager #:	Fax #:
E-Mail Address:	

D. Type of Review being Requested

- ☐ Full Board ☒ Expedited ☐ Reciprocity or Secondary Review
(requesting COMIRB to cede review to another IRB)

E. Funding

1) Do you have any funding for this study? ☒ Yes ☐ No

a. Funding Sponsor(s): **The Kitchen Community** Grant/Project #:

b. Is there any funding from the VA? ☐ Yes ☒ No

c. Is this study funded by a Federal Grant? ☐ Yes ☒ No

If **yes**, is the grant provided? ☐ Yes, ☐ No, grant already on file with COMIRB#:

Umbrella Grant previously submitted provide: COMIRB #: PI:

2) The Institution receiving funding is:

- ☐ University Hospital ☐ Children's Hospital Colorado ☐ UCD Anschutz campus
☐ Denver Health Medical Center ☐ Denver VAMC ☒ Downtown Denver Campus (DDC)
☐ Other (please list):

F. Performance Sites

1) Indicate **ALL** sites where research will take place:

<input type="checkbox"/> University Hospital	<input type="checkbox"/> Children's Hospital Colorado	<input type="checkbox"/> UCD Anschutz campus
Lavi	<input type="checkbox"/> Denver VAMC	<input checked="" type="checkbox"/> Downtown Denver Campus (DDC)
<input type="checkbox"/> Other (please indicate specific UCD-affiliated sites; e.g., CTRC, Barbara Davis Center, Colorado Prevention Center, or other institution-affiliated off-site clinic):		
<input type="checkbox"/> Multi-site study or other non-affiliated site(s) [Complete Attachment A]		
<input type="checkbox"/> International site(s) [Complete Attachment B]		

2) Is this VA research? (**one** of the following **must** be checked)

<input type="checkbox"/> VA-only study	<input type="checkbox"/> Multi-site study involving VA	<input checked="" type="checkbox"/> Non-VA study
Yes, if any one of the following: <input type="checkbox"/> Funding solely from VA <input type="checkbox"/> All procedures performed on VA property, with VA patients, or using VA equipment/resources <input type="checkbox"/> All investigators and study personnel working solely on VA time	Yes, if any one of the following and no criteria for VA-only are met: <input type="checkbox"/> Both VA and non-VA funding <input type="checkbox"/> Some procedures performed on VA property, with VA patients, or using VA equipment/resources <input type="checkbox"/> Some investigators or study personnel working on VA time	Yes, if all of the following: • No VA funding • No procedures performed on VA property, with VA patients, or using VA equipment/resources • No investigators or study personnel working on VA time
► Answer all "VA Requirements" questions in this application ► Submit study materials to VA Research Office to receive Purple Clearance ► VA consent form must be used for all	► Answer all "VA Requirements" questions in this application ► Submit study materials to VA Research Office to receive Purple Clearance ► VA consent may be required for all	► Leave all "VA Requirements" questions in this application blank ► If VA-employed investigators/personnel are working on non-VA time, contact VA Research Office for Yellow Clearance

subjects, regardless of enrollment site	subjects, depending on VA involvement	
If you are unsure which category applies to your study, contact the VA Research Office (303) 399-8020, x2755		

- 3) Are any of the research investigators employed by Denver Health Medical Center? ☐ Yes ☒

If **yes**, SPARO clearance must be submitted

G. Description of Study

- 1) Type of Research Protocol Attached:

Must provide a clear description of the study for review using one of the following formats:

- ☐ COMIRB Protocol
☐ Industry Protocol
☐ NIH Grant/Master Protocol (including DHHS protocol)
☒ Other formatted version of protocol

- 2) Study summary in lay terms:

Provide a brief statement describing the research project **in lay terms**. This section should include the study aims and rationale, as well as a brief overview of how you will answer the research question:

(Approx. 1 paragraph)

School gardens have become an increasingly popular tool used to promote healthy eating habits among children. The Kitchen Community Learning Garden Pilot Project (TKCLG) will provide a unique, engaging and accessible integrated environment through the installation and usage of the new gardens. It is the intent of the Learning Garden to: 1) Increase children's exposure to a garden environment by 20%; 2) Increase children's awareness of fresh fruits and vegetables by 20%; 3) Increase children's consumption of fresh fruits and vegetables by one serving every week; 4) Foster and increase positive types of children's play; and 5) Show a positive correlation between outdoor learning environments and increased science and literacy scores. The University of Colorado in partnership with Kitchen Community will research the impact of TKCLG.

The research question is this: Can the Learning Garden increase children's exposure to a garden, impact awareness / consumption of fresh fruits / vegetables, and also improve children's scores? This will be answered through three research arms: 1) Surveys, 2) Focus Groups, and 3) Direct observation on the schoolyard.

- 3) Special Review Considerations

- a. Would you like this study to be reviewed by the Social/Behavioral panel?

☒ Yes ☐ No

- b. Does the composition of the drug involve human gene transfer or recombinant DNA?

☐ Yes ☒ No

If **yes**, [Institutional Biosafety Committee \(IBC\)](#) approval is needed

- c. Does the protocol involve the use of **radioactive** drugs or materials not under an IND (including PET scans, VQ scans, etc., for research purposes only)?

☐ Yes ☒ No

If **yes**, [Radioactive Drug Review Committee \(RDRC\)](#) approval is needed

- d. Does the protocol involve the administration of therapeutic radiation doses using sealed sources that are for research purposes only?

☐ Yes ☒ No

If **yes**, [Committee for Ionizing Radiation \(CIR\)](#) approval is needed

H. Human Subjects

- 1) State specific age range, including an upper age limit: **5-99**

- 2) Is enrollment limited on the basis of gender, race or ethnicity? **Yes** ☐ **No** ☒

If yes, explain: _____

- 3) Enrollment Numbers (If there are multiple subject groups in this study, provide a breakdown of the requested subject numbers for each subgroup, in addition to the total):

a. Total Number of Local Subjects requested: **Up to 6600**

b. Total Number of Subjects for All Sites: **Up to 6600**

- 4) Inclusion Criteria

Define population to be included in the study:

All students enrolled with the 5 specific schools will be targeted for the study. Parents, teachers and administrators with the specific schools will also be targeted for the study.

- 5) Exclusion Criteria

If applicable, define why a certain population is NOT included in the study, based on specific characteristics (include age < 18 years, pregnant women, prisoners, and decisionally challenged subjects, unless the appropriate population is checked "yes" in #6a below):

Students who are not enrolled in Chicago Public Schools will not be enrolled in this study because this study is limited to the partnership developed with CPS

- 6) Inclusion of Vulnerable Populations: (check all that apply)

- a. These vulnerable populations cannot be enrolled into a study without prior IRB approval. Are any of these populations **likely** to be enrolled into this study?

Children (Under age 18) (Complete Attachment H)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Wards of the state (Complete Attachment H)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Neonates (Birth to 30 days) (Complete Attachment I)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Prisoners (Complete Attachment K)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
People on probation/alternative sentencing (Complete Attachment K)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Pregnant Women/ Fetuses (Complete Attachment J)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

[Attachment J](#) must also be completed if the study intends to follow women who become pregnant during the study

Decisionally challenged [[Complete Attachment L](#)] ☐ Yes ☒ No

Includes cognitively impaired, incompetent to consent, proxy, consenting in life threatening situations

b. Are any of the following populations being **targeted** for recruitment?

Poor/uninsured.....	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Nursing home residents	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Patients with mental illness or learning disabilities	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Patients with TBI	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Terminally ill patients.....	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Students of PI or study staff	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Students to be recruited in their educational setting	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Employees directly under the supervision of PI or co-investigator.....	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
People engaged in illegal activities and/or illegal immigrants	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Others vulnerable to coercion	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If **yes**, to any population in question c above,

i. Please provide reasons for including each vulnerable population checked:

The research requires that students be within the school environment.

ii. List safeguards that are in place to protect the rights and welfare of vulnerable subjects:

Students will not be required to take part in the research.

iii. Describe steps taken to avoid causing potential subjects to be or feel coerced into participating in the research:

Parental consent and student assent will take place.

iv. If no additional safeguards are needed to protect vulnerable subjects in this study, provide justification here:

VA Requirements

☐ N/A

7) If you are enrolling Children, Pregnant Women, or Prisoners into VA research (or a VA site for multi-site studies), a CRADO waiver is required. If you are using drugs that are pregnancy category D or X in VA research (or at a VA site for multi-site studies), a CRADO waiver is required. Have you obtained a CRADO waiver?

☐ Yes ☐ No ☒ N/A

Explain:

I. Procedures

1) Duration of Study Participation for Subjects: 1 year (Spring and Fall semesters)

2) Duration of Entire Study: 2 Years to allow for data analysis.

3) Are all study procedures for local sites accurately described in the protocol? Yes ☒ No ☐

If no, describe how the procedures done at this site differ from those described in the protocol:

4) Research vs. Standard of Care

Does this research involve the delivery of health care? Yes ☐ No ☒

a) If **yes**, Is there a standard of care for this population? Yes ☐ No ☐

b) If **yes**, describe usual treatment for this condition in this population (local standard of care):

c) Is the local standard of care different from the nationally accepted standard? Yes ☐ No ☐

If **yes**, describe how nationally accepted standard care differs:

d) List which procedures are done only as a part of this study, and describe how the research procedures differ from standard care:

5) Are any materials being given to subjects? ☒ Yes ☐ No ☐ N/A

If **yes**, check the box, list the items, and provide a copy with this submission:

List Items

- ☒ Questionnaires/Surveys (including verbally administered)
- ☐ Informational/Educational Materials
- ☐ Diaries
- ☒ Interview/Focus Group guides
- ☐ Other

6) Special Procedures

a) Does this study involve the administration of drug(s) or biological agent(s)?

☐ Yes ☒ No Complete [Attachment C: Use of Drugs or Biologics](#)

b) Does this study use any device(s)?

☐ Yes ☒ No Complete [Attachment D: Use of Devices](#)

c) Will the internet be used to collect research data (e.g., tests, surveys, chat room, Facebook)?

X Yes ☐ No Complete [Attachment G: Use of the Internet to Collect Research Data](#)

d) Will you create a database future recruitment?

☐ Yes ☒ No Complete [Attachment P: Recruitment Database for Future Studies](#)

e) Will this study perform any genetic testing?

☐ Yes ☒ No Complete [Attachment Q: Genetic Research](#)

f) Will biological samples such as blood, urine, or sputum be collected and used for **this** study?

☐ Yes ☒ No Complete [Attachment R: Tissue and Sample Storage for This Study](#)

g) Will data and/or biological specimens be stored (banked) for future *unspecified* research questions?

☐ Yes ☒ No Complete [Attachment S: Request for Data/Tissue/Blood Banking for Future Use](#)

h) Are daycares to grade 12 schools being used as a setting for the research?

☒ Yes ☐ No Complete [Attachment T: Application for Research in Public Schools](#)

VA Requirements	<input checked="" type="checkbox"/> N/A
6) Which research procedures described in the protocol are being performed at the VA (including subject procedures, sample processing, and data analysis)? <input type="checkbox"/> All procedures <input type="checkbox"/> Only the following procedures are, or are not (specify), performed at the VA:	
7) Are human samples being collected at the VA site or for VA-only research? <input type="checkbox"/> Yes <input type="checkbox"/> No Complete Attachment S1: VA Use of Human Specimens for Research	

J. Potential Risks to Subjects

- 1) Do you view the risk of this study as minimal? ☒ Yes ☐ No (Note: the committee may disagree)

Justify this determination:

Observational data does not have any risk for physical harm. Any questionnaire or focus group data will not contain any personal information.

If **yes**, and the investigator is requesting expedited review - complete [Attachment F: Researcher Requesting Expedited Review](#)

- 2) Describe Risks (in a similar format to that used in the consent):

- a. Anticipated Risks (by procedure, if applicable) [[Identify the anticipated risks in order of likelihood and magnitude \(very common, common, uncommon, rare but serious\)](#)]

None

- b. Describe the plan to minimize risk [[Use procedures that are standard of care where possible](#)]

None

- 3) Is it possible that the research team may discover certain incidents/diseases that are reportable to state authorities? ☐ Yes ☒ No

If **yes**, please check the applicable boxes below*:

- ☐ Child Abuse
☐ Immediate risk of harm to self or others
☐ HIV
☐ Hepatitis
☐ Other - Specify:

***Note: The COMIRB standard statement will also need to be added to the consent.**

- 4) Describe the potential benefits of the study: [To determine if school gardens can improve healthy eating habits and encourage positive play.](#)
-

5) Risk/Benefit Analysis:

Describe why the risks to subjects are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing the study:

- a. To participant: No risk involved
- b. To society: No risk involved
- c. Justify the importance of the knowledge gained: The gained knowledge holds the potential for allowing funding to improve the school grounds.

VA Requirements

☒ N/A

6) Describe the relevance of the research to the Veteran population:

K. Recruitment Methods

Recruitment Method and Plan: ☐ N/A (secondary data or sample use only)

1) Check which of the following methods outlined below will be used to identify potential subjects:

a. Do you or have you had a **clinical** relationship with potential subjects?

☐ Yes ☒ No

A clinical relationship is defined as contact with patients you have had, or if you covered for colleagues in the past 5 years.

b. Do you have an existing research relationship with potential subjects, and you have been in contact with them within the past five years?

☐ Yes ☒ No

c. Will you use the HIPAA A Authorization form to obtain permission to recruit patients?

☐ Yes ☒ No

If yes, include this form in your submission packet.

d. Will you identify subjects via a recruitment database?

☐ Yes ☒ No

e. Will you use [ResearchMatch](#) (complimentary recruitment service)?

☐ Yes ☒ No

f. Will you use advertisements to recruit subjects?

☐ Yes ☒ No

g. Other – describe:

2) Describe the setting in which the recruitment will take place, and who will make initial contact:

Teachers and Principals will inform the students of the study.

3) Indicate the forms of recruitment that will be used in this study (check all that apply) or N/A ☐

☒ In-person or face-to-face

☐ Written correspondence (letters/postcards, etc)

a. Will correspondence be sent in an envelope? ☐ Yes ☐ No

If no, please justify:

b. Specify how many letters/postcards will be sent:

Standard practice allows a maximum of 3 attempted contacts. If you plan more than 3 attempts, please justify:

☒ Electronic correspondence (emails)

c. If **checked**, specify how many emails will be sent: 2

Standard practice allows a maximum of 3 attempted contacts. If you plan to send more than 3 e-mails, please justify:

☐ Telephone

d. If **checked**, specify how many telephone calls will be made:

Standard practice allows a maximum of 3 phone calls. If you plan to call more than 3 times, please justify:

☐ Advertisements (check all that apply)

e. If **checked**, indicate which of the following apply:

☐ Flyers

☐ Radio

☐ Television

☐ Newspaper

☐ Internet

☐ Other:

f. Describe where the ads will be posted or how they will be distributed:

Any documents or verbal scripts used in the methods described above must be submitted to COMIRB.

4) Incentives/Reimbursement:

a. Will participants be paid for their time, reimbursed for travel or meal expenses, or receive any sort of "gift" for participating in this study? ☐ Yes ☒ No

If **yes**, please provide the following information:

b. Describe the form of reimbursement and reimbursement schedule per visit:

c. Total amount to be paid to subject:

d. Are any other materials being given to subjects? ☐ Yes ☒ No ☐ N/A

e. If **yes**, provide with this submission or provide photograph:

- ☐ Mugs/Pens etc.
- ☐ Calendar
- ☐ T-Shirt
- ☐ Promotional Items, please list:

VA Requirements

☒ N/A

5) Are you recruiting subjects from the VA? ☐ Yes ☐ No ☐ N/A

If **yes**, please complete the [VA Recruitment Checklist](#)

6) If a VA-only study, will non-veterans be enrolled? ☐ Yes ☐ No ☐ N/A

If **yes**, justify (why are non-veteran subjects necessary?):

7) If a Multisite study involving the VA, will non-veterans be enrolled *at the VA site*? ☐ Yes ☐ No ☐ N/A

If **yes**, justify:

8) Describe any differences in VA recruitment procedures from those described above (e.g., Potential subjects will be initially contacted in person or via letter only [required for VA research]): ☐ None

9) Will Veterans be reimbursed for participation in research? ☐ Yes ☐ No ☒ N/A

If **yes**, justify: ☐ Research makes demands on subjects beyond usual medical care provided by study
☐ Research is not directly intended to enhance subject diagnosis or treatment
☐ This is a multi-site study, and subjects at non-VA sites are paid similarly to participate
☐ Subjects will incur transportation expenses that would not be incurred during usual care
☐ Other:

L. Informed Consent

1) Will subjects be screened prior to consent (e.g., phone screening)?

☐ Yes ☒ No ☐ N/A

a) If **yes**, describe the screening procedures and how you will protect the confidentiality of individuals who are not eligible:

b) Provide a copy of any script or screening questions with this submission ☐

2) Will subjects provide private information about other identifiable individuals, such as relatives or friends, and will that information be used in data analysis (secondary subjects)?

☐ Yes ☒ No ☐ N/A If **yes**, explain:

3) Will consent be obtained prior to any research procedures being done?

☒ Yes ☐ No

a. If **no**, please explain:

If **yes** to any of the questions 1 -3 above, consent waiver must be requested for these activities.

Consent Waiver

4) Is a **waiver of consent** or a **waiver of documentation of consent** being requested?

x Yes No

a. If **yes**, describe which group or portion of study:

A waiver of consent is being requested for the schoolyard / learning garden observation portion of the study only.

Complete **Attachment M**: Request for Waiver of Consent

5) Are you using any level of deception?

☐ Yes ☒ No

a. If **yes**, complete **Attachment M**: Request for Waiver of Consent and **Attachment N**: Research Involving Deception

Consent Documentation

If consent is being documented, please confirm that the following apply:

6) Will a signed and dated copy of the consent form be provided to the subject?

☒ Yes ☐ No

a) If **no**, please explain and (complete **Attachment M**: Request for Waiver of Consent)

Consent Process ☐ N/A

If consent is being obtained, indicate which of the following will apply to the consent process:

7) Will the PI or member of study team be solely responsible for obtaining consent?

☒ Yes ☐ No

If no, answer a and b

a. Describe who will obtain consent:

b. Describe the justification for non-study personnel consenting, the plan for ensuring individuals obtaining consent are appropriately trained in human subject protections, and the plan for keeping a log of non-study personnel that consent subjects:

If yes, answer c

c. Describe steps taken to minimize the possibility of coercion or undue influence: ☐ N/A or

8) Will all persons obtaining consent be trained?

☒ Yes ☐ No

a. Describe:

9) Will consent be obtained in a quiet and private setting?

☐ Yes ☒ No

a. Describe setting: **DESCRIPTION**

10) Will potential participants be given time to read the consent, answer questions and have time to consider whether or not to be involved in the study?

☒ Yes ☐ No

a. Describe:

11) Will comprehension and autonomy be assessed by asking questions about the study and assessing their response?

☒ Yes ☐ No

a. If no, please justify:

12) Who will provide consent or permission?

[More than one box may be checked]

Subject ☒ Yes ☐ No

Locally Authorized Representative ☐ Yes ☒ No

Proxy Decision Maker ☐ Yes ☒ No

[Complete Attachment L]

Parent ☒ Yes ☐ No

[Complete Attachments I and/or H]

Other ☐ Yes ☐ No

If other, describe:

13) Add additional information about the consent process for the committee as needed (☐ N/A) or

Other Consent Considerations

14) Are non-English speaking subjects to be consented? ☒ Yes ☐ No ☐ N/A

If yes, please specify:

- a. Will a copy of the approved consent form be translated into the appropriate language by a certified translator and provided to COMIRB? ☒ Yes ☐ No
- b. Will an interpreter be available? ☒ Yes ☐ No
 - i. If no, justify:
- c. Will a short form be used? ☐ Yes ☒ No

Note: A short form can only be used for the first three subjects before a full consent must be translated into the appropriate language

i. Who will serve as a witness to the short form consent?:

ii. A summary of the study must also be provided for the translator and witness to use.

Will the COMIRB-approved consent (and HIPAA B form, if separate) be used as the summary? ☒ Yes ☐ No

If no, an English version of the summary must be submitted for COMIRB review and approval.

iii. Describe the process for obtaining informed consent using the short form:

15) If subjects who are blind, illiterate, or have similar reading limitations are to be consented, will the following process be used?

☒ Yes ☐ No ☐ N/A

If yes, please specify:

- a) Will the entire consent form be read to the subject? ☒ Yes ☐ No
- b) Who will serve as a witness for the consent process?

VA Requirements

☒ N/A

16) Will the medical record be used to pre-screen subjects at the VA? ☐ Yes ☐ No ☐ N/A

- 17) Describe any differences in VA consent procedures from those described above: ☐ None
- 18) Will all individuals obtaining consent have a VA appointment (paid or WOC)? ☐ Yes ☐ No
- 19) For VA-regulated portions of this study, will consent be documented through the use of VA Consent Form (Form 10-1086)? ☐ Yes ☐ No
- 20) Will a master list of subjects be maintained by the PI for all subjects enrolled in the study (VA-only research) or for all subjects enrolled *at the VA site* (Multi-site study involving the VA)? ☐ Yes ☐ No
- a) If **No**, justify:

M. Privacy and Confidentiality during Study Procedures

Privacy

Privacy refers to persons and their interest in controlling the access of others to themselves.

- 1) Will the PI/research team interact with subjects at study visits to collect information: ☒ Yes ☐ No

a. If **yes**, check all that apply:

- ☐ The subject will choose the setting of the interaction.
- ☐ The investigator will choose a private setting. Describe:
- ☒ Due to the nature of the study, the research cannot take place in a private setting.

Subjects will be informed that privacy cannot be guaranteed (e.g. focus groups).

Describe: The will be conducted at schools and during the school day. For focus groups coordination with the Principal of each school will select an appropriate setting.

- 2) Could association with the research be considered stigmatizing or damaging to the subjects' financial standing, employability, or reputation (e.g. STD/HIV clinic, Substance abuse rehabilitation center)?
- ☐ Yes ☒ No ☐ N/A

a. If **yes**, explain what additional safeguards are in place to protect privacy:

Confidentiality

3) Check if any of the following personal information is collected as research data:

- ☐ Name/Initials ☐ Address ☐ Medical Record/Health Plan/Ascension Number
☐ Email address ☐ Telephone/Fax #
☐ Social Security # (do not check if using for reimbursement or hospital processing only)

a. Explain why this information is necessary to conduct the research:

b. Will personal information elements be stored separately from other research data? ☐ Yes ☐ No

If **no**, explain:

c. Will personal information be available to anyone other than research personnel? ☐ Yes ☐ No

If **yes**, explain to whom and why:

4) If real Social Security Numbers (SSNs), scrambled SSNs, or the last four digits of SSNs be used as research data (not just for payment) what protections are in place to ensure security of this information?

Describe:

5) Will any of study data about an individual, group or institution be considered sensitive? ☐ Yes ☒ No

a. If **yes**, provide the rationale for why this data is needed:

i. Will subjects have the right to refuse to have this sensitive data collected?

☐ Yes ☐ No

If **no**, justify:

VA Requirements

☒ N/A

6) Are any VA sensitive data collected? ☐ Yes ☐ No

a. If **yes**, will you store these data at the VA? ☐ Yes ☐ No

i. If **no**, do you have a waiver from the VA Chief Information Officer? ☐ Yes ☐ No

N. HIPAA

1) Do HIPAA regulations apply to this research (i.e. covered entity accessing, using or disclosing PHI)?

☐ Yes ☒ No

a) If no, why not: **PHI is not being gathered**

2) How are you **accessing** PHI under HIPAA regulations (i.e. what authorizations are in place)?

☐ Treatment relationship (i.e. for clinical purposes)

☐ HIPAA A authorization

☐ Waiver of HIPAA authorization [Complete [Attachment O: Waiver of HIPAA Authorization](#)]

☐ Data Use Agreement

☐ Business Associate Agreement

☐ Other, describe:

3) Will PHI be disclosed outside the covered entity? ☐ Yes ☒ No

a. If **yes**, to whom:

4) What authorizations are in place for the use and disclosure of the PHI collected?

☐ HIPAA B authorization

☐ HIPAA Waiver requested

☐ Data Use Agreement

☐ Business Associate Agreement

5) Will a signed and dated copy of the HIPAA B form be provided to the subject?

☐ Yes

☐ **No** – requesting HIPAA Waiver

☐ **No** – waiver of consent (or waiver of documentation of consent) precludes HIPAA authorization

☐ N/A – combined consent/HIPAA document used

If either “**no**” option selected, complete [Attachment O: Request for Waiver of HIPAA authorization](#)

VA Requirements

☒ N/A

6) Will any PHI from this study be disclosed outside of the VA (even to another UCD-affiliated institution)?

☐ Yes ☐ No

a. If **yes**, do the VA consent and HIPAA B identify this disclosure? ☐ Yes ☐ No

If **no**, do you have a waiver of consent (or HIPAA) and a Data Use Agreement? ☐ Yes ☐ No

O. Data Management and Security Plan:

Electronic Data

1) Will data be stored in **electronic** format? ☒ Yes ☐ No

a. Describe the system/application(s) (e.g. Access, electronic CRF) used for the collection, storage and management of data:

Data will be stored on a HIPAA compliant server at the University of Colorado Denver - Downtown Denver Campus. The entire system is backed up nightly.

b. Describe where the primary data set will be located:

i. Secure server: ☒ Yes ☐ No

If **yes**, describe:

ii. Local Hard Drive: ☐ Yes ☒ No

If **yes**, this is only allowed if the computer is encrypted. Describe protections:

iii. Data transmitted directly to sponsor site: ☐ Yes ☒ No

iv. REDCap data storage: ☐ Yes ☒ No

c. How will this data be protected?

Encrypted ☐ Yes ☒ No

FDA (21 CFR 11) compliant ☐ Yes ☒ No (Note: No UCD servers are Part 11 compliant)

Restricted Access ☒ Yes ☐ No

i. If **restricted** access, who will have access to the data?

Describe:

d. Is removal of **identifiable** data from the department restricted? ☒ Yes ☐ No

i. If **no**, justify:

e. Will **identifiable** data be stored on a mobile device? ☐ Yes ☒ No

ii. If **yes**, describe the device(s) and who will have access to them:

f. Is the data on the mobile device encrypted? ☐ Yes ☒ No

iii. If **no**, justify:

We will not be using mobile devices

iv. If **yes**, describe:

g. Will additional copies of identifiable data be created? ☐ Yes ☒ No

i. If **yes**, describe location, purpose and security:

h. Will data be backed up? ☒ Yes ☐ No

i. If **yes**, describe location and security:

i. Will media used for backups be stored off-site? ☐ Yes ☒ No

i. If **yes**, where and how will it be stored?

j. Will the system/application be accessible via the Internet? ☐ Yes ☒ No

i. If **yes**, complete **Attachment G – Use of the Internet** [not required for e-CRF transmission to sponsor or REDCap data storage]

Audio Recordings, Video Tapes, Digital Videos and Photographs

2) Will data be collected on **audio recordings or digital audio**? ☐ Yes ☒ No

If **yes**, please answer the following:

a. Where/how will the recordings be stored?:

b. Will identifiable information be removed during the transcription process? ☐ Yes ☐ No ☐ N/A

c. Can individuals request portions of the recording be deleted? ☐ Yes ☐ No

d. Will data from or about non-consenting participants be eliminated? ☐ Yes ☐ No

e. Is there a plan for secure destruction or reuse of audio recordings? ☐ Yes ☐ No

f. Will recordings be transported or removed from the worksite? ☐ Yes ☐ No

i. If **yes**, describe plan:

3) Will data be collected on **videos or digital images**? ☐ Yes ☒ No

If **yes**, please answer the following:

a. Where/how will the videos be stored?:

b. Will a release for video imaging be obtained? ☐ Yes ☐ No

c. Will images of consenting individuals be disguised? ☐ Yes ☐ No

(Including tattoos, birthmarks etc.)

i. If **no**, justify:

ii. If **yes**, describe how:

d. Will images of non-consenting individuals be disguised? ☐ Yes ☐ No ☐ N/A

(Including tattoos, birthmarks etc.)

e. Is there a plan for the secure destruction of videotapes/files or reuse of videotapes? ☐ Yes ☐ No
i. If **yes**, describe process:

f. Will videos be removed from the worksite? ☐ Yes ☐ No
i. If **yes**, describe the plan and how videos will be kept secure:

4) Will data be collected on photographs? ☐ Yes ☒ No

If **yes**, please answer the following:

a. Where/how will the photographs be stored?:

b. Will a release for photography be obtained? ☐ Yes ☐ No

c. Will images of consenting individuals be disguised? ☐ Yes ☐ No
Including tattoos and birthmarks etc.

i. If **no**, justify:

ii. If **yes**, describe how:

d. Will images of non-consenting individuals be disguised? ☐ Yes ☐ No ☐ N/A

e. Is there a plan for the secure destruction of photographs? ☐ Yes ☐ No

f. Will videos or photographs be transported or removed from the worksite?
☐ Yes ☐ No

i. If **yes**, describe plan:

Data stored in paper format

5) Will data be stored in **paper** format? ☒ Yes ☐ No

If **yes**, answer the following [Remember this includes consent and HIPAA documents]:

a. List what documents will be stored in paper: **Focus Group Transcripts, Surveys, and Consent Forms**

b. Will paper documents be stored in a locked, secured cabinet? ☒ Yes ☐ No

i. If **no**, justify:

ii. If **yes**, describe location:

These data will be located at the University of Colorado - Downtown Campus in a locked cabinet in a locked office in the College of Architecture and Planning. All offices are card-accessible only outside of business hours and offices kept locked when not occupied during business hours.

c. Will only research staff have access to paper documents? ☒ Yes ☐ No

i. If **no**, describe who will access:

d. Will paperwork be transported or removed from the worksite? ☒ Yes ☐ No

i. If **yes**, describe plan:

Paper copies will be transported in person in a locked portable file device.

Data Destruction Plan

6) Is there a plan to destroy data? ☐ Yes ☒ No

If **yes**, following which agencies criteria:

- ☐ HIPAA regulations: 7 years after IRB acknowledgement of study closure
- ☐ NIH regulations: >3 years from the date the Final Financial Status Report is submitted
- ☐ FDA regulations involving drugs: 2 years following the date a marketing application is approved (or per sponsor requirements which may be longer)
- ☐ FDA regulations involving devices: 2 years following approval for marketing (or per sponsor requirements which may be longer)
- ☐ Other Describe:

VA Requirements

☒ N/A

- 7) Will data obtained from the VA site be stored electronically on VA servers within the VA protected environment (required for VA-only studies)? ☐ Yes ☐ No
- a. If **no**, justify:
- 8) For VA-only studies, biological samples can not be stored outside VA property without a CRADO waiver (see Attachment S1). Indicate which procedure this study will follow:
- ☐ storage at VA ☐ Off-site storage waiver ☐ N/A
- 9) For multi-site studies involving the VA, identify the Coordinating Center where data will be stored:
- ☐ VA ☐ Non-VA site (specify):
- a. If the Coordinating Center is a non-VA site, is it identified in the VA consent and HIPAA forms?
- ☐ Yes ☐ No
- i. If **no**, is there a waiver of consent/HIPAA and a Data Use Agreement? ☐ Yes ☐ No
- 10) Will all VA data be stored separately to allow required ORO data audits? ☐ Yes ☐ No ☐ N/A
- 11) Will VA data be retained indefinitely (current ORO requirement)? ☐ Yes ☐ N/A

P. Data and Safety Monitoring Plan

All studies have potential unanticipated problems (at minimum, breach of confidentiality is a reportable UAP). This includes any “unanticipated event” or any “unexpected adverse event that is at least probably related to the research.” All UAPs must be reported in accordance with current COMIRB Policy using the electronic forms available on protocol manager.

1) Confirm that all unanticipated problems will be reported to COMIRB within 5 days? ☒ Yes

Safety Monitoring

2) Will the PI be responsible for the ongoing review of **local** adverse events and serious adverse events (physical or psychological harms to subjects)?

☒ Yes ☐ No ☐ N/A (study does not involve potential physical or psychological harms)

a. If **no**, explain:

3) Indicate whether local adverse events will be reported to any of the following external entities:

- ☒ Sponsor
- ☐ Coordinating Center/Lead Site
- ☐ FDA
- ☐ Other, describe:

4) Will periodic review of safety and adverse events (SAEs and AEs) across all sites occur? ☒ Yes ☐ No

If **yes**, check all that apply:

- ☒ Principal Investigator
- ☐ Safety/Medical Officer
- ☐ DMC (Internal Monitoring Group)
- ☐ DSMB* / DSMC* [A DSMB or DSMC is an external independent monitoring group comprised of at least 3 individuals who are not related to the study and have appropriate expertise]
- ☐ Other: Specify

For each box checked above in #3 answer the following questions:

a. Describe expertise:

The principal investigator, Lois Brink, will be the primary review of adverse events. Ms. Brink has been working with Public Schools on schoolyard redevelopment for 15 years and has received constant feedback, reviews and understanding of the risks that students face on the schoolyards.

b. How often will the individual/group review the data?

On a weekly basis.

c. Will there be written reports (by DSMB, DSMC, DMC, Safety Officer)? ☐ Yes ☒ No ☐ N/A

i. If **yes**, describe frequency of report:

6) Will an Interim Analysis be performed?

☐ Yes ☒ No ☐ N/A

i. If **yes**, describe purpose and frequency:

7) Are there defined **participant** discontinuation criteria? ☐ Yes ☒ No ☐ N/A

i. If **yes**, describe:

8) Are there **protocol/study** stopping rules? ☐ Yes ☒ No ☐ N/A

i. If **yes**, describe:

Q. Resources for Conducting the Research

COMIRB wants to ensure that the PI has the resources to conduct a safe and compliant study.

- 1) Are there any factors that limit the feasibility of this study (e.g. limited populations, competing resources, other studies, etc.)? ☐ Yes ☒ No

i. If **yes**, describe plan to address:

- 2) Describe the facilities available for the research:

CCCD has facilities available for this research. There is also sufficient funding for support staff.

- 3) Describe resources available to conduct the research (e.g. support staff, time, funding, etc.):

This study is funded for \$35k. This funding will support an appropriate compliment of graduate interns, travel, materials and supplies.

- 4) What resources are available at this site to treat emergencies resulting from study-related procedures? (check all that apply)

X N/A

- ☐ Basic Life Support (BLS) trained personnel
☐ Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
☐ Emergency drugs and supplies to stabilize subject until emergency personnel arrive
☐ Emergency response team within facility
☐ Call 911
☐ Other (specify):

If this site is not a hospital, please name the medical facility to be used in an emergency:

- 5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions: ☐ N/A

All graduate students involved with this study will attend a training session conducted by the PI and research staff at CCCD. This training session will review all aspects of the project.

- 6) Will other medical or psychological resources be required as a consequence of the research (including referral plans for newly identified diagnoses, suicidal ideation, or problem behaviors [e.g., EtOH abuse]):

☐ Yes ☒ No ☐ N/A

i. If yes, describe:

R. Conflict of Interest

The following is based on the UCD Definition of Conflict of Interest:

- 1) Have all investigators/coordinators completed and submitted a COI disclosure form to the **UCD** COI office?

[This form can be completed by accessing InfoEd at <https://era.cu.edu> and clicking on the "External Interests" tab]

☒ Yes ☐ No

a. If no, state who has not submitted the form and explain why this has not occurred:

- 2) Are there any Conflicts of Interest issues to be disclosed for the investigators or key personnel that relate to this study?

☐ Yes ☒ No

If yes, list who has the potential conflict:

[If yes, then a COI management plan must be developed.]

- 3) Has a copy of the management plan [as recommended by the COI committee, if applicable] been submitted to COMIRB?

☐ Yes ☐ No ☐ Pending

S. Attachments

Complete the following attachments that apply to this study: (mark N/A for those that do not apply):

SITES

[Attachment A: Multi-site and Non-Affiliated Site Studies](#)..... ☒ Yes ☐ N/A

[Attachment B: International Research](#)..... ☐ Yes ☒ N/A

FDA Regulated

[Attachment C: Research using FDA Regulated Drugs/Biologics](#) ☐ Yes ☒ N/A

[Attachment D: Research using FDA Regulated Devices](#) ☐ Yes ☒ N/A

PROCESS

[Attachment E: Researcher Requesting Expedited Review](#) ☒ Yes ☐ N/A

[Attachment G: Use of the Internet](#)..... ☐ Yes ☒ N/A

VULNERABLE POPULATIONS

[Attachment H: Research Involving Children](#)..... ☒ Yes ☐ N/A

[Attachment I: Research Involving Neonates](#) ☐ Yes ☒ N/A

[Attachment J: Research Involving Pregnant Women, Fetuses or Neonates](#) ☐ Yes ☒ N/A

[Attachment K: Research Involving Prisoners](#) ☐ Yes ☒ N/A

[Attachment L: Research Involving Decisionally Challenged](#) ☐ Yes ☒ N/A

WAIVERS

[Attachment M: Request for Waiver of Consent](#)..... ☒ Yes ☐ N/A

[Attachment N: Research Involving Deception](#)..... ☐ Yes ☒ N/A

[Attachment O: Request for Waiver of HIPAA Authorization](#)..... ☐ Yes ☒ N/A

Special Procedures

[Attachment P: Future Recruitment Database](#)..... ☐ Yes ☒ N/A

[Attachment Q: Genetic Research](#)..... ☐ Yes ☒ N/A

[Attachment R: Tissue and Sample Storage for This Study](#) ☐ Yes ☒ N/A
[Attachment S: Request for Data/Tissue/Blood Banking for Future Use](#) ☐ Yes ☒ N/A
[Attachment S1: Request for Tissue/Blood Banking for Future Use](#) ☐ Yes ☒ N/A
[Attachment T : Application for Research in Public Schools](#) ☒ Yes ☐ N/A

OTHER INSTITUTIONAL REVIEW REQUIREMENTS

[Attachment U: Pediatric CTRC Utilization Form](#) ☐ Yes ☒ N/A
 (For CTSI use only, does not need to be submitted to COMIRB)
[Attachment W1: Adult CTRC Resource Utilization Form](#) ☐ Yes ☒ N/A
 (For CTSI use only, does not need to be submitted to COMIRB)
[Attachment W2: Clinical Trials Office \(CTO\) Resource Utilization Form](#) ☐ Yes ☒ N/A
 (For CTO use only, does not need to be submitted to COMIRB)

VA REQUIREMENTS

If the VA is a recruitment or research site, additional forms will need to be submitted to the VA for review. [\[Link\]](#)

T. Documents to be submitted for COMIRB review:

The following documents must be submitted for review:

	<input type="checkbox"/> Full Board Review	<input checked="" type="checkbox"/> Expedited Review
1) Current version of the Initial Review Application with appropriate attachments (posted at www.ucdenver.edu/academics/research/AboutUs/comirb)	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
2) Protocol	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
3) Consent form with Assent(s) (if applicable) <input type="checkbox"/> Electronic copy submitted <input type="checkbox"/> No Consent/Assent The Consent Form must also be submitted electronically. A Panel Coordinator will contact you to obtain an electronic version of the consent form.	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
4) Copy of COI management plan [any changes must be submitted to COMIRB for review within 30 days]	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
5) If this study is federally funded, include a copy of the grant	<input type="checkbox"/> 3 copies <input type="checkbox"/> N/A	<input type="checkbox"/> 1 copy <input type="checkbox"/> N/A
6) DHHS approved protocol and consent template [if not submitted as the protocol]	<input type="checkbox"/> 3 copies <input type="checkbox"/> N/A	<input type="checkbox"/> 1 copy <input type="checkbox"/> N/A
7) HIPAA Authorization(s)	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
8) Other materials to be provided to the subjects such as advertisements, questionnaires, subject diaries, etc.	<input type="checkbox"/> 18 copies	<input type="checkbox"/> 1 copy
9) Curriculum Vitae (CV) for Principal Investigator and each Sub-Investigator	<input type="checkbox"/> Included (# provided _____) <input type="checkbox"/> On File in COMIRB	
10) Indicate other sites/committees reviewing this proposal. If approved, include approval letter.	Adult GCRC <input type="checkbox"/> Pending <input type="checkbox"/> Approved <input type="checkbox"/> N/A Pediatric CTRC <input type="checkbox"/> Pending <input type="checkbox"/> Approved	

	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
PRMC	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
IBC	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
RDRC	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
CIR	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
DVAMC	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
DHHA	<input type="checkbox"/> N/A	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved
	<input type="checkbox"/> N/A		
<input type="checkbox"/> Other sites/committees (list): _____			

If a DRUG/BIOLOGIC study, please include these additional documents:

- | | | |
|---|--|---|
| 1) Investigator Drug Brochure
[any changes must be submitted to COMIRB for review as soon as available] | <input type="checkbox"/> 3 copies included | <input checked="" type="checkbox"/> N/A |
| 2) Background Information for Food Supplements | <input type="checkbox"/> 3 copies included | <input checked="" type="checkbox"/> N/A |
| 3) Copy of the FDA 1572 form, if applicable
[any changes must be submitted to COMIRB for review as soon as approved by FDA] | <input type="checkbox"/> 3 copies included | <input checked="" type="checkbox"/> N/A |

If a DEVICE study, please include these additional documents:

- | | |
|--|---|
| 1) Three copies of the Device Manual AND three copies of <u>ONE</u> of the following: | <input type="checkbox"/> Manual Included |
| 2) FDA Letter granting the Investigational Device Exemption (IDE) and a copy of the signed Investigator Agreement, OR | <input type="checkbox"/> Included
<input type="checkbox"/> N/A |
| 3) Letter from Sponsor stating that the study is a non-significant risk study, OR | <input type="checkbox"/> Included
<input type="checkbox"/> N/A |
| 4) Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt or appropriately completed Attachment D . | <input type="checkbox"/> Included
<input type="checkbox"/> N/A |

U. Acknowledgement

Submission of a proposal to the COMIRB requires that **the principal investigator and mentor (if PI is a student, resident, or fellow) sign this page** indicating they have read the definitions of "scientific misconduct" and "conflict of interest" given below and agree to the continuing responsibility to COMIRB statement.

Scientific Misconduct "Scientific Misconduct" shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out or reporting results from research;
2. Material failure to comply with federal requirements for the protection of human subjects, researchers and/or the public;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding author names on publications;
5. Failure to adhere to issues of patient confidentiality as provided in the subject consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

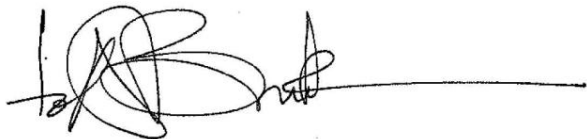
Investigators Continuing Responsibility To COMIRB

Once the protocol has been approved, it is the Principal Investigator's responsibility to report any changes in the research activity prior to implementing the changes. It is also Principal Investigator's responsibility to report any unanticipated problems with the study in accordance with COMIRB policy and submit for continuing review in a timely manner. Failure to obtain approval within the required time will result in the study expiring and being administratively closed. This is viewed as non-compliance by COMIRB. See UCD policy for more details as to investigator responsibilities for human subject protection.

Acknowledgment

I have read the definitions of Scientific Misconduct and listed all potential Conflicts of Interest. I have read the Investigator's Continuing Responsibilities to COMIRB. I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to COMIRB. My signature below attests to my agreement to conduct this research study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed and that I will comply with the continuing responsibilities to COMIRB.

I have completed all required training and I will conduct my study in compliance with all federal, state and local laws and policies.



Signature of Principal Investigator 04-17-2012
Date

Signature of Mentor
(if applicable)

Date

I have reviewed this application and determine that it has scientific merit and is appropriate research to be conducted within this Division/ Department/ School/GCRC/CTRC or put N/A if it is a federally funded study.

Signature of Appropriate Authority
(or their designee)

Date

Print Name of Appropriate Authority
(or their designee)

Position

By signing this document, I also attest that this application is complete and ready for COMIRB review. I have proof-read the application form and attest that it meets the standard for review.

COMIRB Use Only

Action of the Colorado Multiple Institutional Review Board

- ☐ Approved
- ☐ Full Board
- ☐ Expedited
- ☐ Exempt
- ☐ Not Human Subject Research
- ☐ Reciprocity

COMIRB Chair

Date

FOR INTERNAL USE ONLY:

ADDITIONAL COMMENTS (if needed):

Date:

Valid for Use Through:

Study Title: **The Impact Of An Environmental And Curriculum Change On Children's Obesity Related Behaviors: Questionnaire Arm**

Principal Investigator: Lois Brink

COMIRB No:

Version Date: 04-16-2012

Version #:

Your child is being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask any questions you may have about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about how to motivate children to eat healthier by creating a vegetable garden on their playground.

Your child is being asked to be in this research study because we would like to assess the amount of knowledge your child has about healthy eating and how the new garden changes their understanding of healthy eating and active living.

Other people in this study

Up to 5,000 people will participate in this whole study. Of those, 1,000 people from your area will participate in this portion of the study.

What happens if your child joins this study?

If your child joins the study, your child will be asked to complete a questionnaire which assesses healthy eating and perceptions of their playground and its surroundings. Your child is asked to participate specifically for this questionnaire once in the spring and once again in the fall.

What are the possible discomforts or risks?

Your child may feel uncomfortable discussing their eating behaviors. There are no physical risks of this study.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about children's nutrition and the importance of school gardens to help improve their understanding of healthy living. Completing a questionnaire of health and nutrition may increase your child's awareness and motivate her/him to eat better.

This study is not designed to treat any illness or improve health. There may be discomforts involved in sharing personal habits.

Who is paying for this study?

This research is being paid for by The Kitchen Community in collaboration with OpenLands.

Will I be paid for being in the study?

You or your child will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you or your child anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose that your child not take part in this study. If you allow your child to take part, you have the right to stop at any time. If you decline participation or decide to withdraw your child later, you and your child will not lose any benefits or rights to which you or your child is entitled.

Who do I call if I have questions?

The researcher carrying out this study is Lois Brink. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Lois Brink at 720-939-5194. You will be given a copy of this form to keep.

You may have questions about your or your child's rights as someone in this study. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055.

Who will see my research information?

We will keep your child's records confidential to the best of our ability, though it cannot be guaranteed.

The records that identify your child as well as the consent form signed by you may be reviewed by others. This includes:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- People at the University of Hawai'i Committee of Human Subjects.
- The team of researchers.
- National Institute of Child Health and Human Development, which is the company paying for this research study.

We may discuss this research study at meetings. We might also print the results of this research study in relevant journals. However, we will always keep the names of the research subjects, like you, private.

This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

Investigator: _____

Date: _____

Date:

Valid for Use Through:

Study Title: The Learning Garden Pilot Program Evaluation and Recommendation Study

Principal Investigator: Lois Brink

COMIRB No: 09-0582

Version Date: 03/19/2010

Version #: 1

Your child is being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer any questions you may have. Please review the information below and be sure to ask about anything that is not entirely clear to you before deciding whether or not to take part in our study.

Why is this study being done?

The purpose of this study is to learn more about how to motivate children to eat healthier by creating a vegetable garden on their playground.

Your child is being asked to be in this research study because we would like to assess the amount of knowledge your child has about healthy eating and how the new garden can change their understanding of healthy eating and active living.

Other people in this study

Up to 6,600 people will be participating in the entire study. Of those, 1,000 people from your area will participate in this portion of the study.

What happens if your child joins this study?

If your child joins the study, your child will be asked to participate in a focus group which assesses healthy eating as well as their perceptions of the playground and its surroundings. Your child will be asked to participate specifically for this focus group once in the spring and once again in the fall.

What are the possible discomforts or risks?

Your child may feel uncomfortable discussing their eating behaviors. There are no physical risks of this study.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about children's nutrition and the importance of school gardens to help improve their understanding of healthy living. Completing a questionnaire of health and nutrition may increase your child's awareness and motivate her/him to develop healthier eating habits.

This study is not designed to treat any illness or improve health. There may be discomforts involved in sharing personal habits.

Who is paying for this study?

This research is being paid for by the Kitchen Community in collaboration with OpenLands.

Will I be paid for being in the study?

You or your child will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you or your child anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose that your child not take part in this study. If you allow your child to take part, you have the right to stop at any time. If you decline participation or decide to withdraw your child later, you and your child will not lose any benefits or rights to which you or your child is entitled.

Who do I call if I have questions?

The researcher carrying out this study is Lois Brink. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Lois Brink at 720-939-5194. You will be given a copy of this form to keep.

You may have questions about your or your child's rights as someone in this study. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055.

Who will see my research information?

We will keep your child's records confidential to the best of our ability, though it cannot be guaranteed.

The records that identify your child as well as the consent form signed by you may be reviewed by others. This includes:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- People at the University of Hawai'i Committee of Human Subjects.
- The team of researchers.
- National Institute of Child Health and Human Development, which is the company paying for this research study.

We may discuss this research study at meetings. We might also print the results of this research study in relevant journals. However, we will always keep the names of the research subjects, like you, private.

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA form. It will mention companies and universities that will access your research records.

You have the right to request access to your personal health information from the Investigator.

This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

Investigator: _____

Date: _____

Brink, COMIRB # _____, 4/16/12

Date: _____

Valid For Use Through: _____

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

Informed Assent for
**The Learning Garden Pilot Evaluation and Recommendation Study
Related Behaviors: Questionnaire Arm**

Person In Charge of the Study: Lois Brink
Name of Organization: University of Colorado Denver

Why are you doing this study?

I am being asked if I want to be in this study. The reason for this study is to learn what children know how about making healthy choices when they eat. The study is also to find out what children think about their schoolyard, and how much they enjoy them.

Why are you asking me?

I am being asked to help because my class has volunteered to be in the study.

What do I have to do?

If I am in the study, I will write down some of my thoughts about my schoolyard and could be part of a group discussion as well.

If I am in this study I will be asked questions about my physical activity, food I like to eat, if I enjoy having vegetable gardens, and if I know where some gardens are.

Will this hurt?

No. The study is easy and painless.

Do I get anything for being in the study?

If I am in the study, I will have a chance to tell people what I think. I am an important person – every student at my school is important and our opinion counts.

Can I ask questions?

I have asked any questions I had about the study, and my questions were answered.

I know that if I have a question later, I can always ask to get an answer.

I can call Lois A. Brink at 720-939-5194

Do I have to do this?

No. I know that I do not have to be in this study. No one will be mad at me if I say no. If I say no, I can still come to school.

I want to be in the study at this time. ☐ Yes ☐ No

Brink, COMIRB #_____, 4/16/12

I will get a copy of this form to keep.

Child's Printed Name: _____

Child's Signature: _____

Date: _____

Witness or Mediator: _____

Date: _____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _____ *Date:* _____

Initials: _____

Attachment A
Multi-Site and Non-Affiliated Site Studies

COMIRB #:

Approval Stamp here:

Principal Investigator: **Brink, Lois**

Protocol Title: **Learning Garden Pilot Evaluation and Recommendation Study**

Version date: **4-16-2012**

1) Is this a multi-site study (one or more sites external to UCD system)? ☒ Yes ☐ No

a. If yes, how many total sites (count all UCD-affiliated sites as one site)? **5**

b. List external sites:

1. **Lavizzo CPS school**
2. **Ruiz CPS School**
3. **Miles Davis Charter School**
4. **Burr CPS School**
5. **Woodson CPS School**

2) Will each non-affiliated site taking part in the research obtain separate IRB approval from an **appropriate** IRB? ☒ Yes ☐ No

If **yes**, skip to question 5.

a. If no, is COMIRB to be the IRB of record for any non-affiliated site(s)

☐ Yes ☐ No

If yes, **Complete Attachment A1**

3) Are all the non-affiliated sites engaged in research? ☒ Yes ☐ No

a. If no, explain which sites are not engaged in research and justify:

4) Is COMIRB being asked to cede to another IRB? ☐ Yes ☒ No

If **yes**, address the following questions:

a. Justify why COMIRB should agree to cede:

b. Provide the Federal Wide Assurance (FWA) number(s) for the proposed site(s):

c. Provide contact information for each IRB:

d. Does COMIRB have a research contract with this site on file? ☐ Yes ☐ No

e. If **no**, has an IRB Authorization Agreement been signed by the institutional official at each institution? ☐ Yes ☐ No ☒ Pending

[The decision whether or not to cede to another IRB rests with the COMIRB Director or designee]

Attachment A
Multi-Site and Non-Affiliated Site Studies

- 5) Is UCDHSC or one of the Affiliates acting as the coordinating center for a multi-center project? ☒ Yes ☐ No

If **yes**, describe the plan for managing this multi-site study by addressing the following questions:

- a. Who will be responsible for ensuring all IRB approvals are obtained?

Principal Investigator

- b. What training and education plan is in place to ensure consistency across sites?

The research team will be required to undergo Human Subject Ethics and HIPAA training at their home institution

- c. How will protocol modifications be managed across sites?

Conference calls will take place with the PI and research assistants sent into the field for the data collection. Any official modifications will then be made in a manner congruent with UCD and CPS Human Subjects Review Board regulations. The information will then be disseminated to the school principals.

- d. What is the plan to disseminate information on unanticipated problems involving risks to participants or others?

A conference call will take place with the PI and research assistants; appropriate reporting will be conducted with the school principals.

- e. If applicable, who will be responsible for ensuring all applicable adverse events are reported to the FDA? (unless N/A ☒)

- f. Where will data be stored?

Electronic data will be stored at the University of Colorado Denver College of Architecture and Planning server.

All paper data will be stored in a locked cabinet in a locked office with restricted access and the University of Colorado Downtown Campus College of Architecture and Planning.

- g. Who is responsible for managing the data?

The principal investigator.

- h. Will data monitoring of external sites occur? ☐ Yes ☒ No

If yes, describe:

- i. Will biological samples from other sites be stored locally?

☐ Yes ☒ No ☐ N/A

If **yes**, include reference to external specimens on **Attachment R**

Attachment A
Multi-Site and Non-Affiliated Site Studies

Attachment A1

COMIRB #:

Principal Investigator:

Protocol Title:

Contact COMIRB to request IRB Authorization form(s) for COMIRB to be the IRB of record for site(s) below
Complete for each site engaged in research, for which COMIRB is to be the IRB of Record

Non-Affiliated Site	FWA # For Non-Affiliated Sites	COMIRB Panel(s) listed on Applicable FWA [Yes, No, Pending]	Contact information for responsible party at each site	IRB contact information [if applicable]	Research contract with COMIRB [Yes, No]	*Completed IRB Authorization Agreement Form [Yes, No, Pending]

*If **yes**, attach copy of completed IRB Authorization Agreements

ATTACHMENT F
Researcher Requesting Expedited Review

COMIRB #:

Approval Stamp here:

Principal Investigator: **Brink, Lois**

Protocol Title: **Learning Garden Pilot Evaluation and Recommendation Study**

Version date: **4-6-2012**

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is not greater than the risk of doing so as part of routine physical examination.

To qualify for expedited review the research MUST BE NO MORE THAN MINIMAL RISK.

Section 1: Disqualifiers for Initial Expedited review

To qualify for initial Expedited review, the study may not include any of the following:

- a) Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, **and** reasonable and appropriate protections are **not** in place so that risks related to invasion of privacy and breach of confidentiality are **greater than minimal**. Yes ☐ No ☒
- b) Research involving prisoners as subjects Yes ☐ No ☒
- c) Research involving genetic testing with direct or indirect identifiers Yes ☐ No ☒
- d) Research that involves the growth of perpetual cell lines that is/was not disclosed in the consent form Yes ☐ No ☒
- e) Research involving **major** deception (see **Attachment N: Deception**)
[Deception that misleads subject about their health status, the researchers, or the research purpose] Yes ☐ No ☒
- f) Research involving consent via proxy Yes ☐ No ☒
- g) Research involving emergency waiver of consent Yes ☐ No ☒
- h) Classified research involving research subjects Yes ☐ No ☒
- i) Requests for non-significant risk determination for devices Yes ☐ No ☒
- j) Research seeking to prospectively validate greater than minimal risk medical care Yes ☐ No ☒

If yes was checked to any of the questions above, COMIRB cannot conduct an expedited review. Please submit for full board review.

ATTACHMENT F
Researcher Requesting Expedited Review

Section 2: Expedited Review Categories

Select the categories that apply to this study. More than one category can be checked.

☐ (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;

or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body

ATTACHMENT F
Researcher Requesting Expedited Review

or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- ☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (**Note:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- x (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- x (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)

If the research does not fit any of the above categories, it must be reviewed at full board review even if it is minimal risk

COMIRB #:

Approval Stamp here:

Principal Investigator: **Brink, Lois**

Protocol Title: **Learning Garden Pilot Evaluation and Recommendation Study**

Version date: **4-6-2012**

Note: For research conducted in jurisdictions other than Colorado, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The General Counsel of the University's Office will provide assistance with regard to the laws in other jurisdictions.

1. Provide the age range of child subjects: **5-14**

2. Where will the children participate?

a. Check all that apply:

☐ Home ☒ School ☐ University lab/office ☐ Hospital

☐ Other:

*If any of the research will take place in school settings, complete **Attachment T***

b. Describe details of the setting for this research:

Chicago Public Schools (CPS) is a large urban school district serving the City of Chicago. There are a total of 675 schools with 474 of these schools being Elementary (1 – 8). There are an additional 87 Charter School Campuses and 8 Contract schools. Total student body is 404,151 of which 236,452 students are enrolled in Elementary schools. Student racial breakdown is 41.6% African American, 44.1% Latino, 8.8% White, 3.4% Asian/Pacific Islander and 0.4% Native American. 87% of students are from low-income families. Five elementary (K-8/Middle) schools who have applied for and been accepted to participate in the Learning Garden Pilot Program. Approximate size of the pilot schools student body is 350. The research will take place during posted school hours and will not interfere with normal academic activities of the school day.

3. Benefits/Risks of the study:

a. Describe any direct benefits to the child of participating in this research:

By the end of the study all schools will have access to a Learning Garden. A learning garden is a modular, experiential vegetable garden. The intent of the learning garden is to create an outdoor extension of the classroom and an enhancement to the school playground. Children participating in the study will have the opportunity to increase knowledge of healthy eating activities. Children will also indirectly benefit from the addition of a garden to their existing school yards providing them with a positive play environment that is open for their use through the school day as well as before and after school. As the children learn about the healthy food choices and the importance of eating healthy and being active, they may influence the activity and eating behaviors of their entire family. If this intervention significantly prevents childhood obesity, it has the potential to be disseminated all over the country at a fairly low-cost. Large-scale implementation of this intervention may provide a mechanism for counteracting the childhood obesity epidemic. In sum, we believe the risks associated with the proposed study and our assessments to be very small whereas the potential benefits to participants and society are quite substantial.

b. Is the risk age dependent? ☐ Yes ☒ No

If yes, please explain:

c. Are there different study arms involved? x Yes No

If yes, please **describe** the risks associated with each arm that are greater than minimal risk [this includes use of placebo]:

The potential risks to subjects from this project are minimal and are as follows:

Observation Data. There are no risks of physical harm from the observational research. In terms of psychological risk, children may notice they are being observed and feel embarrassed or uncomfortable.

Survey Data. There are no risks of physical harm from the survey research. For the questionnaire, there is a remote risk that children who are at a low reading level may feel uncomfortable completing the survey or that children will feel uncomfortable reporting about their nutrition behaviors. The risk of damage to reputations, social embarrassment or ostracism is minimal for students completing the questionnaire, as confidentiality will be maintained for the study duration.

Focus Group. There are no risks of physical harm from the focus group participation. In terms of psychological risk, children may that they have done something wrong and feel embarrassed or uncomfortable.

Risks Associated with the Intervention. The environmental and curriculum intervention proposed in this research does not vary from the normal educational practices of the school and provides no additional risks than the normal educational procedures.

d. Describe how the risks are minimized:

Observation data. The observers will be graduate students at the University of Colorado Denver who have been trained in SOPLAY (System for Observing Play and Leisure Activity in Youth) for two days to follow the SOPLAY protocol by a certified SOPLAY instructor. The training includes direct practice using modeling and videotaped segments, and field practice in an observational setting. In addition, observers will be trained in the importance of being objective, of strictly following the protocol, of how to act in the observation environment, and of ethical issues related to the research. Observer monitoring and re-training will be continued throughout the data collection period. There are no risks of physical harm from the observational research. In terms of psychological risk, children may notice they are being observed and feel embarrassed or uncomfortable.

Survey data. Risks will be minimized through the survey administration process. Trained staff will administer the survey to students. Students will be told verbally and in writing that if they feel uncomfortable they can choose not to participate in the survey or skip any question that makes them feel uncomfortable. To reduce the risk of social embarrassment that may arise if someone from their class saw their answers, we will provide students with a blank sheet of colored paper to cover their answers during the administration of the survey. Also, the survey administrators will immediately collect the surveys and place in a sealed envelope at the end of the survey administration. All data will be stored in a locked file cabinet or password protected computer.

Focus Group. There are no risks of physical harm from the focus group participation. The principal at each school will assist in the positive non-inhibiting selection of 4 – 6 students to participate in the focus group with a CCD moderator. The moderator will guide discussion about the learning gardens and healthy eating to provide insight into attitudes towards and consumption of fresh

fruits and vegetables. Discussions and/or answers are recorded during the session and later analyzed for common themes. The process will provide a rich conversation and meaningful. The focus groups allow the research team to explore and understand attitudes, opinions, feelings and behaviors of staff, family, community members and students as they participate in the garden process and experience.

Risks associated with the intervention. The environmental and curriculum intervention proposed in this research does not vary from the normal educational practices of the school and provides no additional risks than the normal educational procedures.

4. Risk Category of the study:

Check which one of the following risk categories best applies to your study (a-d).

Note: If there is a placebo group, the risk of the placebo should be identified as well as the risk for the intervention arm. These may be in different categories.

- a. **Minimal Risk:** the risk of participating in this research is the same as the risks that a normal child would face in normal daily life (46.404 or 50.51)? ☒ Yes ☐ No

If yes, describe why:

The study will take place during the normal school day and participation is not mandatory. Also, because this takes place in the educational setting and applies to educational changes, the child will not be exposed to any additional risk other than what they would face in their daily educational experience.

- b. **Greater than minimal risk**, but there is a therapeutic or direct benefit for the child in this research (46.405 or 50.52)? ☐ Yes ☒ No

i. If yes, describe why:

ii. Describe the available alternative therapies:

- c. **Greater than minimal risk** and there is no therapeutic or direct benefit, but an opportunity exists for obtaining generalizable knowledge about the subject's disorder or condition (46.406 or 50.53)? ☐ Yes ☒ No

i. If yes, describe why:

ii. Describe how the research procedures present experiences that are reasonably commensurate with those inherent to their actual or expected medical treatment:

iii. Describe why the research will yield generalizable knowledge of vital importance for the understanding or amelioration of the subject's disease or condition:

- d. If this study does not meet the criteria for questions a, b, or c, then this is research otherwise not approvable which represent an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (46.407 or 50.54) ? ☐ Yes ☒ No

Research in this category requires review by the Secretary of Health and Human Services or the Commissioner of the Food and Drug Administration.

5. What permission will be obtained from the parents?

- a. In general permission from both parents is required for research involving children unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. For Categories 46.404 and 46.405, however, the IRB may find that permission of one parent is sufficient.

☐ Permission will be obtained from both parents where possible.

X Permission from only one parent is being requested

☒ Requesting waiver of parental permission (complete **Attachment M – Waiver of Consent**)

i. Is the waiver request related to child abuse? ☐ Yes ☒ No

ii. Is this a FDA monitored study? ☐ Yes ☒ No
If Yes, then parental permission cannot be waived.

iii. Other justification? ☒ Yes ☐ No

If yes, Specify: We are requesting a waiver of consent for only the observational piece of the study.

iv. If parental waiver is granted what mechanisms are in place to protect the child?

Describe the mechanisms:

No identifying information will be gathered.

b. Does this research relate to diagnosis or treatment of a disease for which Colorado Law allows a minor to consent for themselves? ☐ Yes ☒ No

i. **If yes, Specify:**

ii. Are these minors seeking care when they are recruited (*required*)? ☐ Yes ☐ No

iii. Are any research procedures being done that do not relate directly to the diagnosis or treatment of this condition (e.g., sample banking, non-diagnostic genetic analysis)? ☐ Yes ☐ No
(*not allowed for minors consenting for themselves*)

6. Is the research being conducted in a group setting (e.g., a classroom, focus group, etc)?

☒ Yes ☐ No

If yes, explain what provisions have been made for children whose parents have not given permission for them to participate:

Children do not need to participate in the focus groups sections. Students not participating in the survey will participate in a task of similar duration assigned by the teacher of the class.

7. Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

- a. Will assent be obtained from each child? ☒ Yes ☐ No

If no, under what circumstances will assent **not** be obtained from the child?

- i. ☐ Unable to assent because of age (COMIRB defines this as ≤ 7 y.o.)
- ii. ☐ Unable to assent because of cognitive impairment

Explain how the child's autonomy will be protected:

- iii. ☐ Other

Explain:

- b. Describe how assent will be obtained (unless N/A ☐):

Survey and focus group - The day of the survey administration, children that have parental consent to participate will complete an assent form that explains, in grade-level appropriate language, the same information that is on the parental consent form. This form will be read out loud to children by a trained survey administrator so that children with difficulty reading will hear the information. The survey administrator will answer any questions.

- c. Describe how assent will be documented (unless N/A ☐):

Attach copies of all assent forms, if any.

- d. Will subjects who attain 18 years of age while enrolled on the study be consented?

☐ Yes ☒ No ☐ N/A

If applicable, explain how re-consenting will occur or justify why it will not:

- e. Does the protocol request parental over-ride of a child dissent? ☐ Yes ☒ No

If yes, is there benefit for the child if their dissent is over-ridden? ☐ Yes ☐ No

[The IRB will only consider an over-ride if there is therapeutic benefit.]

If parent over-ride could occur, the following statement should be added to the assent: **"I may not want to be in this study but I know my parents think it is for my best."**

- f. Does the research involve wards (custody) of the State, or any other agency, institution or entity, other than the parents? ☐ Yes ☒ No

- i. **If yes**, is the research risk category (see #6 above) 46.406 or 46.407? ☐ Yes ☐ No

If yes, confirm the following requirements:

- 1. The research is related to their status as wards: ☐ Yes ☐ No

If yes, describe:

2. The research is conducted in schools, camps, hospitals, institutions or a similar setting in which the majority of children involved as subjects are not wards?

☐ Yes ☐ No

Unless the study is minimal risk or has direct therapeutic benefit then an advocate for each ward must be appointed by COMIRB. One advocate may represent more than one child. The advocate must be in addition to any other individual acting on behalf of the child as a guardian or in *loco parentis*.

3. Is a signature line for the advocate provided on the consent form? ☐ Yes ☐ No

- g. Is permission being sought to enroll child prisoners? ☐ Yes ☒ No

If yes, complete attachment K as well

8. Is the study being conducted at the VA? ☐ Yes ☒ No

If yes, then under **VHA Regulations**:

The VA is authorized to care for veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to veterans. Therefore, research involving children must not be conducted by VA investigators while on official duty or at VA or approved off-site facilities unless a waiver has been granted by the CRADO (Chief Research and Development Officer). If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to children as research subjects (see 45 CFR Part 46, Subpart D 46.401 – 46.409, Additional Protections for Children Involved as Subjects in Research). NOTE: For requirements for requesting a waiver contact 202-254-0183.

- a. Has permission been obtained from the VA CRADO (Chief of Research and Development Officer) or designee? (unless N/A ☐)
☐ Yes ☐ No ☐ Pending

Date: _____

Valid For Use Through: _____

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

Informed Assent for
The Learning Garden Pilot Evaluation and Recommendation Study
Related Behaviors: Questionnaire Arm

Person In Charge of the Study: Lois Brink
Name of Organization: University of Colorado Denver

Why are you doing this study?

I am being asked if I want to be in this study. The reason for this study is to learn what children know how about making healthy choices when they eat. The study is also to find out what children think about their schoolyard, and how much they enjoy them.

Why are you asking me?

I am being asked to help because my class has volunteered to be in the study.

What do I have to do?

If I am in the study, I will write down some of my thoughts about my schoolyard and could be part of a group discussion as well.

If I am in this study I will be asked questions about my physical activity, food I like to eat, if I enjoy having vegetable gardens, and if I know where some gardens are.

Will this hurt?

No. The study is easy and painless.

Do I get anything for being in the study?

If I am in the study, I will have a chance to tell people what I think. I am an important person – every student at my school is important and our opinion counts.

Can I ask questions?

I have asked any questions I had about the study, and my questions were answered.

I know that if I have a question later, I can always ask to get an answer.

I can call Lois A. Brink at 720-939-5194

Do I have to do this?

No. I know that I do not have to be in this study. No one will be mad at me if I say no. If I say no, I can still come to school.

I want to be in the study at this time. ☐ Yes ☐ No

I will get a copy of this form to keep.

Child's Printed Name: _____

Child's Signature: _____

Date: _____

Witness or Mediator: _____

Date: _____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _____ **Date:** _____

Initials: _____

Attachment M
Request for Waiver of Consent

COMIRB #:

Approval Stamp here:

Principal Investigator: **Brink, Lois**

Protocol Title: **Learning Garden Pilot Program Evaluation and Recommendation Study – Playground Observation Research Arm**

Version date: **041621012**

Except as provided below, written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116 is required for all research subjects. **Consent waiver is not an option if the study is subject to FDA Regulations, except for under very select circumstances (contact COMIRB).**

With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting an alteration of consent, justify such in accordance with the criteria below established under 45 CFR 46.116(d)(1-4) [**waiver of consent**] or 45 CFR 46.117(c)(1 or 2) [**waiver of documentation of consent**].

For all waivers, the research (or procedures for which the waiver is sought) must involve no more than minimal risk to the subjects.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Notes on study pre-screening:

1) If you are interacting with potential subjects (phone or in person) to screen for eligibility, COMIRB does not consider verifying eligibility criteria listed on the study advertisement to be a research procedure; no waivers are required for such verification. Questioning that goes beyond such verification requires a consent process prior to questioning. Please submit the [pre-screening script](#) to read to potential subjects and request a waiver of *documentation of consent* using this Attachment. Please see [COMIRB's Guidance on Pre-screening](#).

2) For VA research: Using the medical record to pre-screen potential subjects requires full waiver of consent (and waiver of HIPAA).

Note on HIPAA: If this study is subject to HIPAA regulations, you are using the combined consent/HIPAA document, and you are requesting a waiver of consent or waiver of documentation of consent, you will also need to complete Attachment O (Waiver of HIPAA Authorization).

Attachment M
Request for Waiver of Consent

This request is for:

- ☒ **Full Waiver** [Not an option if the study is subject to FDA regulation]
[If deception is used, also complete **Attachment N – Deception**]
- ☐ **Waiver of Written Documentation** (i.e. verbal consent or information sheet)

A. For researchers requesting a Full Waiver:

If requesting a waiver or alteration from the requirements for obtaining informed consent, justify such in accordance with all of the criteria established under 45 CFR 46.116(d)(1-4).

1. Explain why the research poses minimal risk to the subjects:
2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects:
3. Explain why the research could not practicably be carried out without the waiver or alteration (*note: a survey can provide subjects with all elements of consent in writing; see postcard consent template on the COMIRB website*):
4. Explain whether it is appropriate to provide the subjects with additional pertinent information after participation (i.e., once subject has completed the study, will an information sheet be given to, or other debriefing done with, the subject?):

B. For researchers requesting a Waiver of Written Documentation:

If requesting a waiver or alteration from the requirements for written documentation of informed consent, justify such in accordance with at least one of the criteria established under 45 CFR 46.117(c)(1 or 2).

1. Meets Criteria under 45 CFR 46.117(c)(1)

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Justify:

In this case, each subject will be asked whether s/he wants documentation linking the subject with the research, and the subject's wishes will govern.

Attachment M
Request for Waiver of Consent

Describe this process and how a copy of the consent form will be provided to subjects (and submit the consent form/information sheet):

OR

2. Meets Criteria under 45 CFR 46.117(c)(2)

The research (or screening procedures for which the waiver is sought) presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Justify:

The observation portion of this study is merely documenting the geographic location of students within the playground and the type of play occurring. There will not be a record of which student is where or which student is doing what. As there is no risk to the students nor any documentation regarding connecting a specific student to a particular location or activity it is important that we create a low profile during these observations. Requiring consent forms during open and free play would make this research activity almost impossible.

C. For VA studies only:

1) If you are requesting a waiver of consent, are you also requesting waiver from the requirement to maintain a master list of subjects enrolled in this study?

☐ Yes ☐ No ☐ N/A

2) If you are requesting a waiver of documentation of consent, are you also requesting waiver from the requirement to maintain a master list of subjects enrolled in this study? ☐ Yes ☐ No ☐ N/A

If Yes, Does the maintenance of a master list pose a potential risk to the subjects from a breach of confidentiality? ☐ Yes ☐ No

Describe how:

Attachment T
Application for Research in Public Schools

COMIRB #:

Principal Investigator: **Brink, Lois**

Protocol Title: **Learning Garden Pilot Evaluation and Recommendations Study**

Version date: **4-16-2012**

1. Will research occur in a school setting (K-12 or daycare)? ☒ Yes ☐ No

a) Have you obtained the necessary permission from the school district?

☐ Yes ☐ No ☒ Pending

b) Has a school IRB, or other review process, approved the project (if appropriate)?

☐ Yes ☐ No ☒ Pending

2. Will the researcher be altering or comparing educational practices? ☐ Yes ☒ No

If yes, describe how the research educational practice differs from standard educational practice:

3. Will the researcher require access to student records? ☐ Yes ☒ No

4. Is there a plan for providing feedback and/or debriefing subjects (and parents, if student subjects)?

☐ Yes ☒ No

If yes, please describe:

5. What is the relationship between the investigator and students? **Research only**

- If the investigator has a teacher-student relationship, please explain what additional measures will be taken to ensure participants do not feel unduly pressured to participate:

6. Population to be studied:

FOCUS GROUP	NUMBER NEEDED	AMOUNT OF TIME REQUIRED	SPECIFIC CHARACTERISTICS OF GROUP (e.g. grade level, sex, special ed., etc.)
Students	1650	5 min/survey	Grade level
Administrators	50	20 min/school	School
Teachers	50	20 min/school	School
Parents	50	20 min/school	School
Other			

TKC Learning Garden Survey – Student Participants – Grades 1-5

Thank you for participating in the Learning Garden Survey. Please answer the following questions as best you can.

1. School Name: _____

2. Your grade (circle one):

1 2 3 4 5

3. Gender (circle one):

Male Female

4. Ethnicity (Please choose one):

- ☐ American Indian/Alaskan Native
- ☐ Asian
- ☐ African American
- ☐ Native Hawaiian (or other Pacific Islander)
- ☐ Hispanic
- ☐ White
- ☐ Other (please specify)

5. Do you want a school garden (circle one)?

YES NO

6. When would you visit your school garden (circle as many as you would like)?

- ☐ Everyday
- ☐ Only when my teacher tells me to
- ☐ During recess
- ☐ Before school
- ☐ After school
- ☐ I would not visit a school garden

TKC Learning Garden Survey

7. Why would you go to your school garden (circle as many as you would like)?

- ☐ Because my teacher told me to
- ☐ Because I want to play
- ☐ Because I like plants
- ☐ Because I like a quiet place to be with my friends
- ☐ Because I like it better than the playground
- ☐ I would not go to my school garden

8. What would you grow in your Learning Garden (rate 1-5 with 1=grow the most to 5=grow the least)?

- ☐ Vegetables
- ☐ Fruits
- ☐ Herbs
- ☐ Flowers
- ☐ Bugs

9. Do you like fruit (please circle one)?

YES NO

10. Do you like vegetables (please circle one)?

YES NO

11. Do you grow fruits and vegetables at your home (please circle one)?

YES NO

12. Do you vegetables and fruits grow in your neighborhood (please circle one)?

YES NO

13. Does anyone in your family grow fruits and vegetables (please circle one)?

YES NO

14. Do you think a vegetable garden is fun (please circle one)?

YES NO

15. The next big question is about fruits and vegetables. Please tell us if it is a fruit or a vegetable and if you like it:

Is it a (please circle one)?:

Do you like it (please circle one)?:

	Fruit	Vegetable		Yes	No	Don't Know
Apple	Fruit	Vegetable		Yes	No	Don't Know
Cucumber	Fruit	Vegetable		Yes	No	Don't Know
Carrot	Fruit	Vegetable		Yes	No	Don't Know
Snap Peas	Fruit	Vegetable		Yes	No	Don't Know
Radish	Fruit	Vegetable		Yes	No	Don't Know
Strawberry	Fruit	Vegetable		Yes	No	Don't Know
Pepper	Fruit	Vegetable		Yes	No	Don't Know
Collard	Fruit	Vegetable		Yes	No	Don't Know
Cauliflower	Fruit	Vegetable		Yes	No	Don't Know
Eggplant	Fruit	Vegetable		Yes	No	Don't Know
Banana	Fruit	Vegetable		Yes	No	Don't Know
Kale	Fruit	Vegetable		Yes	No	Don't Know
Orange	Fruit	Vegetable		Yes	No	Don't Know
Broccoli	Fruit	Vegetable		Yes	No	Don't Know
Jicama	Fruit	Vegetable		Yes	No	Don't Know
Sweet Potatoe	Fruit	Vegetable		Yes	No	Don't Know
Soy Bean	Fruit	Vegetable		Yes	No	Don't Know
Spinach	Fruit	Vegetable		Yes	No	Don't Know
Tomato	Fruit	Vegetable		Yes	No	Don't Know
Bean	Fruit	Vegetable		Yes	No	Don't Know
Melon	Fruit	Vegetable		Yes	No	Don't Know
Cilantro	Fruit	Vegetable		Yes	No	Don't Know
Chiles	Fruit	Vegetable		Yes	No	Don't Know
Squash	Fruit	Vegetable		Yes	No	Don't Know

TKC Learning Garden Survey

16. Please answer each of the following by choosing "True" or "False":

	True	False
a. Picking vegetables in the garden uses the same amount of energy as playing soccer	<input type="radio"/>	<input type="radio"/>
b. Your goal should be to eat at least 4 ½ cups of fruits and vegetables per day	<input type="radio"/>	<input type="radio"/>
c. Healthy eating focuses only on proteins, meat, and steak	<input type="radio"/>	<input type="radio"/>
d. Healthy eating includes fruits and vegetables	<input type="radio"/>	<input type="radio"/>
e. You should get at least 120 minutes of exercise a day	<input type="radio"/>	<input type="radio"/>
f. Energy balance is "calories in = calories out"	<input type="radio"/>	<input type="radio"/>
g. You can find out how many calories are in the food you eat by looking at the Nutrition Facts on the package	<input type="radio"/>	<input type="radio"/>
h. Helping in the garden is considered physical activity	<input type="radio"/>	<input type="radio"/>

The next question asks about food you ate or drank during the past 7 days. Think about all the meals and snacks you had from the time you got up until you went to bed. **Be sure to include food you ate at home, at school, at restaurants, or anywhere else.**

17. During past 7 days, how many times did you:

	Never during the last week	1 to 3 times per week	4 to 6 times per week	1 time per day	2 times per day	3 times per day	4 or more times per day
a. Drink 100% fruit juices such as orange juice, apple juice, or grape juice? (Do not count punch, Kool-Aid, sports drinks, or other fruit-flavored drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Eat fruit? (Do not count fruit juice.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Eat vegetables? (Do not count French fries, fried potatoes, or potato chips.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Drink a can, bottle, or glass of soda/pop, such as Coke, Pepsi, or Sprite? (Do not include diet soda or diet pop.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Drink a glass of milk? (Include the milk you drank in a glass or cup, from a carton, or with cereal. Count the half pint of milk served at school as equal to one glass.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

TKC Learning Garden Survey

18. Do you eat 4 ½ cups or more of fruits and vegetables each day? (Please choose one)
(1 cup = 1 small apple = 1 baseball = 1 tennis ball)

- ☐ No, and I do not plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 30 days.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day, but for less than 6 months.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day for more than 6 months.



Thank you! Please hand the survey in.



TKC Learning Garden Survey – Student Participants – Grades 6-8

Thank you for participating in the Learning Garden Survey. Please answer the following questions as best you can.

1. School Name: _____

2. Your grade (circle one):

6 7 8

3. Gender (circle one):

Male Female

4. Ethnicity (Please choose one):

- ☐ American Indian/Alaskan Native
- ☐ Asian
- ☐ African American
- ☐ Native Hawaiian (or other Pacific Islander)
- ☐ Hispanic
- ☐ White
- ☐ Other (please specify)

5. Do you want a school garden (circle one)?

YES NO

6. When would you visit your school garden (circle as many as you would like)?

- ☐ Everyday
- ☐ Only when told by a teacher
- ☐ During a free period
- ☐ Before school
- ☐ After school
- ☐ I would not visit a school garden

TKC Learning Garden Survey

7. Why would you go to your school garden (circle as many as you would like)?

- ☐ Because I was told to
- ☐ Because I want to spend my free time there
- ☐ Because I like plants and gardening
- ☐ Because I like a quiet place to be with my friends
- ☐ Because I like it better than other places in the school
- ☐ I would not go to my school garden

8. What would you grow in your Learning Garden (rate 1-5 with 1=grow the most to 5=grow the least)?

- ☐ Vegetables
- ☐ Fruits
- ☐ Herbs
- ☐ Flowers
- ☐ Bugs

9. Do you like fruit (please circle one)?

YES NO

10. Do you like vegetables (please circle one)?

YES NO

11. Do you grow fruits and vegetables at your home (please circle one)?

YES NO

12. Do vegetables and fruits grow in your neighborhood (please circle one)?

YES NO

13. Does anyone in your family grow fruits and vegetables (please circle one)?

YES NO

14. Do you think a vegetable garden would be fun to use (please circle one)?

YES NO

15. The next question is about fruits and vegetables. Please tell us if it is a fruit or a vegetable and if you like it:

Is it a (please circle one)?:

Do you like it (please circle one)?:

	Fruit	Vegetable		Yes	No	Don't Know
Apple	Fruit	Vegetable		Yes	No	Don't Know
Cucumber	Fruit	Vegetable		Yes	No	Don't Know
Carrot	Fruit	Vegetable		Yes	No	Don't Know
Snap Peas	Fruit	Vegetable		Yes	No	Don't Know
Radish	Fruit	Vegetable		Yes	No	Don't Know
Strawberry	Fruit	Vegetable		Yes	No	Don't Know
Pepper	Fruit	Vegetable		Yes	No	Don't Know
Collard	Fruit	Vegetable		Yes	No	Don't Know
Cauliflower	Fruit	Vegetable		Yes	No	Don't Know
Eggplant	Fruit	Vegetable		Yes	No	Don't Know
Banana	Fruit	Vegetable		Yes	No	Don't Know
Kale	Fruit	Vegetable		Yes	No	Don't Know
Orange	Fruit	Vegetable		Yes	No	Don't Know
Broccoli	Fruit	Vegetable		Yes	No	Don't Know
Jicama	Fruit	Vegetable		Yes	No	Don't Know
Sweet Potatoe	Fruit	Vegetable		Yes	No	Don't Know
Soy Bean	Fruit	Vegetable		Yes	No	Don't Know
Spinach	Fruit	Vegetable		Yes	No	Don't Know
Tomato	Fruit	Vegetable		Yes	No	Don't Know
Bean	Fruit	Vegetable		Yes	No	Don't Know
Melon	Fruit	Vegetable		Yes	No	Don't Know
Cilantro	Fruit	Vegetable		Yes	No	Don't Know
Chiles	Fruit	Vegetable		Yes	No	Don't Know
Squash	Fruit	Vegetable		Yes	No	Don't Know

TKC Learning Garden Survey

16. Please answer each of the following by choosing "True" or "False":

	True	False
a. Picking vegetables in the garden uses the same amount of energy as playing soccer	<input type="radio"/>	<input type="radio"/>
b. Your goal should be to eat at least 4 ½ cups of fruits and vegetables per day	<input type="radio"/>	<input type="radio"/>
c. Healthy eating focuses only on proteins, meat, and steak	<input type="radio"/>	<input type="radio"/>
d. Healthy eating includes fruits and vegetables	<input type="radio"/>	<input type="radio"/>
e. You should get at least 120 minutes of exercise a day	<input type="radio"/>	<input type="radio"/>
f. Energy balance is "calories in = calories out"	<input type="radio"/>	<input type="radio"/>
g. You can find out how many calories are in the food you eat by looking at the Nutrition Facts on the package	<input type="radio"/>	<input type="radio"/>
h. Helping in the garden is considered physical activity	<input type="radio"/>	<input type="radio"/>

The next question asks about food you ate or drank during the past 7 days. Think about all the meals and snacks you had from the time you got up until you went to bed. **Be sure to include food you ate at home, at school, at restaurants, or anywhere else.**

17. During past 7 days, how many times did you:

	Never during the last week	1 to 3 times per week	4 to 6 times per week	1 time per day	2 times per day	3 times per day	4 or more times per day
a. Drink 100% fruit juices such as orange juice, apple juice, or grape juice? (Do not count punch, Kool-Aid, sports drinks, or other fruit-flavored drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Eat fruit? (Do not count fruit juice.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Eat vegetables? (Do not count French fries, fried potatoes, or potato chips.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Drink a can, bottle, or glass of soda/pop, such as Coke, Pepsi, or Sprite? (Do not include diet soda or diet pop.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Drink a glass of milk? (Include the milk you drank in a glass or cup, from a carton, or with cereal. Count the half pint of milk served at school as equal to one glass.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

TKC Learning Garden Survey

18. Do you eat 4 ½ cups or more of fruits and vegetables each day? (Please choose one)
(1 cup = 1 small apple = 1 baseball = 1 tennis ball)

- ☐ No, and I do not plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 30 days.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day, but for less than 6 months.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day for more than 6 months.



Thank you! Please hand the survey in.



TKC Learning Garden Survey – Adult Participants

Thank you for participating in the Learning Garden Survey. Please answer the following questions to the best of your knowledge.

1. School Name: _____
2. What best describes your role in a Learning Garden (circle one):
 - ☐ Community Volunteer
 - ☐ Teacher
 - ☐ School Administrator
 - ☐ Other School Staff
 - ☐ Parent Volunteer
3. Do you want a Learning Garden (circle one)?
YES NO
4. Do you think a Learning Garden is worth the cost (circle one)?
YES NO I DON'T KNOW
5. How is your schoolyard used (circle all that apply)?
 - ☐ Recess
 - ☐ PE
 - ☐ Community Use
 - ☐ Outdoor Instruction
 - ☐ All School Events
6. When would you use a Learning Garden (circle all that apply)?
 - ☐ During class time
 - ☐ Weekends
 - ☐ During recess
 - ☐ Before school
 - ☐ After school
 - ☐ I would not use a Learning Garden

TKC Learning Garden Survey

7. What part of the Learning Garden design do you like (circle all that apply)?

- ☐ Planters
- ☐ Open (no fence) concept
- ☐ Ease of construction
- ☐ Ease of maintenance
- ☐ Community build aspect
- ☐ I do not like the design

8. Do you think gardening in a raised planter is a better way to garden on the school grounds?

YES NO

9. How would you use your Learning Garden (circle all that apply)?

- ☐ Classroom instruction
- ☐ Garden maintenance
- ☐ Special incentives for students
- ☐ An addition to traditional recess
- ☐ Before/after school activities
- ☐ Personal reflection
- ☐ I would not use a Learning Garden

10. What would you grow in your Learning Garden (Please rate choices below 1-5 with 1=grow the most to 5=grow the least)?

- ☐ Vegetables
- ☐ Fruits
- ☐ Herbs
- ☐ Flowers
- ☐ Bugs

11. Do you have a fruits or vegetables growing at your home (please circle one)?

YES NO

12. Do you have fruits or vegetable growing in your neighborhood (please circle one)?

YES NO

13. Does anyone in your family grow fruits and vegetables (please circle one)?

YES NO

TKC Learning Garden Survey

14. Do you think a Learning Garden is important for the school (please circle one)?

YES NO

Please Explain _____

15. Do you think every school in your district should have a Learning Garden (please circle one)?

YES NO

16. Would you help with the maintenance of the Learning Garden (please circle one)?

YES NO

If Yes: How many days a month would you be able to contribute?

17. Please answer each of the following by choosing "True" or "False":

	True	False
a. Gardening uses the same amount of energy as exercise	<input type="radio"/>	<input type="radio"/>
b. Your goal should be to eat at least 4 ½ cups of fruits and vegetables per day	<input type="radio"/>	<input type="radio"/>
c. Healthy eating focuses only on proteins, meat, and steak	<input type="radio"/>	<input type="radio"/>
d. Healthy eating includes fruits and vegetables	<input type="radio"/>	<input type="radio"/>
e. You should get at least 120 minutes of exercise a day	<input type="radio"/>	<input type="radio"/>
f. Energy balance is "calories in = calories out"	<input type="radio"/>	<input type="radio"/>
g. You can find out how many calories are in the food you eat by looking at the Nutrition Facts on the package	<input type="radio"/>	<input type="radio"/>
h. Gardening is considered physical activity	<input type="radio"/>	<input type="radio"/>

TKC Learning Garden Survey

The next question asks about food you ate or drank during the past 7 days. Think about all the meals and snacks you had from the time you got up until you went to bed. **Be sure to include food you ate at home, at school, at restaurants, or anywhere else.**

18. During past 7 days, how many times did you:

	Never during the last week	1 to 3 times per week	4 to 6 times per week	1 time per day	2 times per day	3 times per day	4 or more times per day
a. Drink 100% fruit juices such as orange juice, apple juice, or grape juice? (Do not count punch, Kool-Aid, sports drinks, or other fruit-flavored drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Eat fruit? (Do not count fruit juice.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Eat vegetables? (Do not count French fries, fried potatoes, or potato chips.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Drink a can, bottle, or glass of soda/pop, such as Coke, Pepsi, or Sprite? (Do not include diet soda or diet pop.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Drink a glass of milk? (Include the milk you drank in a glass or cup, from a carton, or with cereal. Count the half pint of milk served at school as equal to one glass.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

19. Do you eat 4 ½ cups or more of fruits and vegetables each day? (Please choose one)
(1 cup = 1 small apple = 1 baseball = 1 tennis ball)

- ☐ No, and I do not plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 6 months.
- ☐ No, but I plan to start eating 4 ½ cups or more of fruits and vegetables a day in the next 30 days.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day, but for less than 6 months.
- ☐ Yes, I have been eating 4 ½ cups or more of fruits and vegetables a day for more than 6 months.

20. The next section is about fruits and vegetables. Please tell us if it is a fruit or a vegetable and if you like it:

Is it a (please circle one)?:

Do you like it (please circle one)?:

	Fruit	Vegetable		Yes	No	Don't Know
Apple	Fruit	Vegetable		Yes	No	Don't Know
Cucumber	Fruit	Vegetable		Yes	No	Don't Know
Carrot	Fruit	Vegetable		Yes	No	Don't Know
Snap Peas	Fruit	Vegetable		Yes	No	Don't Know
Radish	Fruit	Vegetable		Yes	No	Don't Know
Strawberry	Fruit	Vegetable		Yes	No	Don't Know
Pepper	Fruit	Vegetable		Yes	No	Don't Know
Collard	Fruit	Vegetable		Yes	No	Don't Know
Cauliflower	Fruit	Vegetable		Yes	No	Don't Know
Eggplant	Fruit	Vegetable		Yes	No	Don't Know
Banana	Fruit	Vegetable		Yes	No	Don't Know
Kale	Fruit	Vegetable		Yes	No	Don't Know
Orange	Fruit	Vegetable		Yes	No	Don't Know
Broccoli	Fruit	Vegetable		Yes	No	Don't Know
Jicama	Fruit	Vegetable		Yes	No	Don't Know
Sweet Potatoe	Fruit	Vegetable		Yes	No	Don't Know
Soy Bean	Fruit	Vegetable		Yes	No	Don't Know
Spinach	Fruit	Vegetable		Yes	No	Don't Know
Tomato	Fruit	Vegetable		Yes	No	Don't Know
Bean	Fruit	Vegetable		Yes	No	Don't Know
Melon	Fruit	Vegetable		Yes	No	Don't Know
Cilantro	Fruit	Vegetable		Yes	No	Don't Know
Chiles	Fruit	Vegetable		Yes	No	Don't Know
Squash	Fruit	Vegetable		Yes	No	Don't Know