PROJECT REVIEW FORM

Project Title: University of Arizona Cooperative Extension 4-H Youth Development Health Rocks! Program

Title on consenting documents (if different from project title): ________________________________

IDENTIFICATION OF PI(S)

Principal Investigator(s): Degr e(e(s)): Status/rank: Department: College:
Lisa A. Lauxman, Ph.D Ph.D Associate agent Cooperative Extension, Cooperative Extension, Agricultural Education Agriculture and Life Sciences

PI CONTACT INFORMATION

Contact phone: 520-621-7131 Fax: 520-621-1314
Email: lauxman@ag.arizona.edu Campus Mailing address: Forbes 301, P.O. Box 210036, Tucson, AZ 85721-0036

PROJECT START DATE: JULY 1, 2008 PROJECT END DATE: 8-1-2008

SUPPORT

Is this research project supported by intra- or extramural funding? ____ Yes X No

If “yes”, sponsoring agency(ies):

Amount of funding:

NOTE: The full grant application must be submitted if the research described in your PRF is in conjunction with a grant proposal.
All individuals conducting research involving human subjects (with or without financial support of any sponsoring organization or agency) must complete Human Subjects training. Those individuals include principal investigators, co-investigators and all other individuals involved in the conduct of research. Students and their advisors must meet the same standard as faculty and staff.

Please list all individuals involved in the above-cited research study:

<table>
<thead>
<tr>
<th>Name</th>
<th>Research Role (PI, Co-PI, Collaborator, Sub-I, Data Mgr, Research Asst, etc.)</th>
<th>Affiliation</th>
<th>Will this person be involved in the consenting process?</th>
<th>Training Title</th>
<th>Completion Date(s) for each Human Subjects training listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa A Lauxman</td>
<td>PI</td>
<td>UA</td>
<td>YES</td>
<td>CITI-SBS</td>
<td>12-31-06</td>
</tr>
<tr>
<td>Julie Adamcin</td>
<td>Collaborator</td>
<td>UA</td>
<td>YES</td>
<td>CITI-SBS</td>
<td>9-05-06</td>
</tr>
</tbody>
</table>

*Consent forms are to be signed and dated by the subject (or their legal representative) and by the Principal Investigator or Co-Principal Investigator (no other study personnel may sign as Investigator without prior approval of the IRB). Other study personnel involved in the consenting process may sign as Presenter, but not as Investigator.

**CITI-Biomed, CITI-SBS:** Collaborative Institutional Training Initiative – [www.citiprogram.org](http://www.citiprogram.org)

Author: University of Miami

Comment [DM4]: Per IRB: Anyone involved in the consenting, data collection, and/or handling of identifiable data should be listed on the VOTF.

Comment [LAL5]: CITI certification training is required. Training information can be found on the IRB website under Human Subjects training.

Comment [LAL6]: CITI-SBS is the training required for those in youth development typically.

Comment [LAL7]: Anyone who will be involved with the data—collection, entry, analyses, reporting, and presenting of data must be certified.

Comment [LAL8]: Note one must be current with the training. A completion notice with date will be sent. Keep a copy on file so use can reference later.
PROJECT REVIEW FORM
ASSURANCES

If appropriate, after review by the Departmental Review Committee, please forward their opinions and comments along with the signatures on the Project Review Form to the Human Subjects Protection Program, University of Arizona, 1235 N. Mountain Avenue, PO BOX 245137, Tucson, Arizona 85724-5137. Only one copy is required and will be retained for the Human Subjects Protection Program files and eventually microfilmed for a permanent record. Please provide responses to all of the following items.

1. PRINCIPAL INVESTIGATOR
By signing below, I, the Principal Investigator, assure that all other investigators (co-investigators, collaborating investigators, involved statisticians, consultants, or advisors) are fully aware of, and concur with, the project submission and that all Human Subjects training verification information provided in this form is accurate. I agree that no procedural changes relating to the research will take place without prior review by the IRB.

The following statement refers to concerns regarding Conflict of Interest, such as financial, administrative, or authoritative matters that may influence any aspect of your research for which the IRB Committee should be aware.

Financial Interest Statements:

a) Do ANY of the investigators or research personnel (or relatives) serve as a speaker or consultant to the sponsor, the manufacturer, or the owner of the product or program being evaluated?  
× NO

b) Do ANY of the investigators or research personnel (or their relatives) have a proprietary interest, derive a direct or indirect benefit, hold equity or receive income annually from the sponsor, manufacturer, or owner of the product or program being evaluated?  
× NO

c) Do ANY of the investigators or research personnel (or relatives) serve in an administrative or advisory capacity to the sponsor (e.g., Board of Directors with or without compensation)?  
× NO

If yes to ANY of the above, attach copy of UA Conflict of Interest and Commitment Disclosure Form.(see UA Individual COI and COC Policy at http://vpr.arizona.edu/conflict-of-interest/index.html)

Principal Investigator (Print)  Signature  Date  Department

Advisor’s Name (Print)  Signature  Date  Department

2. DEPARTMENTAL REVIEW COMMITTEE
We/I have examined the proposal cited above, and certify that ALL of the following are true:

• The information contained herein is complete;
• The scientific aspects of the project include appropriate provision for protecting the rights/welfare of the human subjects;
• The required forms have been completed in accordance with the Federalwide Assurance filed by the U of A with DHHS

Based on review of the proposal, the Departmental Review Committee has determined that this project (check only one):

___ should be exempt from IRB review
___ places human subjects at minimal risk.
___ places human subjects at more than minimal risk.

Chairman of Departmental Review Committee (Print)  Signature  Date  Department

If this project recruits participants at the SAVAHCS or conducts any research activity at the SAVAHCS, the following must be completed prior to submission:

The undersigned certifies that all VA staff listed as researchers on this project have met all VA training requirements.

Chairman of R & D Committee SAVAHCS (Print)  Signature  Date  Department

Comment [LAL9]: Usually we in Extension do not have to answer “yes” to these questions, but, if you do, please note you must include a UA Conflict of Interest and Commitment Disclosure form – see below the comment

Comment [LAL10]: Only if one has answered “YES” to any of the above questions

Comment [LAL11]: Signatures are required from the appropriate departmental review committee. I have used both FSHD as well as AG Ed for Human Subjects depending upon the type of evaluation

At present, Cooperative Extension does not have it’s own departmental review committee

Comment [DM12]: PER IRB: The ‘departmental review chair’ and ‘supervisory official’ should be two different people, and they cannot be listed on the VOTF. Who signs the forms is not determined by the IRB, but rather who has the authority to attest to the statement on the IRB form. For example, if the departmental chair is out of town who would sign official documents on their behalf? Note: It is not appropriate to have the budget officer sign.
3. SUPERVISING OFFICIAL
I certify that (1) the resources necessary to protect human participants are available. Such resources include but are not limited to; staffing and personnel (in terms of availability, number, expertise, and experience); psychological, social, or medical services (e.g., counseling or social support services required due to research participation); psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and resources for participant communication (e.g., language translation services) (2) I assume the responsibility for ensuring the competence, integrity, and ethical conduct of the investigator(s); (3) no procedural changes relating to the human subjects involved will be allowed without prior review by the Human Subjects Committee; (4) I am satisfied that the procedures to be used for obtaining informed consent comply with the spirit and intent of DHHS and FDA regulations; (5) I certify that the investigator(s) is fully competent to accomplish the goals and techniques stated in the attached proposal.

I certify that signed consent forms will be filed in _Forbes 306___ (administrative room/building) and retained for a period of 6 years.

Name of Department Head, Dean of the College or comparable authority (Print)  Signature  Date  Title

Please provide answers to all of the following questions. All projects submitted for review must be typed (no handwritten proposals accepted). If appropriate, after review by the Department Review Committee, please forward their opinions and comments along with the signatures on the Project Approval Form to the Human Subjects Protection Program Office, University of Arizona, 1235 N. Mountain Avenue, PO BOX 245137, Tucson, Arizona 85724-5137. Only one copy is required and will be retained for the Human Subjects Protection Program files and eventually microfilmed for a permanent record.
PROJECT REVIEW FORM

PROJECT ABSTRACT

In the space below, provide an abstract of the project in 400 words or less. Include information about (a) the background and rationale for the study; (b) the purpose and objectives; (c) methods to be employed and (d) significance of the study.

(a) Background and Rationale: *Health Rocks!* is a youth development program developed by National 4-H Council to teach youth healthy decision-making skills. The program involves teen mentors leading a series of learning activities with preteen youth.

(b) Purpose of the Study: The goal of the study is to determine the impact of the program on the preteen youth and their beliefs concerning good health decisions.

(c) Methods: A survey will be administered upon completion of the Health Rocks! program to those youth who have given assent and their parent/guardians who have given consent.

(d) Significance: Responses from the youth participants will assess the decision-making benefits derived from participating in the Health Rocks! Program.
1. POPULATION

a. Number of persons to be recruited for participation in the study: The goal is to reach 5,000 youth ages 8 to 12.

b. Describe the population to be recruited and rationale for their participation (indicate age range, gender, and ethnicity). Note any special efforts to encourage the recruitment of women and/or representatives from racial or ethnic minority groups. The Health Rocks! Program is designed to be delivered to youth ages 8 to 12 years of age. The population to be recruited will be those youth who participate in a Health Rocks! Program who receive consent to participate in the study.

c. Does your study involve vulnerable populations such as children, pregnant women, prisoners, or cognitively impaired subjects, or populations at risk of transitioning into one of these vulnerable categories during the course of your study (e.g. a longitudinal study involving illegal drug users who are at risk of becoming incarcerated while in the study)? The target population is youth between 8 to 12 years of age.

d. What are the inclusion and exclusion criteria for study participation? Inclusion: youth participants in Health Rocks! Programs ages 8 to 12 years of age. It’s voluntary to participate in the study’s survey from Health Rocks! program participants.

2. RECRUITMENT AND CONSENT PROCEDURES. For each response in this section, note whether the activity will be done orally, in writing, or both. List points to be covered in an oral or written presentation here. Place consent documents in Appendix A. Include copies of any visual material (advertisements, flyers, web announcements, etc.) in Appendix B for approval.

a. Describe how potential participants will be identified and how you will respect and protect their privacy during recruitment. Health Rock! Program participants will be contacted to be participants in the study.

b. Describe how you will contact individuals who may become participants in the study (e.g., web site, email, flyers, phone calls, advertisements). Potential participants will be contacted in a written format when they sign up to participate in the Health Rocks! Program.

c. Describe how the project will be explained to individuals when you recruit them for participation (include the text of advertisements, phone solicitations, etc). Include any pre-screening questions or surveys that may be used. There are no pre-screening questions. The study will be explained in written format to the youth’s parents/guardians. A sample letter is attached.

d. Describe how informed consent will be obtained. If the participants are minors or of another vulnerable population, explain how assent or legal consent will be secured. Include if appropriate, the steps you will take to allow sufficient time for the participant to think about their participation or time to review the consent form with family or friends, prior to consenting. If an informed consent document is inappropriate for your project, explain why and how you will ensure informed consent. First, parental permission will be obtained in writing (see attached form). Two assent/permission forms will be included along with a letter to the parents. One assent/permission form is to remain attached to the letter to the parents for their records and the second signed form is to be returned when the youth are signed up by their parents/guardians to participate in the program. The youth who have on file a signed assent/permission form will be given a survey at the end of the Health Rocks! program. The youth will be assured that no adverse consequences will happen to them should they choose not to participate. A permission/assent form states specially that participation in the study is voluntary and that the subjects can withdraw at any time. (all are attached) No surveys may be completed without the signed permission of the parent/guardian nor the minor’s assent.
e. How will you make it clear to the recruits that their participation is voluntary and that they may withdraw at any time? The assent/consent and the parental/guardian letter are stress that participation is voluntary and that the subject can withdraw at any time.

f. Describe the additional safeguards you will use to protect participants from coercion or undue influence, during recruitment and throughout the study (e.g. if the participants are students and the investigator is their teacher). The PI and the collaborator have no formal or informal authority over the participants. The study includes a one-time completion of a survey. The participant may decide not to participate without repercussions to them.

3. METHODOLOGY AND DATA COLLECTION PROCEDURES

a. Is your project evaluating an active intervention or treatment procedure (to determine whether an intervention/treatment is effective for the people undergoing it)?
   - Yes___ No X_
   - If yes, in lay terms provide a summary of the intervention and/or treatment methods and procedures to be employed

b. What type of data collection and recording will be employed? Check all that apply and provide an explanation. (If Administrative Records are to be used, include a letter of authorization from the appropriate agencies in Appendix C. Include samples of all data collection instruments in Appendix D.)
   - X__ Questionnaires
   - ___ Surveys
   - ___ Interviews/Focus Groups
   - ___ Observations
   - ___ Records Review (medical, educational, etc.)
   - ___ Videotaping
   - ___ Audiotaping
   - ___ Photography
   - ___ Other (define):
   - ___ Participant observation

c. In lay terms, provide a description of the research methods (including deception) and procedures for data collection that will be employed. The Health Rocks! program will be conducted regardless of the questionnaires. All youth participants in the Health Rocks! Program will be asked to participate with the paper version instrument.

d. Describe the procedures you will use to respect and protect the research participant’s privacy (physically, behaviorally, or intellectually) during the data collection process (e.g. during the interview the participant will meet with the researcher in a location away from his/her place of employment). The participants will be given the survey at the conclusion of the Health Rocks! program after receipt of their assent/consent form. To ensure confidentiality, there are no names of the participants included. When finished, all survey participants will place their completed instruments in a box face down. The instruments will be destroyed at the conclusion of the project. All reports and publications resulting from the study will consist of group data and no individual participant could possibly be identified.

e. Describe when appropriate, how the research plan makes adequate provision for monitoring of data when participant safety is a concern, or identification of or support for distressed participants to ensure their safety (e.g. Participants who may self-identify for depression will be provided with referral information so they may seek professional help.) There is no identification attached to the survey as the data and the name is separated once received. Here’s the statement from the Parent’s letter for the use of the survey “.... Your son/daughter’s confidentiality will be maintained at all times during the study. After receiving the survey information and verifying that we have consent letters, your son/daughter’s name will be removed from the data permanently.”
f. Where will the project be conducted? If study is to be conducted anywhere outside your department (e.g., in another department, at an off-campus agency or organizational location), include a letter of authorization in Appendix C, or state when it will be provided to the Human Subjects Protection Office. If your project takes place off-campus but site authorization is inappropriate, explain why. **Health Rocks! Programs is a Cooperative Extension Program 4-H Youth Development Program that is being delivered by various sites off-campus as that is how Cooperative Extension Programs are delivered. Site authorization is not necessary.**

g. Are you the lead investigator of a multicenter study? NO

i. If yes, describe the plan for communicating the following information (relevant to the protection of research participants) among the sites involved in this study:

   o Unexpected problems
   o Protocol modifications
   o Interim results

4. **CONFIDENTIALITY OF PERSONAL IDENTIFYING INFORMATION**

   a. What procedures will be followed to ensure that the information obtained about them will be stored in a secure manner? (Specify how the confidentiality of data will be maintained throughout the research.) **The instruments used will not identify youth participants nor will there be any identifying questions asked to specifically indicate who the individual respondent is. The survey information will be collected, and only those who have clearance may view the data collected. There will no names nor any other identifying information collected for the surveys. There will be no way to match a survey with an individual.**

   b. What are the plans for retention and/or destruction of linkages between study data and personal identifying information? (Specify when and how personal identifying information will be destroyed.) **There is no personal identifying information collected. The surveys will be destroyed or shredded after the data is entered within one year to allow for checking and correcting possible data entry errors.**

c. If these linkages will not be destroyed, explain how you will maintain confidentiality of the personally identifying information. **NA**

d. In the event that personally identifying information will not be kept confidential, explain why not and explain how you will ensure that the subjects are consenting to your sharing this information. **NA**

e. Will a Certificate of Confidentiality (through DHHS or another Federal agency) be utilized? **NA**

5. **BENEFITS, COSTS, COMPENSATION & RISKS**

   a. Benefits: i. What are the potential benefits directly to the participants, if any? **Youth participants are better able to make decisions based upon skills learned and able to discern the consequences related to their decisions.**

   Benefits: ii. What are the potential broader benefits of the study? **This study will lead to a dissemination of the program benefits Health Rocks! offers to pre-teens in decision-making.**

   b. Costs: What are the costs to the participants (monetary, time, etc)? **Other than the time of to take the**
c. Compensation: Will monetary or other compensations be offered to the subjects? (If so, identify the amount of compensation and method of payment.) **The youth participants receive no compensation for their participation.**

d. Risks: i. What risks to the participants could be encountered through participation in this project (physical, psychological, sociological, financial, economic, etc)? **None**
e. Risks: ii. Describe the approaches you will take to minimize these risks and/or to minimize their impact. **N/A**

6. **APPENDICES**

Attach the following appendices to the PRF, in the order specified, labeled as indicated, and with a table of contents identifying all appendix materials. Use titles that are consistent with those used in the text of the PRF.

A) Parent/Guardian Letter for On-Line Survey
B) Parent/Guardian Consent/Assent Form
C) Data Collection Instruments
• Paper Version of Survey Instrument

Revised: 10/07 (rkd)