Expanded Food and Nutrition Education Program Institutional Review Board Toolkit for EFNEP Coordinators

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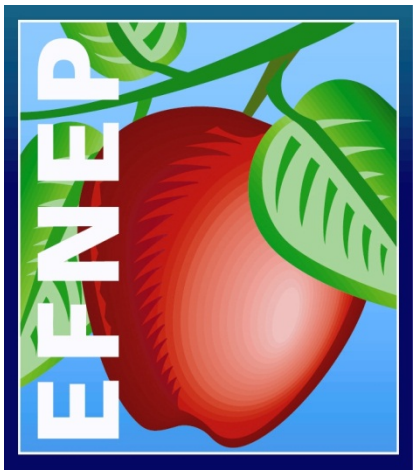

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This document was produced by the Expanded Food and Nutrition Education Program (EFNEP). IRB Taskforce commissioned by Helen Chipman in February 2012 to address building concerns of EFNEP coordinators located at Land-grant Institutions regarding the Institutional Review Boards (IRB) at their local institutions. The intent is to address EFNEP's possible need for IRB review and approval at local institutions. It does not address IRB review and approval related to EFNEP specific research. The taskforce included the following members:

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Expanded Food and Nutrition Education Program
Institutional Review Board
Toolkit for EFNEP Coordinators

Section 1: An Introduction to Institutional Review Boards (IRB)

The Expanded Food and Nutrition Education Program (EFNEP) is a federally funded program "designed to assist limited resource audiences in acquiring the knowledge, skills, attitudes, and changed behavior necessary for nutritionally sound diets, and to contribute to their personal development and the improvement of the total family diet and nutritional well-being."[1] The Web-Based Nutrition Education Evaluation and Reporting System (Web-NEERS) is EFNEP's revised data collection and reporting system. It stores information on: 1) adult program participants, their family structure and dietary practices; 2) youth group participants and their dietary practices; and 3) staff. It also incorporates EFNEP's other reporting requirements. EFNEP's evaluation and reporting system adheres to the Office of Management and Budget's (OMB) standards for maintaining, collecting, and presenting federal data, and protecting personally identifiable information. Security measures are in place to ensure that collection and storage of program data including personal identifying information are handled appropriately and the individuals participating in the program and the integrity of program staff and data are protected.

What Is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is established at each institution to review proposed human subject research. The IRB may approve, require modifications (to secure approval), or disapprove research. The IRB's purpose is to protect the rights and welfare of the potential research subjects by examining areas such as risks and benefits, informed consent, selection of subjects, privacy, confidentiality, and anonymity.[2]

Does the National Office Require Each EFNEP Institution to Have an IRB Approval?

The national office requests that each institution determine need for IRB approval by consulting with the respective institution's Extension Directors/Administrators and IRB office.

How Do I Know if My Institution Requires an IRB Approval?

Even though routine EFNEP programming is not research, the fact that the program collects personal information along with outcome data for participants may trigger the need for an IRB approval at your institution. Also, if researchers want to utilize past or present EFNEP data for

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[1] ***EFNEP Program Policies.*** **Retrieved June 26, 2012 from USDA National Institute of Food and Agriculture:** *http://www.nifa.usda.gov/nea/food/efnep/pdf/program-policy.pdf.*

[2] ***About IRBs – A brief Overview of the Institutional Review Boards (IRBs).*** **Retrieved June 26, 2012 from Michigan State University: *http://humanresearch.msu.edu/about_irbs.html*.**

research purposes, IRB approval is required. The following table outlines typical EFNEP scenarios and whether IRB approval will likely be needed.

Type of EFNEP-Related Activity	IRB Approval Status
General EFNEP programming with adult audiences	Possibly. Discuss with Extension Directors/Administrators and consult IRB office.
General EFNEP programming with youth audiences (S*ee section on Vulnerable Populations)*	Yes. Approval is probably needed. Discuss with Extension Directors/Administrators and consult IRB office.
Research projects and/or/plans to publish EFNEP data	Yes. Approval is required.
Follow-up data collection with participants after conclusion of regular EFNEP program *(post- assessments)*	Yes. Approval is required. Even if you are using this for program evaluation, it is outside the scope of regular EFNEP data collection. If questions, follow your institution's guidelines.

Visit with your institution's Extension Directors/Administrators and IRB Office to determine if your institution requires IRB approval for the EFNEP data collection process.

It may also be a good idea to visit your institution's IRB website. Look for flow sheets or checklists that provide institution-specific information on what types of projects require approval.

Examples of checklists and flow charts to determine if IRB approval is needed may be found at:

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
http://www.irb.wsu.edu/flowchart.asp
http://www.irb.wsu.edu/Documents/Forms/PDF/IRB_Determination_Checklist.pdf
http://www.irb.cornell.edu/documents/IRB%20Decision%20Tree.pdf

What Should I Be Prepared to Discuss When I Meet with My Institution's IRB Office Representative?

When you meet with your institution's IRB representative, key points to describe include:

- Data collection methods, records, distribution, retention
- Who can access personal identifying information from participants
- What happens to personal information when data are sent to the national office
- How data are used (general EFNEP program evaluation versus research)

Questions you may be asked include:

- Do you intend to collect information and then present it to a public audience or at a conference?
- Do you intend to publish findings or disseminate information based upon your work?
- Will you be conducting interviews, surveys or focus groups?
- Will you need access to or collect sensitive data or records?
- Is there any way to link the data you plan to collect with identifying information?
- Are you collecting data from any vulnerable populations?
- Do you have an informed consent process?

What Is Meant by "Vulnerable Populations"?

If an activity intentionally focuses on or includes one or more specific populations, it may require IRB approval. Such populations could include:

- Children under 14 years outside established educational setting
- Neonates/ Fetuses
- Prisoners (Incarcerated adults are not an EFNEP appropriate audience)
- Pregnant women
- Adults unable to consent
- HIV/AIDS patients
- Crime victims
- Students or employees under the supervisory or evaluative authority of the researcher
- Substance abusers
- Non-English speaking individuals
- Terminally ill people

What Is "Informed Consent"?

Informed consent is the process of fully informing participants of the risks, benefits, and procedures involved in a study.[3] It is a standard requirement in research with human participants. To meet ethical and legal standards, informed consent must disclose all the facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate in a "research" protocol. This applies to ALL types of research including surveys, interviews, and observations in which participants are identified, and other experiments, such as diet, drug and exercise studies. For a complete list of the components of informed consent considered essential by your institution, check your institution's Office of Research website. The website will have information about human subjects, informed consent, and other IRB requirements.

[3] ***What does "informed consent mean? What are its essential components?*** **Retrieved June 26, 2012 from Cornell University Office of Research Integrity and Assurance:** *http://www.irb.cornell.edu/faq/#con1*

Are There Different Types of Informed Consent?

The informed consent process can take on various forms:

- Signed informed consent is the standard expectation in research with human participants. This is in the form of a document with the elements of informed consent, signed and dated by the participant and kept as a record by the researcher.
- In research with children (individuals under 18 years old), assent of the child and parental permission are standard requirements.
- In some circumstances, investigators can seek alternatives to standard informed consent procedures. Examples are:
  - A waiver of signed consent form (e.g., giving participants an information sheet but not collecting signatures)
  - A waiver of written consent (e.g., using oral consent procedures)
  - A waiver of some or all of the elements of informed consent (e.g., in research that involves deception)

For a complete list of the options for informed consent procedures, and the requirements, contact your institution's IRB office.

What Kind of IRB Proposal Might I Have to Submit?

If you need to submit an IRB proposal, visit with your institution's IRB office to determine what type of application you will need to file. Applications typically include Exempt, Expedited, and Full Board review.

What is meant by "exempt" review?

According to federal guidelines (U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46), research that presents little or no risk to human subjects (non-vulnerable subjects) does not require review by a convened Institutional Review Board[4]. Although the project does not require full board approval, staff, in consultation with an IRB chair, must certify the exemption before the research study may commence. More information about exempt research is available at http://www.hhs.gov/ohrp/index.html, US Health and Human Services Office for Human Research Protections. An example of an institution's overview of IRB exempt categories is available at http://orrp.osu.edu/irb/exempt/index.cfm.

EFNEP's research is typically exempt because it is research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

What is meant by "expedited" review?

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the entire IRB.[5] The term

[4] ***Regulations.*** **Retrieved July 4, 2012 from http://www.hhs.gov/ohrp/humansubjects/index.html.**

[5] ***Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure.*** **Retrieved July 4, 2012 from U.S. Department of Human Services**

"expedited" can be misleading: reviews of this type are not "quicker" or conducted with less rigor, but fewer reviewers are required for approval. There are several types of research that may qualify for expedited review. In general, research may be considered for expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate consent procedures.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please keep in mind that research does not count as having "minimal risk" simply because it involves minimal physical risk or is non-invasive. There are many kinds of risk including financial risk, employment risk, criminal/civil liability, stigmatization, insurability and embarrassment. It is important to consider all of these when assessing risk.

Researchers engaged in human subject research that qualifies for expedited review must still complete a full application form and prepare an informed consent statement. Researchers must engage in practices that minimize risk, maximize benefit and ensure privacy.

What is meant by "full board" review?
Full Board Review is conducted by the convened IRB for any research presenting more than minimal risk to subjects, or any research using data collection techniques not expressly authorized under exempt or expedited review. Please allow additional processing time for a full board review.[6]

Office for Human Research Protections (OHRP) - Categories of Research, http://www.hhs.gov/ohrp/policy/expedited98.html.

[6] ***What is the difference between Exempt, Expedited, and Full Board Review?*** **Retrieved June 26, 2012 from Texas A&M University Research Compliance and Integrity.**
http://rcb.tamu.edu/humansubjects/faqhumansubjects.

Section 2: EFNEP Adult Program (Program for Families with Children)

Description of Program

EFNEP targets low-income adults (families) with young children with key food and nutrition related educational messages. In order to assess the effectiveness of adult education strategies, institutions are asked to use standard evaluation tools to capture knowledge and behavior change among adults participating in EFNEP.

Description of EFNEP Adult Evaluation Requirements

The national EFNEP office requests that all EFNEP adult participants respond to a series of enrollment questions (demographics), a 24 hour dietary recall and a behavior checklist. These common measures are used so EFNEP data can be aggregated at the federal level and show national impact. The standard adult evaluation tools and measures are available from the national EFNEP office.

The 24 hour dietary recalls and behavior checklist questions are administered at entry and exit and entered into the Web-Based Nutrition Education Evaluation and Reporting System (Web-NEERS), the national EFNEP reporting system. All entry and exit evaluations are matched by name of adult or another unique identifier for entry into the EFNEP reporting system.

Adult program data entry into Web-NEERS includes basic demographic and program status data about the adult participants. This includes some personally identifiable information as well as dietary and behavior change data. Data entered into Web-NEERS are available for review at the regional level (data entry/county/parish). Web-NEERS is password protected and only authorized EFNEP personnel are able to access it. At the institution (state) and federal levels data are only available in summative form; no personally identifiable information is transmitted forward.

Options for Collection of Adult Evaluation Data

As described above, evaluation data for participating EFNEP adults should be collected and matched for each individual client/participant. Examples of sample scripts for adult data collection and to obtain informed consent from participants are included at the end of this section for reference purposes. Forms and other required information may differ at your institution.

The Role of IRB in the EFNEP Adult Program

General definitions and concepts concerning IRB and its relevance for EFNEP have been covered in the previous section. As described previously in this document, adults/clients may or may not be considered as a 'vulnerable population' from the IRB perspective. If the adults/clients constitute special groups such as pregnant teens and adults or non-English speaking groups, they may need special considerations for IRB approval**.** Each institution will need to collaborate with its Extension Directors/Administrators, IRB office and/or program delivery partner to determine what type of IRB approval would be needed, if any. From there, each institution should prepare its IRB application for submission to the appropriate IRB governing board, if required.

If the EFNEP adult evaluation tools will be used for research purposes with EFNEP participants, it is the responsibility of each institution to follow the policies and procedures of their human research protection program.

Suggestions for IRB Adult Protocol

If an institution is required to submit an IRB application for approval, the following points may be useful in preparing the application packet:

- EFNEP provides nutrition education to low-income adults with young children. Adult evaluation data collected by the program are used to ***evaluate the effectiveness of the program and teaching efforts of EFNEP nutrition educators.***
- Although adult evaluation data are collected at the individual level, ***they are aggregated*** after they are entered into Web-NEERS (the EFNEP reporting system). Specifically, data for adults are aggregated at the regional level for reporting and program management purposes. All personally identifiable information is stripped from the regional level data before it is sent forward to the institution level. At the institution level, only aggregated data is available. This aggregated data is then submitted to the federal level to be combined with data from other institutions. At the institution and federal levels, there is no access to any type of unique identifier for a specific adult. At the regional level, security procedures are in place to ensure demographic data (race, ethnicity, education level, income, participation in assistance programs) collected via enrollment forms and evaluation data collected via the 24-hour diet recall and the behavior checklist are kept in a secure, locked cabinet for a predetermined period of time and then destroyed according to a predetermined protocol.

Some Specific Situations to Discuss/Clarify with IRBs/Administrators:

- If the program intends follow-up evaluations after completion and graduation of participants/clients from the program, will it be considered research? Follow-up is generally regarded as research rather than standard programming and will likely require IRB approval.
- Is there intent to utilize/analyze evaluation data for papers in peer reviewed journals and publications, and/or presentations at professional /scientific conferences?
- Is there intent to create knowledge which will be generalizable?

Protocols and procedures for training staff with access to data at the regional level are addressed in Section 4 of this document and need to be clearly articulated and communicated at all levels.

Protocols for maintaining the safety and confidentiality of data at the regional level also need to be established and communicated. ***All paper and electronic copies of adult evaluation surveys must be kept in a secure location per institution guidelines and EFNEP federal guidelines***.

Please see the appendix for sample informed consent documents.

Section 3: EFNEP Youth Program

Description of Program

In addition to adult audiences, EFNEP targets low-income children and youth (grades K-12) with key food and nutrition related educational messages. For the purposes of this document we will use "youth" to refer to EFNEP's child/youth program.

Youth are reached through group enrollment strategies; they are not programmed to individually. In order to assess the effectiveness of youth education strategies, institutions are asked to use standard evaluation tools to capture knowledge and behavior change among youth participating in EFNEP.

Description of EFNEP Youth Evaluation Requirements

The national EFNEP office requests that demographic information on all youth participants is collected using an enrollment form. This data includes personally identifiable information, but it is collected in aggregate (group) form. It cannot be tied back to an individual participant. A behavior checklist for all youth is also required. In general the checklists are as follows for each grade level:

- Kindergarten – 2nd grade: Includes a set of 10 questions administered to youth in these grade levels
- 3rd – 5th grade: Includes a set of 14 questions administered to youth in these grade levels
- 6th – 8th grade: Includes a set of 14 questions administered to youth in these grade levels
- 9th – 12th grade: Includes a set of 14 questions administered to youth in these grade levels

The checklist data is collected individually for each youth participant, but cannot be tied back to demographic data. Common measures are used so EFNEP data can be aggregated at the federal level and show national impact. The standard youth evaluation tools are available from the national EFNEP office.

The national EFNEP office recommends entering the entry and exit checklists at exit into Web-NEERS, but it is possible to enter them at entry and then at exit if that is the preference of the institution. All entry and exit checklists should be matched. To do this, Web-NEERS requires that each youth in an enrolled group has a unique identifier when youth impact data are entered. The identifier should be an assigned number, letter(s), or combination of the two. Before using a child's name as a unique identifier, consult with your IRB office.

Youth program data entry into Web-NEERS should include the Youth Group Enrollment Form as well as matched evaluation data for each child in that group. Data entered into Web-NEERS is available for review at the regional level (data entry level). Web-NEERS is password protected and only authorized EFNEP personnel are able to access it. At the institution and federal levels data are only available in summative form; no personally identifiable information is transmitted forward. Keep all paper and electronic copies of the youth evaluation surveys in a secure location per institution guidelines and federal EFNEP guidelines.

Collection of Group Information (Outputs) – Web-NEERS Enrollment Form

Each youth group participating in EFNEP should have a completed youth group enrollment form for entry into Web-NEERS. The demographic information (race/ethnicity, grade, gender, residence) will be summative for the respective youth group. In addition, some sort of attendance verification for the classes may be required by the institution (sign-in sheet, roster, or other verification of attendance). The following are options to assist in collection of youth group information:

1. The EFNEP staff member could ask the program delivery partner to complete the demographic information required for the form.
2. The EFNEP staff member can collaborate with the program delivery partner to gather demographic information for the participating children.

Collection of Individual Youth Evaluation Data (Outcomes)

As described above, checklist data for participating EFNEP youth should be collected and matched for each individual child. A script for youth data collection will be forthcoming. The following is a recommended procedure for collection of youth evaluation data.

- Each child participating in the EFNEP educational series should be assigned a code by the program delivery partner or EFNEP staff member. The code should be indicated on the entry and exit survey for the respective child. For example, some schools use student identification numbers and each student is required to learn his/her own unique code. Following the class, the EFNEP staff member should match the entry and exit surveys for each child. This option for data collection has an advantage in that names of youth are not collected keeping surveys anonymous and de-identified.

The Role of IRB in the EFNEP Youth Program

As described previously in this document, children under 14 are considered a vulnerable population and may need special considerations for IRB approval. Each program will need to collaborate with its institution's Extension Directors/Administrators, IRB office, and/or program delivery partner to deter mine what type of IRB approval would be needed, if any. From there, each institution should prepare its IRB application for submission to the appropriate IRB governing board, if required.

If the EFNEP youth evaluation tools will be used for research purposes with EFNEP participants, it is the responsibility of each institution to follow the policies and procedures of their human research protection program.

Suggestions for IRB Youth Protocol

If an institution is required to submit an IRB application for approval, the following points may be useful in preparing the application packet:

- EFNEP provides nutrition education to low-income youth. Youth evaluation data collected by the program are used to evaluate the effectiveness of the program and teaching efforts of EFNEP nutrition educators.

- Demographic data for the EFNEP youth program are collected for the youth group, not on each individual child. Therefore, demographic information cannot be tied back to an individual child.
- A unique identifier such as a number, letter(s), or combination of the two will be assigned to each child for purposes of matching pre and post questionnaires.
- Although youth evaluation data are collected at the individual level, they are aggregated after they are entered into Web-NEERS (the EFNEP reporting system). Specifically, data for each group are aggregated at the regional level for reporting and program management purposes. All personally identifiable information is stripped from the regional level data before it is sent forward to the institution level. At the institution level, only aggregated data is available. This aggregated data is then submitted to the federal level to be combined with data from other institutions. The institution and federal levels do not have access to any type of unique identifier for a specific youth. At the regional level, security procedures are in place to ensure group demographic data collected via group enrollment forms and evaluation data collected via the youth checklists are kept in a secure, locked cabinet for a predetermined period of time and then destroyed according to a predetermined protocol.

Some Specific Situations to Discuss/Clarify with IRBs/Administrators:

- If the program intends follow-up evaluations after youth participates complete the EFNEP program, will it be considered research? Follow-up is generally regarded as research rather than standard programming and will likely require IRB approval.
- Is there intent to utilize/analyze evaluation data for papers in peer reviewed journals and publications, and/or presentations at professional /scientific conferences?
- Is there intent to create knowledge which will be generalizable?

Protocols and procedures for training staff with access to data at the regional level are addressed in Section 4 of this document and need to be clearly articulated and communicated at all levels.

Protocols for maintaining the safety and confidentiality of data at the regional level also need to be established and communicated. ***All paper and electronic copies of adult evaluation surveys must be kept in a secure location per institution guidelines and EFNEP federal guidelines***.

IRB Training Requirements

Additional information on IRB training requirements will be covered in Section 4 of this document. However, EFNEP staff working directly with youth's identified data should follow their institutional requirements in terms of IRB training. If EFNEP staff will work in a research study involving EFNEP participants, it is the responsibility of each institution to assure that staff members have been trained in human research protection.

Section 4: Implications of IRB Approval

Once it is determined that IRB approval is needed for an institution, there are some universal steps that must be taken (application, staff training). Programming in subsequent years will require annual renewal; changes during a program year will require amendments to approved IRB protocol. Each institution will have its own process, but this is important to take note of because EFNEP is a year-round continuous program. You do not want to experience delays due to lapses in IRB approval. IRB training at the institutional level is generally required for anyone collecting, analyzing, storing and/or using data collected from humans. The general steps are outlined below.

Application/Renewal Process

Complete IRB application required by institution *before* conducting any programming (you must have approval before doing any research activities)

- Timelines for submission – there may be an open application schedule, or there may be specific times during the year when new applications are accepted and reviewed. Check with your institution's IRB office to determine when the IRB committee meets and what the deadlines are.
- Timelines for review – submission deadlines may be well ahead of the IRB meeting schedule so board members have time to review all applications. Check to ensure you have enough lead time prior to the beginning of a new fiscal year, or the beginning of a project requiring IRB approval, so you can begin on time.
- Staff training may be required prior to any approvals being granted.

Yearly update/renewal of IRB approval is required and includes reporting:

- Numbers of people reached
- Numbers of people dropped
- Estimated number of participants to be reached
- Any protocol deviations or problems
- An update of any protocol changes

Review of Forms, Materials and Related Resources

Based on your institution's IRB protocol the following items may be required in an application:

- Subject population (inclusion and exclusion criteria)
- Study location
- Funding
- Risks/Benefits
- Description of procedures/processes
- Recruitment materials
- Data collection materials
- Storage protocols/confidentiality protocols
- Training protocols
- Conflicts of interest
- Educational materials given to participants
- Consent forms/cover letters

Staff Training

Investigators and research staff must have the necessary training and expertise in IRB to:

- Ensure that the rights, welfare, and safety of participants are protected
- Comply with regulations concerning IRB review and approval, including:
  - Informed consent requirements
  - Reporting requirements
- Maintain and retain records (keep complete files and maintain confidentiality during the research and for the number of years after the research ends as required by the institution and by federal guidelines (3 years))
- Oversee that research is conducted in compliance with IRB rules and regulations
- Apply relevant professional standards that are applicable to the research
- Follow institutional requirements for training academic staff vs. program staff
  - The Collaborative Institutional Training Initiative (CITI) course is typically required of faculty, students, and staff handling data.
  - CITI training vs. other training
    - Varies by institution, for example, at Cornell University, all investigators and research staff must successfully complete the CITI Program for training in the ethical conduct of research with human participants and update it at least once every five years
    - Refresher training is typically required every 3 to 5 years
    - All newly hired staff who handle data must complete training before working with data

Amendments During the Year

- When making any changes to procedures/processes of an approved IRB protocol, an amendment needs to be submitted *before* changing programming. This includes changes in procedures, forms, data storage, etc. The amendment must be approved by the IRB before implementing changes in the field.
- Be aware of IRB submission and approval guidelines to ensure programmatic changes can be implemented in a timely fashion.

Consequences of Not Following the Protocol Submitted

- The principal investigator must ensure all procedures/processes outlined in approved IRB protocol are followed by all staff. This includes: procedures, processes, forms, recruitment materials, educational materials, consent forms/cover letters, numbers of people reached, and data collection and storage.
- Quality assurance measures must be implemented to ensure:
  - Protocols are being followed by all staff at all times including administering informed consent, maintaining confidentiality, use of approved forms and materials
  - Any changes to protocol are approved through an amendment
- Quality assurance measures could include:
  - Periodic review of materials used by county level staff through program reviews, drop-in class observations, agency visits (observing that recruitment materials are posted), and on-going training

- Deviations
    - If a deviation from approved protocol occurs, report it to IRB immediately and follow IRB recommendations for addressing the deviation.

Closing Out a Protocol

- If IRB approval expires, all study procedures related to the protocol must cease, including: recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information. Continuing is a violation of federal regulations. You need to receive continued approval through protocol renewal from the IRB in order to continue programming.
- Once the research project is complete, each investigator needs to close the protocol and report to the IRB:
    - Numbers of people reached
    - Numbers of people dropped
    - Reporting any protocol deviations or problems
    - General outcome of the project/program

Section 5: APPENDIXES

Appendix A

SAMPLE INFORMED CONSENT DOCUMENT FOR PARTICIPANTS
Source: Colorado State University Extension

Dear EFNEP Participant,

This letter is to inform you that some of the information you provide on the EFNEP surveys will be used by XXXXXX University for research purposes. This research poses no risks or benefits to EFNEP participants. Your confidentiality will be protected at all times.

The survey that you fill out upon enrollment and completion of the EFNEP program will be entered into the EFNEP database. In order to protect your confidentiality, your name and contact information will be removed before the information is shared with our research project team. The surveys that you fill out will remain in a locked file cabinet in the EFNEP program director's office. Your information will be combined with information from other EFNEP participants. When we write about the research and share the results with other researchers, we will write about the combined information we have gathered. You will not be identified in these written papers. We may publish the results of this study, but your name and contact information will remain confidential.

If you do not want the information you provide in the surveys to be used for research purposes, you can contact EFNEP at the number below to withdraw you participation in this research. As stated above, there are no risks or benefits involved with this research. If you have further questions about this study, please contact XXXXX at XXX-XXX-XXXX.

Sincerely,

XXXXX XXXXXXXXX
EFNEP Program Coordinator

Appendix B

SAMPLE INFORMED CONSENT DOCUMENT FOR PARTICIPANTS

Source: Cornell University

Consent for Food and Nutrition Education

Welcome! During our time together we may share information on

* keeping food safe,
* buying food,
* making healthy meals,
* being active, and
* the advantages of breastfeeding.

We hope that you will come to all of the sessions. You may benefit from learning new ways to eat healthy and be active. We will ask you to fill out a form with information about you and your family. You do not have to give us the information and you can still participate. However, the information will help us meet your needs. We will ask you to fill out the form when you begin the sessions and when you end the sessions. You will receive feedback on the diet information you provide that will let you know how well you are eating compared to what is recommended. You will not receive money for participating.

Only staff that work with the nutrition program will see the information on your forms. We will keep forms in a locked cabinet. In XX years, we will destroy them. We will put your information with information we collect from other people across the State. This will help us see if the sessions are helpful, and how to make the sessions better. The combined information from all participants across the State will be used in research papers, but none of your personal information will be identified.

If you have any questions, before signing, please ask them. If you have questions later, please call or write to your local Cooperative Extension Office or XXXXX University at XXX-XXX-XXXX or XXXX@XXXX.edu.

I understand the above statements and agree to participate in the program.

_____Yes _____No

Staff from XXXX University may contact you by phone a few months after the sessions end. If they do, they will ask questions about how you are doing and how the sessions affected you and your family. I understand the above statement and agree to participate in the follow-up phone call.

_____Yes _____No

_____ _____

Signature Date

_____ _____

Signature of staff collecting consent Date

If you have any questions regarding your rights as a participant in this study, you may contact the Institutional Review Board for Human Participants (IRB) at XXXX@XXXX.edu or XXX-XXX-XXXX, or visit their web site, www.XXXX.edu. You may also report your concerns or complaints anonymously by calling XXX-XXX-XXXX. You will be given a copy of this form for your records.

Section 6: References

1. ***EFNEP Program Policies.*** **Retrieved June 26, 2012 from USDA National Institute of Food and Agriculture:** *http://www.nifa.usda.gov/nea/food/efnep/pdf/program-policy.pdf.*

2. ***About IRBs – A brief Overview of the Institutional Review Boards (IRBs).*** **Retrieved June 26, 2012 from Michigan State University: *http://humanresearch.msu.edu/about_irbs.html***

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4. ***Regulations.*** **Retrieved July 4, 2012 from *http://www.hhs.gov/ohrp/humansubjects/index.html*.**

5. ***Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure.*** **Retrieved July 4, 2012 from U.S. Department of Human Services Office for Human Research Protections (OHRP) - Categories of Research, http://www.hhs.gov/ohrp/policy/expedited98.html.**

6. ***What is the difference between Exempt, Expedited, and Full Board Review?*** **Retrieved June 26, 2012 from Texas A&M University Research Compliance and Integrity.** *http://rcb.tamu.edu/humansubjects/faqhumansubjects.*