East Texas
Human Needs Network

University of Texas
Tyler

2016 Comprehensive Community Needs Assessment

IRB Training & Research Ethics

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Module 1: Historical and Ethical Issues

Researchers must take every precaution to protect research subjects from physical or mental harm or discomfort, either short term or long term.

As such, the relationship between researchers and participants is critical and should be based on accurate and complete information, trust, and respect.

History of Ethical Dilemmas In Research

- Ethical guidelines for the conduct of research involving humans began in the late 1940's
- Although not the first example of harmful research on unwilling human participants, the experiments conducted by Nazi physicians during World War II were unprecedented in their scope and the degree of harm and suffering to which human beings were subjected.
- Others included the Tuskegee Study; Jewish Chronic Disease Hospital Study; Willowbrook Study

The Tuskegee Syphilis Study

Long term study on Black males with syphilis; some were denied treatment known to be effective; some misinformed about diagnostic tests (spinal taps were "treatment"

The Jewish Chronic Disease Hospital Study:

Debilitated subjects misinformed about having live cancer cells injected

The Willowbrook Study

Children intentionally infected with hepatitis virus; subsequent parents had little or no choice for children to participate in study

The Development of Codes of Research Ethics

Three documents regulate how we make decisions on the IRB:

- Belmont Report: 3 Principles researchers must adhere to: beneficence; justice; respect for persons
- Statutory: Code of Federal Regulations (DHHS): CFR45, Part 46 is based on the Belmont report, and also known as **The Common Rule.**These are enforced by Office of Human Research Protections (OHRP)
- The UT Tyler IRB Handbook (based on the above 2 documents)

Belmont Report

- Beneficence: This principle requires that researchers maximize benefits and minimize harms associated with research. Research-related risks must be reasonable in light of expected benefits.
- Justice: This principle requires equitable selection and recruitment and fair treatment of research subjects
- Respect for Persons: This principle acknowledges the dignity and freedom of every person. Respect for persons demands that participants enter into the research voluntarily and with adequate information.

Module 2: Human Subject Protection in Research - The Basics

Definition Of Human Subjects

Human subjects involve any type of interaction or involvement
with a human being, and include:

- Bodily materials, such as cells, blood or urine, tissues, organs, and hair or nail clippings, even if the researcher did not collect these materials.

- Residual diagnostic specimens, including specimens obtained for routine patient care that would have been discarded if not used for research.
- Private information, such as medical data that can be readily identified with individuals, even if the information was not specifically collected for the study in question. Research on cell lines or DNA samples that can be associated with individuals falls into this category.

The Role Of The PI

The Principal Investigator (PI) (the person in charge of conducting the study) acknowledges and accepts responsibility for:

- Protecting the rights and welfare of human research subjects
- The scientific and ethical conduct of the research study by all involved in the research
- Complying with all applicable Federal, State, local, and institutional regulations and guidelines.
- Ensuring that the study is properly designed, scientifically sound, and yields valid results.
- Ensuring that the study is approved by the IRB and is conducted according to the protocol.

Module 3: Vulnerable Research Populations

Children; Pregnant Women, Fetuses and Neonates; Prisoners; DecisionallyImpaired Persons; Terminally Ill Persons; Students; Employees; Comatose Persons.

Vulnerable research participants are persons who are relatively or absolutely incapable of protecting their own interests

One example is that individuals in relationships of unequal power or dependence have historically been particularly vulnerable to coercion

For Example…..

- Students (non-participation would have an adverse effect on a course grade)
- Employees (loss of promotion as a result of not participating)
- Soldiers (threatened reprimand if they refused to participate in research)
- Others include children, pregnant women and fetuses, the terminally ill, and cognitively impaired persons

Protection Of Children Involved In Research
Policy On Informed Consent Of Children

Several categories of research, e.g., research involving aptitude tests, educational strategies, and others that are minimal risk are exempt from full board or expedited review, but must always still be approved through IRB review. If doubt exists as to whether a project may be classified as research, contact the UT Tyler IRB Chair

For any project undergoing full board review due to a project being classified as more than minimal risk, a child expert in the area being proposed must be a part of the IRB review process.

Refer to *UT Tyler's Protection Of Children Involved In Research* for any research involving human subjects under the age of 18 years.

Research with Children and Assent To Research

Federal regulations specify special provisions regarding children's participation in research, and include:

- Requirements for obtaining **permission/consent** from parents or guardians and **assent** from children.
    - *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
    - *Permission/Consent* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

- At UT Tyler, a child between the ages of 7 and 12 years oldmust be able to verbally assent
- Children between 13 and 17 must be able to provide written assent in addition to parental permission/consent.
- Some exceptions to this rule exist, as in waivers of consent (see 46.116)

Requirements For Permission By Parents Or Guardians And For Assent By Children

An *Exception* to Parental Consent:

If the UT Tyler IRB determines that a research protocol is designed for conditions, or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements

See UT Tyler's policy on Informed Consent for Children in the UT Tyler IRB Handbook

Protection of Pregnant Women, Human Fetuses and Neonates In Research

For children who are pregnant, assent and permission are also obtained: refer to the UT Tyler IRB Handbook for details.

The same rules discussed about children and exempt categories apply to pregnant women also.

If the proposed research is very minimal risk, proposals are not reviewed by full board or through expedited process, but must still be approved administratively as exempt research.

Refer to the UT Tyler IRB Handbook for additional important policies that include:

- approval of exceptional cases
- viability issues of neonates
- termination of pregnancy
- cases that involve, *after deliver, the placenta, dead fetus or fetal material*

Protection of Prisoners In Research

Prisoner means any individual involuntarily confined or detained in a penal institution: Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and non-coerced decision whether or not to participate as subjects in research

Research involving prisoners, despite the level of risk, must always be a full board review

Refer to the UT Tyler Handbook for acceptable and restricted protocols

Protection of The Decisionally Impaired in Research

These individuals, as vulnerable populations, **may** have difficulty protecting their own rights.

Their ability to do so will depend on a careful assessment of their cognitive status and decision-making ability.

Some of these individuals include:

- Persons with **psychiatric** illnesses
- **Neurological** conditions
- **Substance** use history
- Various **metabolic** disorders.

Since they may not be able to give informed consent, "permission" for certain kinds of research can be given by a legally authorized representative and **"assent"** of the participant is substituted.

- Persons who are **terminally ill** may be influenced, inadvertently or otherwise, to be in a research study with the false hope of a cure, or, they may also be decisionally impaired due to pain relieving medications or effects of the illness on their levels of consciousness
- **Employees** may participate in a study to "please" their boss, or may feel coerced to do so, inadvertently or otherwise
- **Students** may participate in a study to "please" their teachers, or may feel coerced to do so, inadvertently or otherwise
- **Comatose persons** are decisionally impaired

Module 4: Informed Consent

Informed consent is a condition that follows directly from the Belmont principle:

Respect for Persons

Informed consent is not just a one-time event: it should be an ongoing process throughout the study!

What is Informed Consent?

A process that involves:

- conveying accurate and relevant information about the study and its purpose;
- disclosing known risks, benefits, alternatives, and procedures;
- answering questions; and
- enabling the potential participant to make an informed decision about whether to participate.

Determining Voluntariness

- Individuals who feel "coerced" into making a decision about research participation or are in a position in which it is impossible or extremely difficult for them to say no should not be enrolled into research.
- Coercion occurs if there is some threat of harm or punishment for refusal to participate.
- Examples of these populations are described under the “Vulnerable Populations” unit in this Training Post and in the UT Tyler IRB Handbook

Informed Consent

Potential subjects must understand the ***voluntary*** nature of participation without coercion! In addition, they must:

- Understand implications of their participation;
- Have freedom to ask as many questions as they want and are comfortable that their questions have been effectively addressed;
- Decision to participate must be an informed decision!

Elements Of Consent

- Purposes of the study and how it contributes to society

- Participant's role: activities and duration of involvement
- Thorough description of procedures (must specify if the research is experimental)
- Risks and ways to address them if they occur
- Freedom to participate and/or withdraw without consequences are but a few of the requirements.

Presentation of Consent

Note:

Informed consents may be written or verbal, but if verbal, a script that demonstrates what will be told to the potential participant must also be approved by the IRB

Elements Of Consent

- Most are written or explained at the 5th-8thgrade reading level, or at reading level of target population
- Translated consents are done at least twice: must be translated the first time, and then "backwards" translated (back to English) also by an objective translator who knows nothing of the study.
- The best way to ensure participant understanding of the informed consent is to ask them to describe their role as participants.
- Refer to the UT Tyler Handbook for additional requirements of informed consent components.

Documentation Of Consent

- By Federal regulation, a signature is required on the written document containing all the required elements of information
- A copy of the signed consent must be given to the person signing the form.
- The IRB may waive the requirement of written informed consent if it determines:
- There is a confidentiality risk, and the only link between the participant and the research would be the consent document.
- The research presents no more than minimal risk of harm and involves no procedures that normally require informed consent outside of research.

- Other special issues of language barriers, oral presentations, ethnic/cultural contexts, and capacity to consent are in the UT Tyler IRB Handbook

NOTE: Waiver of written informed consent does not mean that verbal or implied consent is waived!

Ongoing Informed Consent

When changes in the study occur, and/or significant new findings develop during the course of the study that may affect the participant and his or her willingness to continue participation:

- Additional informed consent may be necessary.
- Continuation of the study may require having participants sign a new consent form (obtaining re-consent)
- All proposed changes in the protocol and the consent must be submitted to the IRB using a Modification Request form.

Module 5: Health Insurance Portability And Accountability Act (HIPAA)

HIPAA Privacy Rule Policy in Research

The Health Information Portability Accountability Act (HIPAA) Policy may also be referred to as the "Privacy Rule"

The Privacy Rule is directed toward privacy of individual protected health information (PHI)

Guidelines for this policy were taken from the DHHS at the following site:

http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf

HIPAA: The Privacy Rule And Research

Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information…

While….at the same time…ensuring that researchers can have access to health information that is vital to research

HIPAA: De-identified Information

PHI can be "de-identified" as long as "identifiers" are not linked with the PHI being released.

For example….Some identifiers include names, medical record/account numbers, geographical information, health plan numbers, phone/fax numbers, dates (birthday, admission/discharge dates, etc.), license numbers.

HIPAA: De-identified Information

• HIPAA regulations apply regardless of information having identifiers, the setting, or research funding

• Other identifiers are in the UT Tyler IRB Handbook

HIPAA: Minimum Necessary Information

Under no circumstances is PHI to be released for research purposes without IRB and from the institution in possession of the PHI

UT Tyler researchers and anyone else involved with protected health information must be knowledgeable about the federal regulations regarding protecting the privacy of research participant PHI!

PHI Consent

A health care facility may release PHI under certain conditions without the patient's knowledge (with completion of Waiver of Authorization form).

This can only be done with written IRB approval!

HIPAA: Forms And Policies Relating To Enforcement Of The UT Tyler Privacy Rule

• Protected Health Information Use In Research (policy)

• Waiver Of Authorization To Use Protected Health Information (policy)

• Research Participant Authorization To Use Protected Health Information (form)

• Request for IRB Approval of Waiver of Authorization to Use Protected Health Information (form)

• Protected Health Information Use IRB Application (form) Refer to the UT Tyler IRB Handbook for information concerning these policies and forms

End of IRB training

Please go to the site below to take quizzes on these five modules:

http://www.uttyler.edu/research/compliance/irb/training/

Interviewer training for the ETHNN Needs Assessment Survey

Amy Wilson, LPC-S, Training Clinic Director, Psychology and Counseling, UT Tyler

General Qualifications of Research Interviewers

- **Healthy**. Field workers must have the stamina required to do the job.
- **Outgoing**. The interviewers should be able to establish rapport with the respondents.
- **Communicative**. Effective speaking and listening skills are a great asset.
- **Pleasant appearance**. If the field worker's physical appearance is unpleasant or unusual, the data collected may be biased.
- **Educated**. Interviewers must have good reading and writing skills.
- **Experienced**. Experienced interviewers are likely to do a better job.

Soliciting Participation

Making the Initial Contact –

Although the following information is provided in a script at the beginning of the survey, you will need to solicit participation and should do so by providing these key points.

Provide your full name, as well as the name of ETHNN

Explain the goal for this data collection, and how it is expected to benefit the low income members of the ET community.

Indicate the approximate length of time that the interview might take.

Explain that the answers will all be anonymous (not identified by name) and will be kept strictly confidential

Participation is Important

- Interviewers should explain how important it is that people participate in the survey so that we have a better understanding of the needs of all kinds of people.
- Interviewers must NOT, however, say anything which might coerce people into participating. They should be assured that participation is voluntary, and will not affect their access to services in any way.

Asking the Questions

1. Be thoroughly familiar with the questionnaire.
2. Ask the questions in the order in which they appear in the questionnaire.
3. Use the exact wording given in the questionnaire.
4. Read each question slowly.
5. Repeat questions that are not understood.
6. Ask every applicable question, but do not insist on an answer to each.

Problematic responses

- Occasionally a respondent's reply will seem to indicate that they have not understood the question
- Probing – Some commonly used probing techniques:
    1. Repeating the question and/or the response choices.
    2. Repeating the respondent's reply to make sure you heard it correctly.
    3. Using a pause or silent probe.
    4. Boosting or reassuring the respondent.
    5. Eliciting clarification.
    6. Using objective/neutral alternative wording.
        1. This should be a last resort in clarifying, since we do not want to risk any change in meaning that would elicit a different answer.

Voluntary nature of responses

- Always keep in mind that the survey participant has the right to refuse to answer any question he or she does not want to answer. Assure them that it is ok to skip questions they are uncomfortable answering and move on to other questions.

Recording the Answers to open-ended items

- – Guidelines for recording answers to unstructured questions:
    1. Record responses during the interview.
    2. Use the respondent's own words.
    3. Do not summarize or paraphrase the respondent's answers.
    4. Include everything that pertains to the question objectives.

5. Repeat the response as it is written down.

Terminating the Interview – The respondent should be left with a positive feeling about the interview.

Protocol and consistency

- Good research protocols must be kept throughout the process and for each participant, so that we know that any difference in answers is NOT due to differences in the way questions are asked.
- Although it can seem stilted and formal to read each question exactly, we still must do so to maintain our protocols
- It's as important with the last participant as with the first, so don't let your words or manner change over time.

Informed Consent &Confidentiality

- In agreeing to participate as an interviewer in this research project, you are agreeing to abide by government regulations regarding the treatment of human subjects in research. In a survey study, the two most important are:
  - Participation MUST be voluntary
    - Participants must understand that there is no penalty to not participating and that they can refuse answers to any or all of the questions.
  - Confidentiality
    - You must not discuss with anyone other than the project investigators (as necessary) any of the responses made by participants

Technology for the Survey Data Collection

Eric Bressler, Graduate Research Assistant, Psychology and Counseling, UT Tyler

Supported Platforms

- Devices: Phone, tablet, laptop, desktop
  - Please ensure phones and small tablets are set to retrieve mobile versions of webpages in your settings
    - Devices should be set to their appropriate mode by default
  - Small devices will still function outside of mobile settings, however the survey will continue off screen
- Operating systems: Apple, Android, Microsoft
- Officially supported browsers: Mozilla Firefox (4+), Google Chrome (2+), Apple Safari (3+), and Internet Explorer (7+)
- While other browsers should work, use an officially supported browser first when possible

Survey Properties: Skip Logic

- Some questions contain skip logic
- Skip logic tells the survey how to proceed
  - Q: Are you able to work
    - If Yes, survey continues as normal
    - If No, survey skips to question: Do you have reliable telephone access
  - How come?
    - If unable to work, then questions about employment status, job, looking for work, unemployment, and job related activities are not applicable
    - The same applies to being unemployed, if you are unemployed then we do not ask about job satisfaction
  - Consequences
    - Sudden advancement in question number

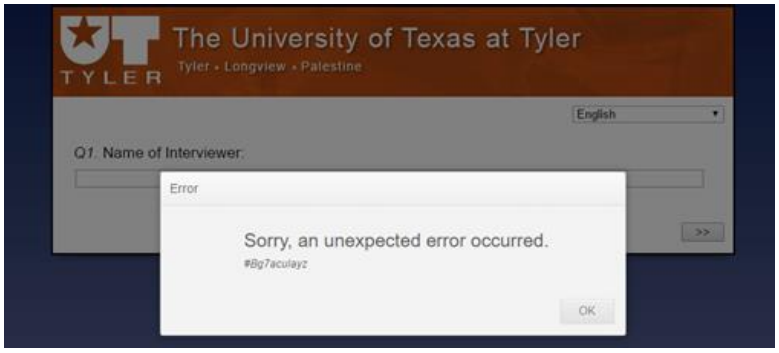
- This may occur several times

Survey Properties: No Forced Response

- Due to ethical considerations, we cannot force participants to answer
- Consequences:
  - When skip logic is present and no answer is selected the survey asks all following questions
  - May agitate clients
- Suggestions:
  - Reassure/inform participants they do not have to answer the following questions

Survey Properties: Connection and Signal Loss

- Survey may be taken on most electronic devices with Wi-Fi or data plans
  - No offline survey available
  - Do not use Qualtrics App – For offline only



- If connection is lost:
  - Do not panic
  - Survey will return an error when attempting to advance and remain on page
  - Survey will allow continuation when connection is restored
  - Survey will appropriately submit all data at end despite interruptions
  - Survey will continue uninterrupted on cellphone data plan

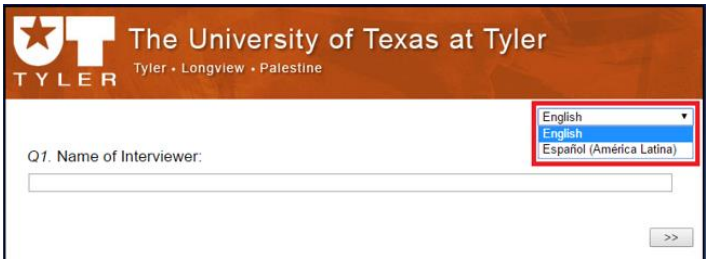
Survey Reading Rules

- When reading questions, read them exactly as they appear
- If the question does not provide guidance on whether or not to read the answers, then <u>do not read them.</u>

- If the question does provide guidance on whether or not to read the answers, then do what the question indicates.

Taking the Survey

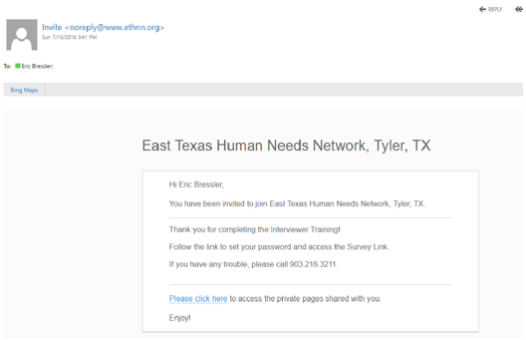
- Select language (available on all pages)



- Begin survey

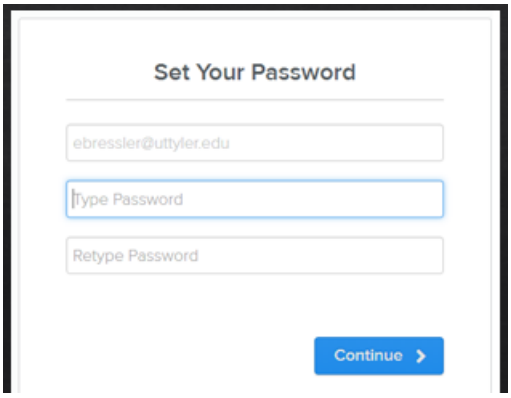
Accessing the Survey

- Check e-mail and click on “Please click here”



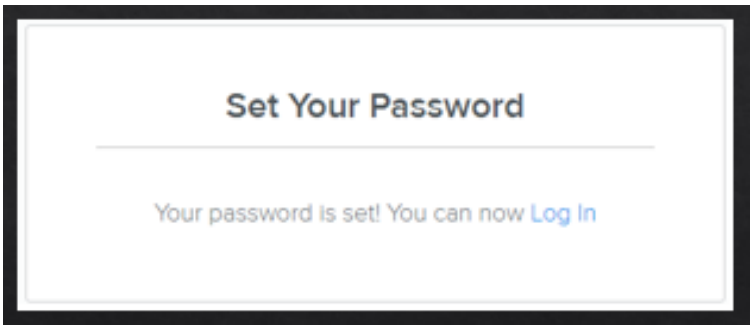
Accessing the Survey

- A registration page with your e-mail pre-filled will open
- Enter a password (twice) and click continue

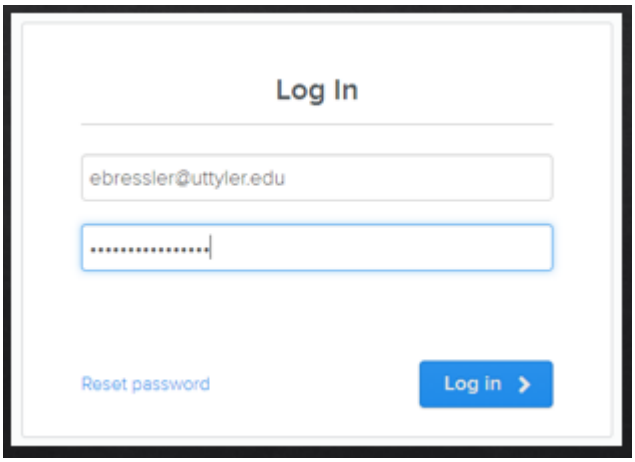


- The site will confirm your password was successfully set

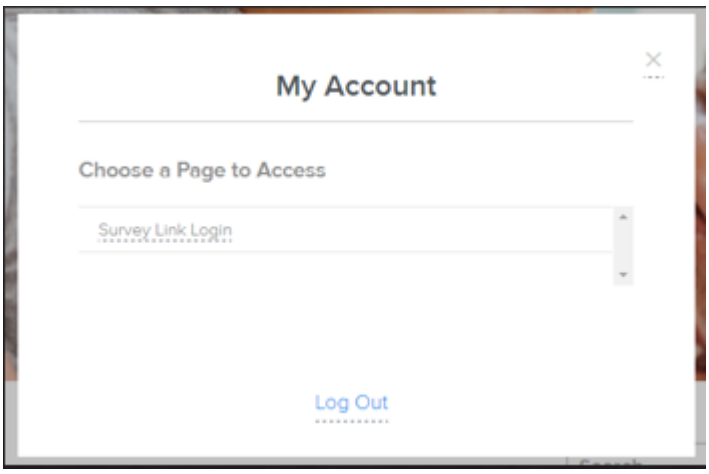
- Once set, click “Log In”



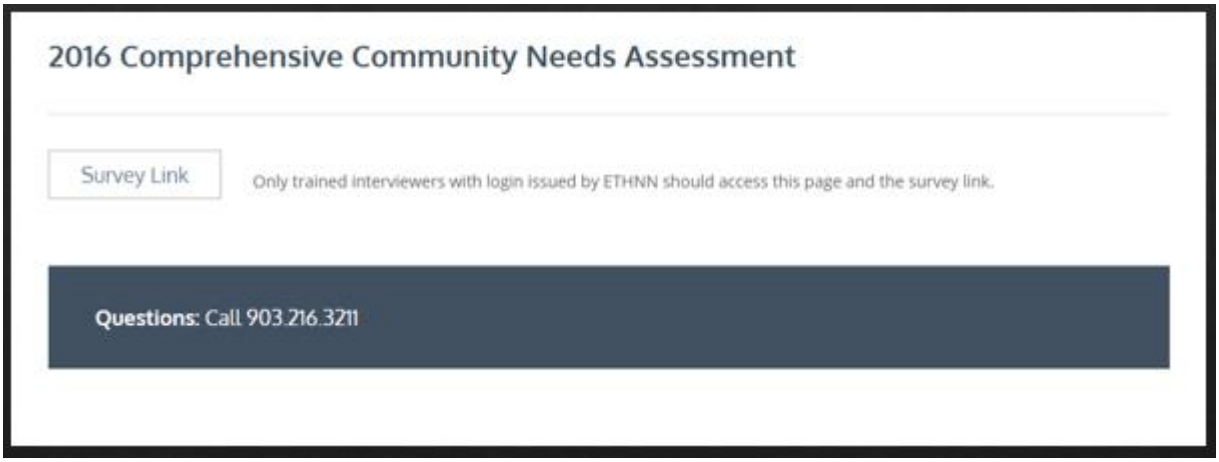
- Enter your e-mail and password then click “Log in”



- Click on “Survey Link Login”



- Click on “Survey Link” to open the survey



- Questions?

Practice!

- Everyone break into groups of 2-3
- Take turns administering the survey to each other
- If you need help please raise your hand or get our attention
- We will walk around the room and provide feedback as necessary