Nutrition Incentive Hub

IRB Guidance for Data Collection and Evaluation

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The Nutrition Incentive Hub (NTAE) is supported by Gus Schumacher Nutrition Incentive Grant Program grant no. 2019-70030-30415/project accession no. 1020863 from the USDA National Institute of Food and Agriculture.

About the Nutrition Incentive Hub

National coalition of partners that provides training, technical assistance, and evaluation for SNAP incentive and produce prescription programs

Our objective: Strengthen access to fruits and vegetables

- Supporting Gus Schumacher Nutrition Incentive Program (GusNIP) grantees
  - Funded through 2018 Farm Bill
  - Formerly known as the Food Insecurity Nutrition Incentive Program (FINI)

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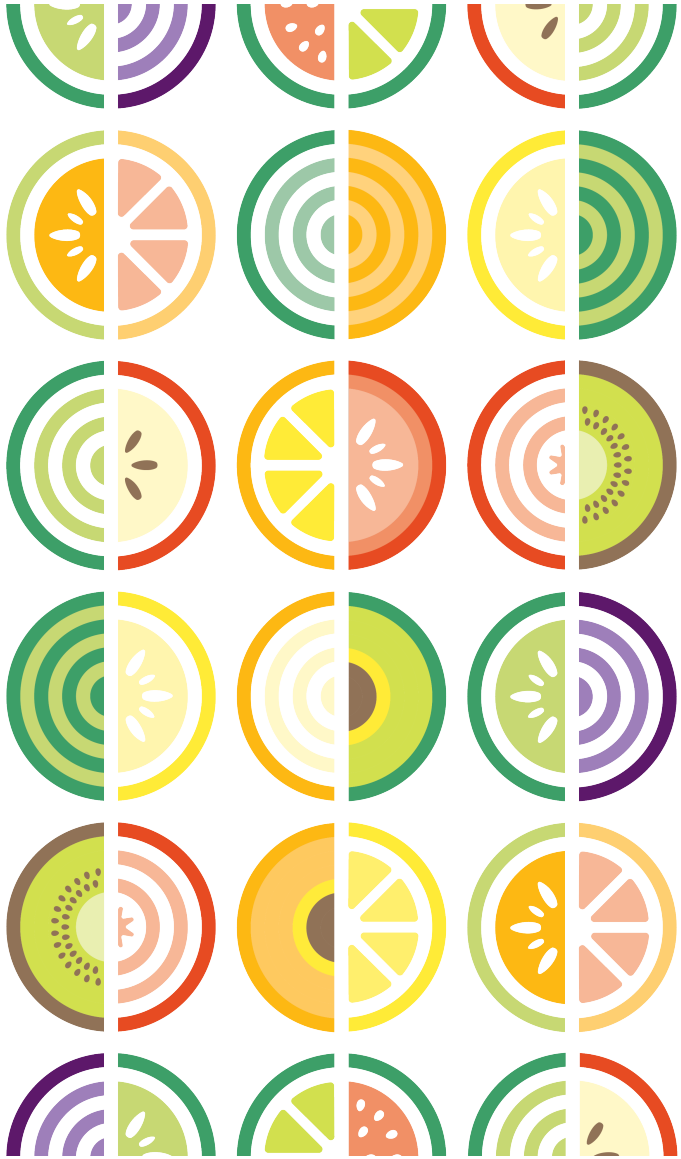
Understanding our objective requires EVALUATION

Evaluation that Involves Human Subjects

- Requires review from an Institutional Review Board, also called IRB
- To protect the rights, privacy, and welfare of study participants



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Webinar Goals

PPR and SI grantees will provide an overview of:

1. IRB requirements and structure
2. Guidance for grantees in finding and working with local IRBs
3. Steps for completing an IRB application
4. Human subjects training

Nutrition Incentive Hub IRB Resources

nutritionincentivehub.org

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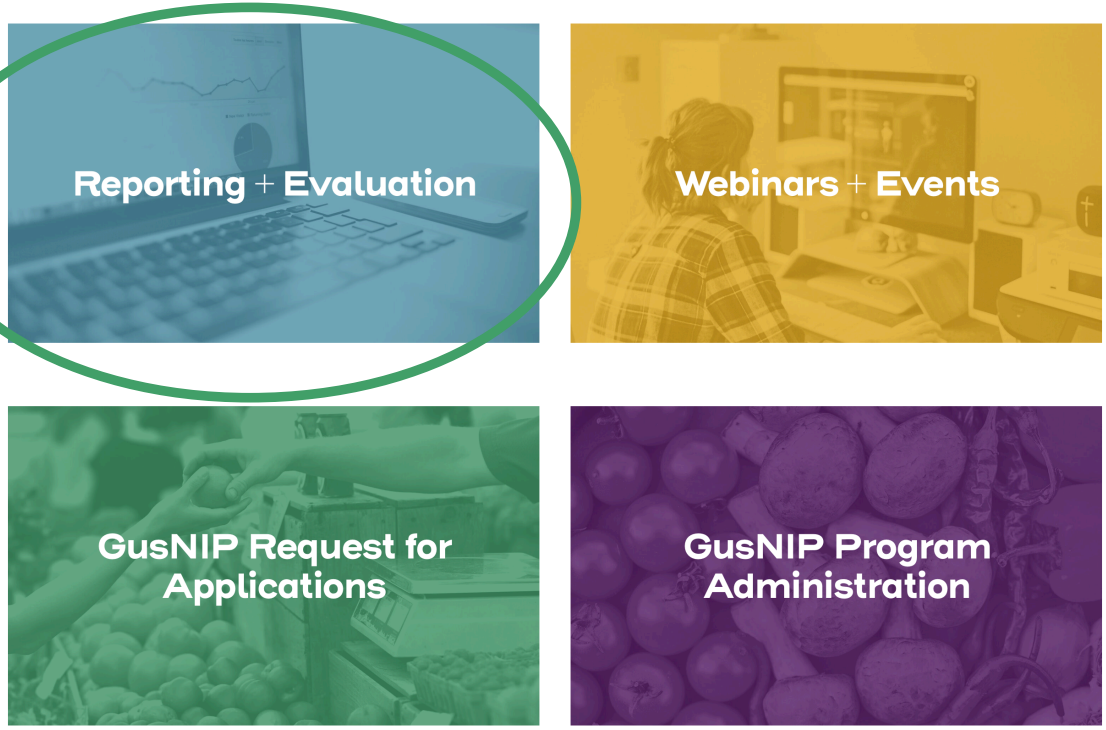

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Nutrition Incentive Hub IRB Resources

Contents

Information on how to navigate the Institutional Review Board (IRB) process for your project, including how to communicate with your local IRB, how to go through human subjects research training, and for example IRB applications.

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Nutrition Incentive Hub IRB Resources

Institutional Review Board (IRB)

These documents are guides and resources about the process of working with Institutional Review Boards, or IRBs. IRBs are administrative organizations established to protect the rights, privacy, and welfare of human subjects that are recruited to participate in research activities. GusNIP grantees that are conducting research with the Nutrition Incentive Hub (the Hub) must engage in an IRB review to ensure that research is ethical, unbiased, and complies with laws and regulations designed to protect program participants. Whether you are a current or prospective GusNIP grantee, get started by reviewing the "Guide to Institutional Review Boards" for common questions and answers about the IRB process.

DOWNLOAD FULL IRB TOOLKIT

Individual Downloads

Guide to Institutional Review Boards	DOWNLOAD
CITI Training Guide	DOWNLOAD
Sample E-Mail to Local IRB (PPR)	DOWNLOAD
Sample E-Mail to Local IRB (SNAP)	DOWNLOAD
HIPAA Worksheet	DOWNLOAD

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ANY research, including evaluation, conducted with human subjects requires review from an IRB

Examples of Research with Human Subjects

- Surveys
- Questionnaires
- Interviews and focus groups
- Analysis of existing human data
- Collection of biological specimens
- Epidemiological studies
- Evaluations of social or educational programs
- Experiments
- Medical chart review

What are Institutional Review Boards?

- IRB are administrative organizations that are given authority by the Food and Drug Administration to approve, disapprove, or require modifications to human subjects research
- IRBs ensure that research, including evaluation, is ethical, unbiased, and complies with laws and regulations designed to protect human subjects, including informed consent of participants.

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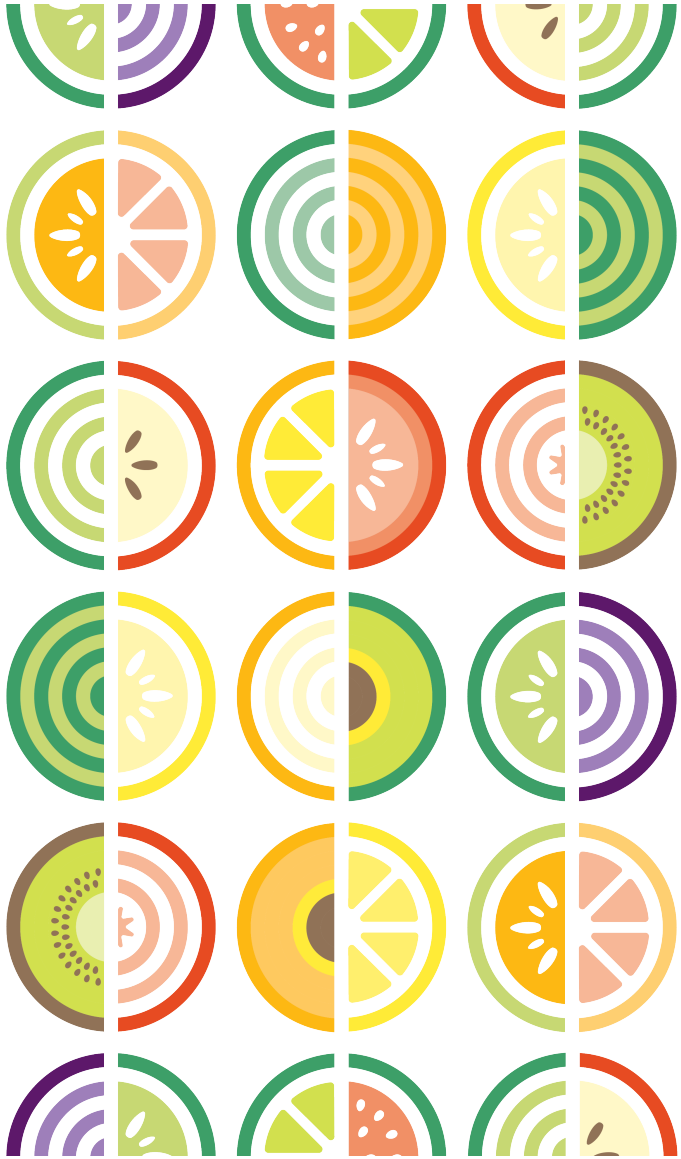
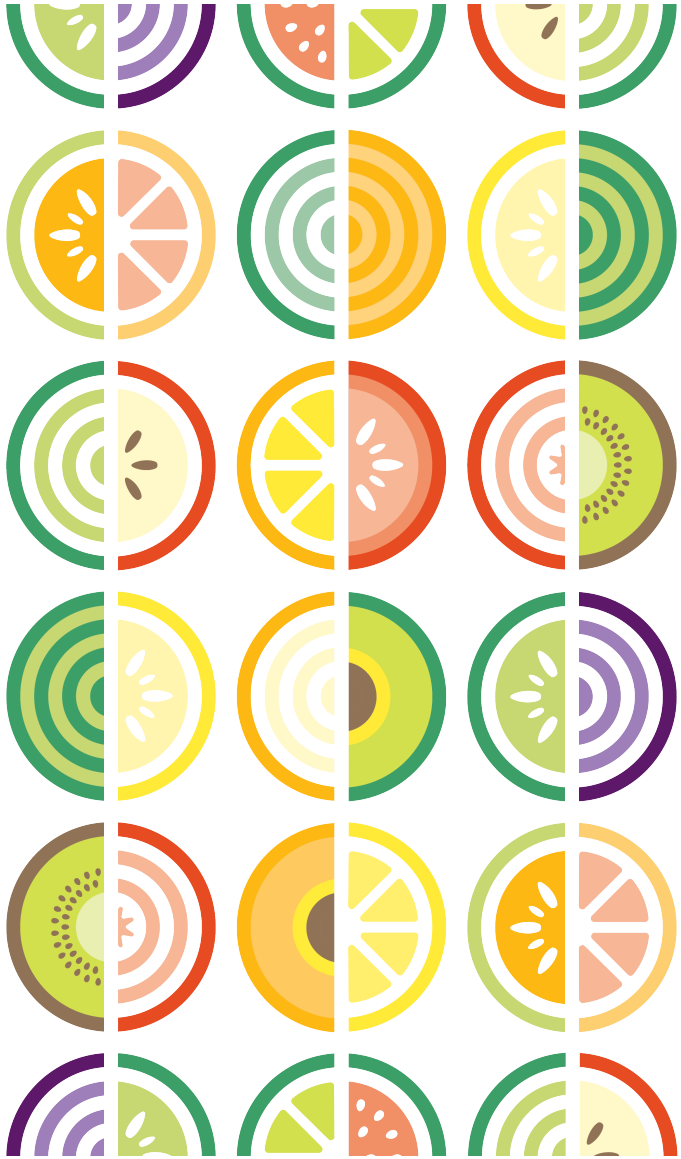


Where can I find an Institutional Review Board?

- Typically housed within universities, medical institutions, and governmental agencies that conduct human subjects research
- Submit applications to an IRB that is in geographic proximity to your research site (same state or region)



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Who can help me to find an Institutional Review Board?

If your project includes an employee of a university or clinic, contact this individual to determine if an IRB office exists locally.

If you do not have an employee of a university or clinic on your team, contact your nearest university to find a local IRB.

If no local IRB is accessible to you, contact the Hub to discuss alternatives and next steps.

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Levels of IRB Review

Based upon the research protocol within the documents submitted, the IRB will determine if the research project is exempt, requires expedited review, or should undergo full review.

Exempt

Expedited

Full

Levels of IRB Review

Exempt

- Studies that qualify as exempt are determined to present no more than minimal risk to the participant and fit into this federally designated review category (e.g. educational research; surveys, interviews, or observations; benign behavioral interventions; programmatic evaluation).

Minimal Risk: Defined by the FDA, minimal risk is the probability of physical or mental harm or discomfort that is not greater than those risks ordinarily encountered in daily life or during routine examinations or tests.

Levels of IRB Review

Expedited

- Studies that qualify as expedited are determined to present no more than minimal risk to the participant and fit into this federally designated review category (e.g. clinical studies; collection of blood samples; audio or video recordings).

Levels of IRB Review

Full

- Studies that qualify as full are determined to present more than minimal risk to the participant and do not qualify for exempt or expedited review.

Levels of IRB Review

Based upon the research protocol within the documents submitted, the IRB will determine if the research project is exempt, requires expedited review, or should undergo full review.

Exempt

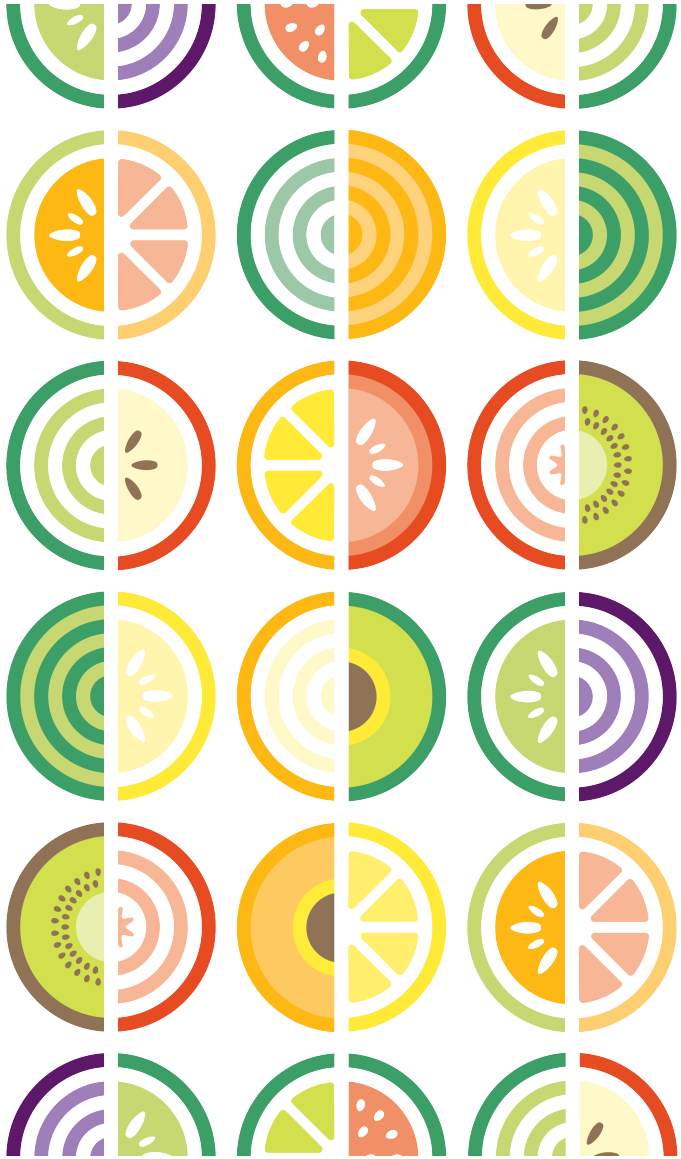
Expedited

Full

Ask the IRB to help determine level of review if you are not sure using the Sample E-mail to Local IRB on the Hub website

Starting an IRB Application

- Once you know the level of review, visit the local IRBs and follow the stated directions to complete the specific exempt, expedited, or full application



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An IRB application must be submitted and approved before collecting any human subjects data

Standard Parts of an IRB Application

- study team
- description of the project
- specify application type (i.e., exempt, expedited, full)
- sponsor or funder
- location(s) of research activity research design
- study population
- recruitment and screening procedures
- benefits and risks to human subjects
- study forms (e.g., survey)
- questions about vulnerable populations
- informed consent process
- confidentiality and privacy

Informed Consent

- Permission granted by the participant in the knowledge of the possible risks and benefits
- If an anonymous survey, can usually include consenting information at the top or on the first page of the survey
- If not anonymous survey or other type of data collected, a consent form needs to be completed. Template can be found at your local IRB.

Informed Consent – Anonymous Survey

Thank you for considering your participation in this survey. If you are an adult (at least 18 years of age), currently participating in nutrition incentives, you are eligible for this survey. If you complete this survey, it will be entered into a research study evaluating the program. Participation in this study is voluntary and anonymous. Your name and contact information will not be linked with your responses. You can choose to not answer any questions you do not want to answer and/or you can stop at any time. We will protect the information that you provide by not attaching your name to your responses and safely storing this information. The provided information will be combined with responses from other individuals.

You may contact our research team at [e-mail] if you have any questions about this research. You may also contact a representative a [name of IRB] with any questions about your involvement in this study at [e-mail].

- I agree to my survey responses being part of a research study.
  - Yes
  - No

Informed Consent Form – Any Other Data

Informed Consent Agreement for Participation in a Research Study

Investigator:

Contact Information:

Title of Research Study:

Sponsor:

Introduction (recommended)
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: (In a few sentences, describe the overall purpose of the study. For this section, and all sections of the consent form, use simple, plain English. This section is required.)

Procedures to be followed: (Here describe the research procedures to be followed, including duration of the subject's participation. Experimental procedures must be identified. This section is required.)

Risks to study participants: (Describe any reasonably foreseeable risks or discomfort to the subject. This section is required.)

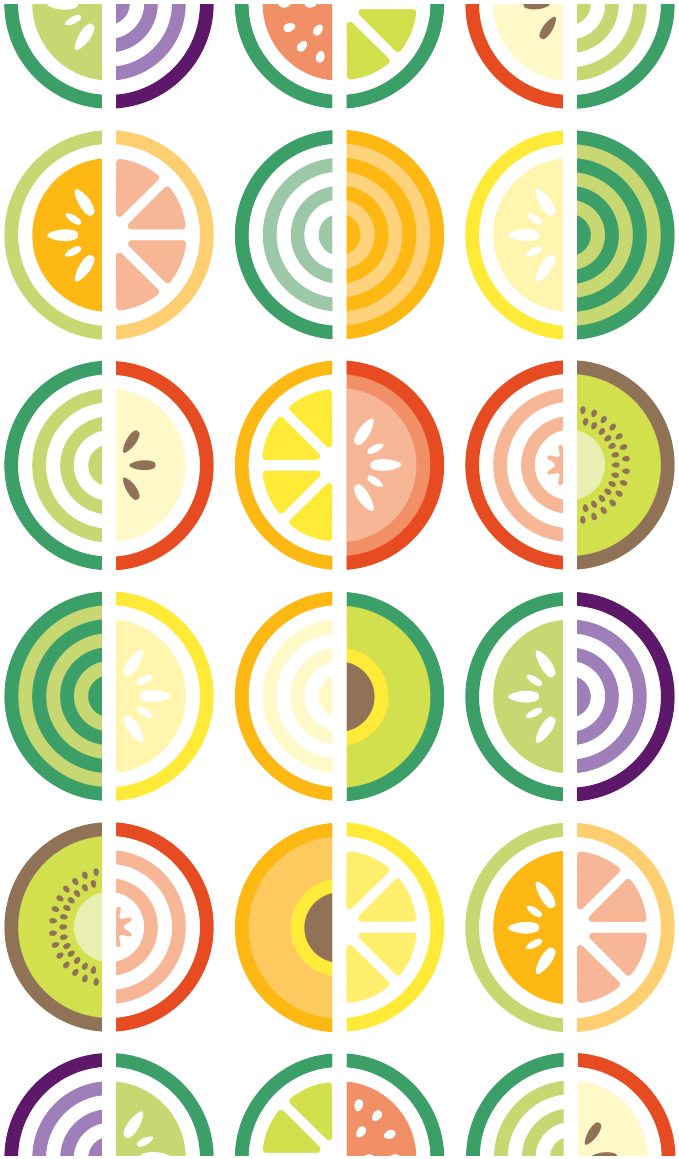
Benefits to research participants and others: (Here describe benefits, if any, to the subject or to others which may reasonably be expected from the research. Do not list compensation, if any, as a benefit. If there are no benefits to the subject, indicate that there are none. This section is required.)

Alternative procedures or treatments available to potential research participants: (Here list any appropriate alternative procedures or courses of treatment that might be advantageous to the subject. If none are known, omit this section.)

Record keeping and confidentiality: (Describe record keeping procedures, including who will have access to records, whether and how confidentiality will be maintained, and what information is expected to be reported. Include the following statement, "Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain

IRB for Projects with Multiple Institutions or Firms

- You can rely on one local IRB to approve your research project.
- You must explain the details about how data will be collected at each site.
- All members of your team that will collect or see data collected need to complete training for research with human subjects and be added to the IRB application.



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IRB for Projects with Multiple Institutions or Firms

- In some instances it is simpler for each site to apply to a separate IRB to approve individual research projects.
- It is acceptable for each site to apply to a separate IRB to approve individual research projects.
- Any person who will collect or view human subject's data is required to be included on the IRB application.

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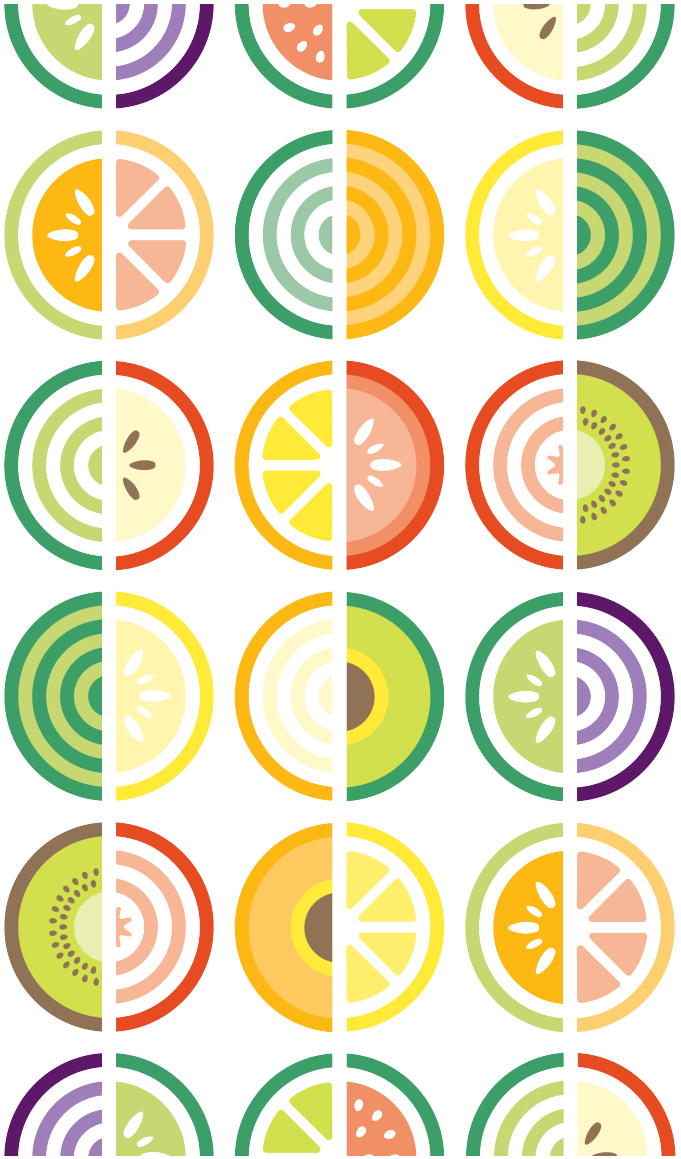
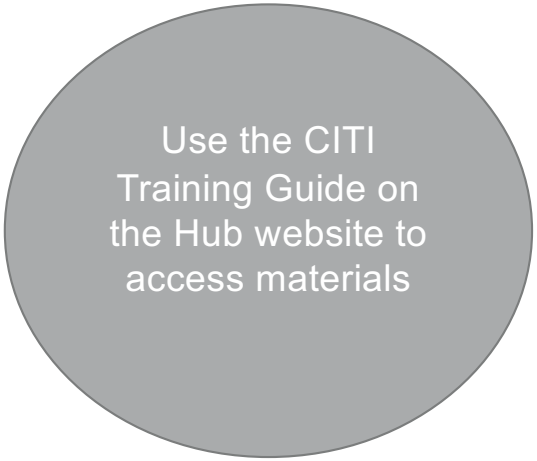


Individuals handling data need human subjects training

Human Subjects Training



- Requirement from IRB that all team members that collect or see participant data complete human subjects research training
- CITI program is an online training designed to provide uniform education to research team members about human subjects research

CITI Training

- Register with the affiliation of the local IRB you plan to use (or you can pay)
- Takes individuals 2 to 6 hours to complete, depending upon the speed at which you learn
- Learning modules followed by tests
- At the end, each team member will receive a certificate of completion
- The certificate of completion should be sent to the person who will submit your team's IRB application
- Each certificate will be submitted with the IRB application
- CITI certification must be renewed every 3 years.

Directions

The directions may slightly differ depending upon if CITI changes their platform, but generally follow these steps.

1. Go to **https://www.citiprogram.org/**
2. Choose Register in the top tool bar
3. Under 'Select Your Organization Affiliation'
   - Type in the local university, health care system, or state government that you are affiliated with. If the organization appears, click on it. This ensures that the modules are FREE for you to take. Agree to the terms of service and, if applicable, that you are an affiliate by using the check boxes.
   - If the organization does not appear and you are not affiliated with a local university, health care system, or state government, choose 'Independent Learner Registration'. Fees apply.
4. Continue through the steps to create your CITI name and password.
5. Choose 'NO' for Continuing Education Credits, unless you choose to do so (this costs money and takes time).
6. Complete all of the information denoted by a red asterisk. You can include your own e-mail address and contact information. Your role in the research is likely 'Co-Investigator.'
7. For the dropdown menu that asks, 'Which course do you plan to take?' Choose 'Basic Human Subjects - Social and Behavioral Focus.'
8. Select 'I do not want to take a laboratory animal welfare course at this time.'
9. Select 'Social and Behavioral Research' (SBE) for the course that you need to begin.
10. On Step 7 of registration, for questions 3 - 9, select the 'No,' 'Not at this time,' 'I am not,' or 'I do not want' options, as appropriate.
11. 'Finalize Registration' and 'View Courses.'

The Hub is here to help!

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Questions?