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Instructions:

This protocol template is to be used as a guide. You may use a different format, order, or add additional information as needed. Information provided in this template is intended to be a prompt, if something does not apply to your study, delete it.

Use good version control of your document as you make edits. Keep an electronic copy of your final draft. You will need to modify this copy when making future changes.

Delete all instructional text from the final copy, indicated by italics.

Protocol Title: *<Include full protocol title as listed in the IRB application forms>*

Principle Investigator: *<Include the principle investigator's name as listed in the IRB application forms>*

Student Investigator: *<If this is a student project, include the student's name as listed in the IRB application forms.>*

IRB Review History: *<If you have submitted this protocol for review to another IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information. This section would be applicable if you are performing research at another institution and that institution's IRB has approved it. If this applies, explain the situation. If not, delete this section.>*

Study Objectives: *<In this section, provide your study hypothesis/objectives. What is the question to be answered? Describe the purpose, specific aims or objectives as concise as possible. If multiple aims, number them and include them all.>*

Background: *<Describe relevant prior experience. What does current literature say about the topic? Are there any gaps in current knowledge and what is the importance of this study to fill in those gaps? Describe any relevant preliminary data.>*

Study Recruitment: *<Describe the study's recruitment plan.*

- Describe sites or locations where the research team will conduct the research.*
- Identify where or how your team will identify and recruit potential subjects. Example: Subjects will be identified by a record search for X (specify search criteria). Subjects will be approached to participate at next <state encounter, i.e. next focus group session>.*
- Describe when the subjects will be approached and identify any barriers that could affect the consenting process. Issues are present when subjects are approached during emergencies, such as prior to entering surgery, or when distracted, such as during a community event where other distractions are possible. If the consenting process may be compromised by the setting, describe how this will be minimized. For example, waiting for a time period after the emergency is over or letting the subjects take the consent home to think it over when no longer distracted or approaching during lulls that naturally occur.>*

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Inclusion/Exclusion Criteria:

- Describe how you will screen individuals for eligibility.
- Describe criteria that will define who are included or excluded.
- If you will exclude certain populations include scientific justification for that exclusion. For example, if excluding men or women a scientific justification may be that the disease being studied is not found in men/women. If excluding non-English speaking persons, a scientific justification may be that the study survey has not been validated in other languages.
- If you are including vulnerable populations, state what additional safeguards will be in place to minimize the potential for coercion. Example: If recruiting employees, what measures are in place that they do not feel forced to participate? How are you ensuring their supervisors do not know whether they chose to participate or any outcome of their participation?

Subject Compensation: <Describe if the study will compensate subjects. If no compensation, state None or delete section.>

- Describe amount of payment. If not paying in cash, describe the fair market value of item given to subjects.
- Describe timing of payments, i.e. throughout the study or upon completion of study milestones.

Consent Process:

Indicate whether you will you be obtaining consent, and if so describe:

- Where will the consent process take place
- Any waiting period available between informing the prospective subject and obtaining the consent.
- Any process to ensure ongoing consent.
- The role of the individuals listed in the application as being involved in the consent process.
- The time that will be devoted to the consent discussion.
- Steps that will be taken to minimize the possibility of coercion or undue influence.
- Steps that will be taken to ensure the subjects' understanding.

Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- Waiver of the consent process only applies to non-FDA regulated studies.
- If asking for a waiver, be sure to describe:
 - How the research involves no more than minimal risk to subjects.
 - How the waiver or alteration of the consent process will not adversely affect rights and welfare of subjects;
 - That the research could not practicably be carried out without the waiver being granted.

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- *Mere inconvenience in contacting individuals to consent is not a justification that has been accepted by OHRP.*
- *OHRP guidance finds that just because it is a retrospective chart review does not necessarily mean that consent is impracticable. Be sure to include justification why it is really hard to contact subjects and ask for consent.*
- *If subjects will be approached and given a HIPAA Authorization or survey, then this element is likely not to be met.*

If enrolling certain populations, additional informed consent considerations needs to be addressed.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

Subjects who are not yet adults (infants, children, teenagers)

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
- *Describe whether parental permission will be obtained from:*
 - *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
 - *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
- *When assent of children is obtained describe whether and how it will be documented.*

Cognitively Impaired Adults

- *Describe the process to determine whether an individual is capable of consent.*
- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
- *Describe the process for assent of the subjects. Indicate whether:*

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- Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
- If assent will not be obtained from some or all subjects, an explanation of why not.
- Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Consent Documentation:

Describe whether and how consent of the subject will be documented in writing. If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

- *If asking for a waiver of documentation, describe:*
 - *How the research involves no more than minimal risk to subjects and the procedures involved do not normally require consent outside the research context.*
 - *Note: if accessing medical records, then this does not apply because under HIPAA a person's authorization (or consent) is required by law to obtain a person's medical record.*
 - *Or describe how the only record linking the subject and the research is the consent document and the principle risk of harm is from a breach of confidentiality. This option is useful for an anonymous survey situation. If this applies, be sure to describe how the identifiers collected to identify the subject will be destroyed or not linked to the survey results.*

Number of Subjects:

- **Local number:** *Indicate the total number of subjects to be accrued locally. This will be the total number you are approved by the IRB to enroll. If you need more subjects, an amendment will be required. So be sure not to underestimate. If applicable, distinguish between the number of subjects expected to be enrolled and screened and the number needed to complete research procedures (i.e. the number of subjects minus screen failures).*
- **Study wide number:** *If multisite, include total number of subjects to be enrolled across all sites.*

Study Statistical Considerations:

- *Describe and explain the study's primary and secondary endpoints.*
- *Describe the data analysis plan, including any statistical procedures.*
- *Provide a power analysis.*
- *Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.*

Procedures Involved:

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- Describe and explain study design and procedures.
- This section must include all research procedures to be performed. Failure to include a procedure that is performed will be a protocol deviation. Be sure to accurately define those procedures that are being done for standard of care or per normal operating processes (i.e. Ask yourself, but for this study would this be done on subjects. If the answer is yes, then you can describe but clearly state that this is a standard procedure/process done that subjects will experience no matter their decision to participate in research).
- Describe the source records that will be used to collect data about subjects. Provide a copy of all surveys, scripts, data collection forms.
- Describe the risks of these procedures and steps taken to minimize the risk. Note even minimal risk studies have risks – even if that risk is simply a risk to one’s privacy/confidentiality. Then describe how it is minimized, i.e. data is recorded in de-identified fashion, subjects are asked to participate or fill out the survey in a private area, survey or focus group questions do not ask sensitive questions that may place subjects at risk of embarrassment, stigmatization, legal or social harm if answers were disclosed.

Study time-lines:

- Describe the duration of the individual’s participation in the study. This should match the informed consent form.
- Duration of anticipated enrollment.
- Estimated date for investigators to complete this study.

Data management:

- Describe procedures used for quality control of collected data.
- Describe how long you will retain data after study completion

Data and Specimen Banking*

- If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.
- List the data to be stored or associated with each specimen.
- Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

References

- Provide the citations for all publications and presentations referenced in the text of the protocol.



CHECKLIST: Human Subjects Research Determination			
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The purpose of this checklist is to provide support for individuals in determining whether an activity is Human Subjects Research. This worksheet is to be used. It does not need to be completed or retained.

1 Research as Defined by DHHS Regulations. (Check if “Yes”.) (If not all checked, then Not Involving Research)

Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)

Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)
Example: Case reports of reviewing less than 3 patients.

Is the systematic investigation designed to develop or contribute to generalizable knowledge?
Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.
Generalizable: Universally or widely applicable; contributes knowledge applicable beyond local institution

The activity does not fall within the activities excluded as research.

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

The activity is not a quality improvement project. To be a quality improvement project, activities must be limited to:

- Assessing and ensuring compliance with a standard or regulation;
- Monitoring a process that is place to see if it is reaching a target or measurable goal or monitoring performed to meet requirements by a regulatory or accrediting body;
- Implementing a practice to improve the quality of patient care;
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical or administrative purposes; or
- Measuring and reporting provider performance data for clinical, practical, or administrative uses.

If all items are checked, then the project is Research under DHHS regulations. Continue to determine if human subjects are involved.

2 Human Subject Under DHHS Regulations (Check if “Yes”.)

Is the investigator conducting the Research gathering data about *living* individuals?
If the project involves any living individual or obtains information about the deceased living relatives (e.g. genetic information), this does not apply.

One of the two options below must be checked for the project to involve human subjects. (Check if “Yes”.)

Will the investigator gather that data through intervention or interaction by performing:
 Physical procedures by which information or biospecimens are gathered (“intervention”)
OR

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	<input type="checkbox"/> Manipulations of those individuals or their environment (“intervention”) OR <input type="checkbox"/> Communication or interpersonal contact with the individuals. (“interaction”)?
<input type="checkbox"/>	Will the investigator obtain, use, study, analyze or generate identifiable private information or identifiable biospecimens? <input type="checkbox"/> Private information <input type="checkbox"/> Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and <input type="checkbox"/> Individuals provided data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record. <input type="checkbox"/> Identifiable: Private information/biospecimens in which the identity of the subject is or may be readily ascertained by the investigator.

If the first question is checked and either of the later 2 questions is checked, the project is Human Subjects Research under DHHS regulations.

3 Human Research Under FDA Regulations (Check if “Yes”)

<input type="checkbox"/>	The activity involves any of the following: (If “Yes” to any of the options below, the activity is Human Research under FDA regulations.) <input type="checkbox"/> Activity is conducted in the United States and will involve the use of a drug ⁱ in one or more persons that is NOT the use of an approved drug in the course of medical practice. <input type="checkbox"/> Activity is conducted in the United States and will evaluate the safety or effectiveness of a device ⁱⁱ in one or more persons. <input type="checkbox"/> Data regarding subjects or control subjects or use of the device on human specimens (identified or unidentified) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit.
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If the activity is Human Research under DHHS regulations or under FDA regulations, the project requires IRB Review.

ⁱ The term “drug” means:

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

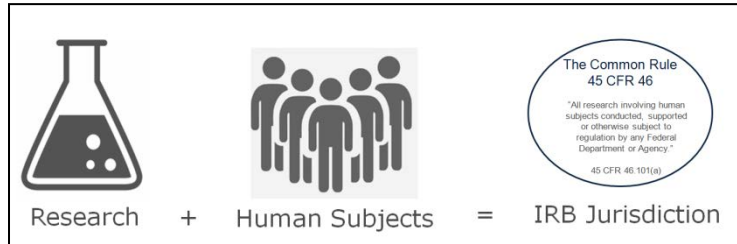
ⁱⁱ The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Guidance: Do I need to Submit for IRB Review?

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Generally, IRB review is required for projects that are considered research involving human subjects.



Not Involving Research

The first part of this equation is to define research.

If the project is a "clinical trial"¹ or "clinical investigation"², then the project is research requiring IRB review.

Otherwise, research is defined as a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**. 45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(1)(1/19/2017).

Click [here](#) to learn more about projects not considered involving research.

Not Involving Human Subjects

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(e)(1) (1/19/2017)

Click [here](#) to learn more about projects not considered involving human subjects.

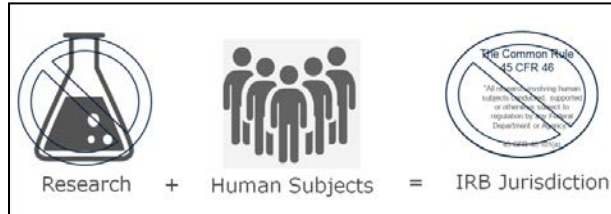
¹ Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

² FDA has defined "clinical investigation" to be synonymous with "research". "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. 21 CFR 56.102; 21 CFR 50.2

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Not Involving Research FAQ



What are some examples of projects not considered research?

- **Case Reports**

Case reports are not considered research. In medicine, a case report is a detailed report of the symptoms, signs, diagnosis, treatment and follow-up of an individual patient. Case reports are professional narratives providing feedback on clinical practice guidelines. They can be shared for medical, scientific, or educational purposes.

- **Quality Improvement Projects**

Quality improvement projects are focused on monitoring a process/policy in place to determine if it is reaching a target or measurable goal. QI projects aimed solely at promoting adherence to or implementing a best practice may not be considered research.

To be a quality improvement project, the project must be limited to:

- Assessing and ensuring compliance with a standard or regulation;
- Monitoring a process that is in place to see if it is reaching a target or measurable goal or monitoring performed to meet requirements by a regulatory or accrediting body;
- Implementing a practice to improve the quality of the process;
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical or administrative purposes; or
- Measuring and reporting provider performance data for clinical, practical, or administrative uses.

- **Scholarly and journalistic activities**

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individual about whom the information is collected, is not considered research. 45 CFR 46.102(1)(1) (1/19/2017).

- **Public health surveillance activities**

Public health surveillance activities, including collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. 45 CFR 46.102(1)(2)(1/19/2017).

How do I get a letter from the IRB stating I am not doing research?

Click [here](#) for information on how to request a Not Human Subjects Determination.

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Not Involving Human Subjects FAQ









What are some examples of projects not involving human subjects?

- Projects involving only deceased persons.**
All subjects included in the project must be deceased. Identifiable information about the deceased’s living relatives cannot be included.
- Projects involving access to only de-identified data or biospecimens.**

What’s the difference between a retrospective chart review study that is considered not human subjects versus a chart review that is exempt?

Secondary research can fall in various levels of IRB review, depending on what is being done with identifying information. To be not human subjects, the study team cannot view (as shown by the eye ball) or record identifying information. Exempt research allows the study team to view identifiers, but not record identifiers (shown by paper/pen). If expedited, the study team can both view and record identifying information.

Not Human Subjects	Exempt Category 4	Expedited
		
		

How do I get a letter from the IRB stating I am not doing research?

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Requesting a Not Human Subject (NHS) Determination

When should I submit a NHS request?

Failure to secure IRB review prior to performing research involving human subjects is a serious non-compliance issue. Therefore, it is advisable to seek consultation prior to starting a project to ensure it does not require IRB review.

The NHS Determination process is the mechanism to get a review of the project to determine whether it requires IRB review or not.

What will be the outcome if I'm successful in my request?

If successful, then a letter will be received stating the project is either not research or does not involve human subjects. The project may then proceed without prior IRB review. This letter can be provided to journals if they ask for IRB review during the publication process.

How do I submit a Not Human Subject (NHS) Determination?

Send the proposal to irb@tamucc.edu. The proposal should include:

1. A detailed project plan.
2. If performing the project at location off-campus, a letter of support for the project from the site where the project will be performed.

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The purpose of this guidance is to provide a quick reference for the differences between the pre-2108 and 2018 requirements for exempt determinations.

1 GENERAL EXCLUSIONS FROM EXEMPTIONS (All must be “No”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is FDA-regulated unless applying for Category 6.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research involves prisoners, except for research involving broader subject population incidentally including prisoners.

2 Commonly accepted educational settings

45 CFR 46.101(b)(1)(pre-2018)	45 CFR 46.104(d)(1)(1/19/2017)
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

3 Use of educational test, survey procedures, interview procedures, or observations of public behavior

45 CFR 46.101(b)(2)(pre-2018)	45 CFR 46.104(d)(2)(1/19/2017)
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.	Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to subjects; (ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement , or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

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Limitation on children: research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.	Limitation on children: Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research with children.
4 Use of educational test, survey procedures, interview procedures or observations of public behavior of elected or appointed public officials or candidates	
45 CFR 46.101(b)(3)(pre-2018)	45 CFR 46.104(d)(1/19/2017)
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior is not exempt under category above, if: The human participants are elected or appointed public officials or candidates for public office; or Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.	No equivalent
5 Research Involving Benign Behavioral Interventions	
45 CFR 46.101(b)(3)(pre-2018)	45 CFR 46.104(d)(3)(1/19/2017)
No equivalent	Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of

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	the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.
6 Secondary research	
45 CFR 46.101(b)(4)(pre-2018)	45 CFR 46.104(d)(4)(1/19/2017)
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.	<p>Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:</p> <p>(i) The identifiable private information or identifiable biospecimens are publicly available;</p> <p>(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;</p> <p>(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or</p> <p>(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.</p>

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7 Research or demonstrative projects conducted by/supported by a Federal department or agency head	
45 CFR 46.101(b)(6)(pre-2018)	45 CFR 46.104(d)(5)(1/19/2017)
<p>Research and demonstration projects which are conducted by or participant to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (1) The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit or services programs; (2) Procedures for obtaining benefits or services under those programs; (3) Possible changes in or alternatives to those programs or procedures; or (4) Possible changes in methods or levels of payment for benefits or services under those programs.</p>	<p>Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.</p> <p>(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.</p>
8 Taste and food quality evaluation and consumer acceptance studies	
45 CFR 46.101(b)(3)(pre-2018)	45 CFR 46.104(d)(3)(1/19/2017)
<p>Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed; or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be</p>	<p>Taste and food quality evaluation and consumer acceptance studies:</p> <p>(i) If wholesome foods without additives are consumed, or</p> <p>(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or</p>

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safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
9 Storage and Maintenance for Secondary Research	
45 CFR 46.101(b)(pre-2018)	45 CFR 46.104(d)(7)(1/19/2017)
No equivalent	Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review.
10 Secondary Research for which Broad Consent is Required	
45 CFR 46.101(b)(pre-2018)	45 CFR 46.104(d)(8)(1/19/2017)
No equivalent	Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Sec. __.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Sec. __.117; (iii) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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Research Training Requirements

Frequently Asked Questions

What training is required to conduct human subjects research?

Researchers conducting human subject research must take **one of the following** courses within the last three (3) years:

- Social & Behavioral Responsible Conduct of Research - Basic Course
- Social & Behavioral Responsible Conduct of Research - Refresher

If funded by the National Institutes of Health (NIH) or National Science Foundation (NSF) “Responsible Conduct of Research” is also required by the funding agency.

When does training expire?

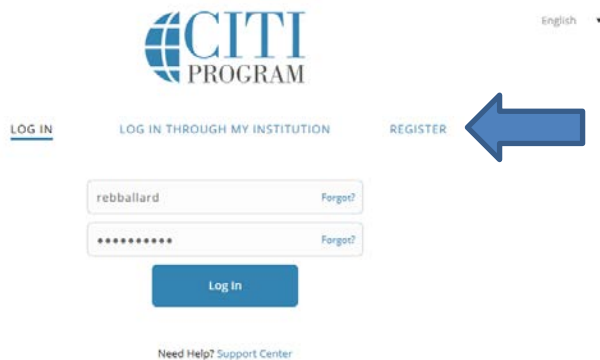
Courses expire every 3 years.

Where do I go to take the training?

Training is managed through [CITI](#).

Login at: <https://www.citiprogram.org>

If new to CITI, click Register to create an account.



Select the Course you want to take.

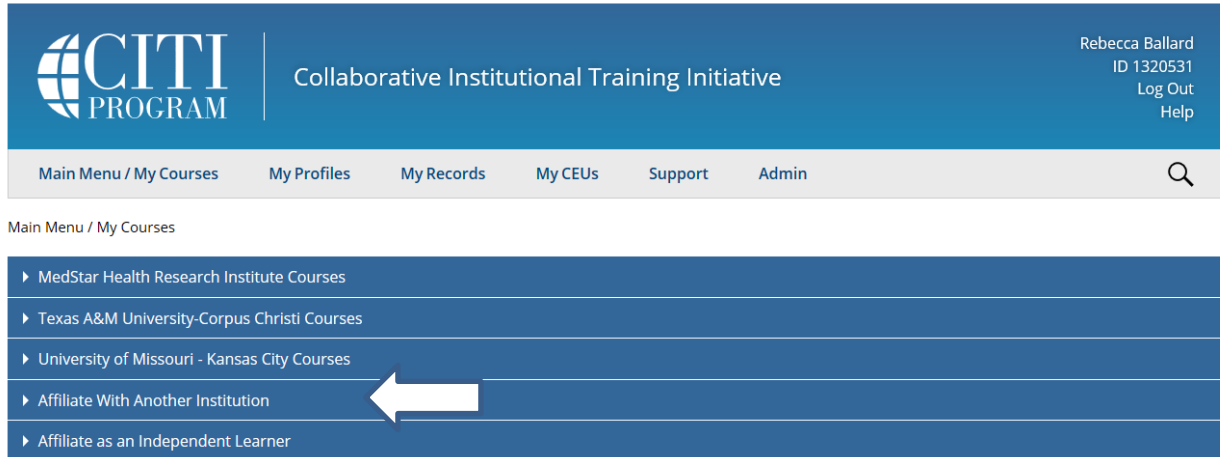
If I've taken the course at another institution, do I have to retake the course?

No. Non-TAMUCC collaborators can include a print-out of their course completion certificate with the IRB application.

FAQ: Research Training Requirements

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Another option is to affiliate within CITI to Texas A&M University-Corpus Christi. This allows us as admins to verify training directly within CITI.



The screenshot shows the CITI PROGRAM interface. The header includes the CITI PROGRAM logo, the text 'Collaborative Institutional Training Initiative', and user information for Rebecca Ballard (ID 1320531) with links for Log Out and Help. A navigation bar contains links for Main Menu / My Courses, My Profiles, My Records, My CEUs, Support, and Admin, along with a search icon. Below the navigation bar, the 'Main Menu / My Courses' section is expanded to show a list of options: MedStar Health Research Institute Courses, Texas A&M University-Corpus Christi Courses, University of Missouri - Kansas City Courses, **Affiliate With Another Institution** (highlighted with a white arrow), and Affiliate as an Independent Learner.

Click on Affiliate with Another Institution, type in “Texas A&M University-Corpus Christi”, and follow prompts.



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Research Personnel Requirements

Frequently Asked Questions

When do I list study staff on the IRB submission?

Any individual interacting, intervening or accessing identifiable information for research purposes are engaged in human subjects research and must be listed in the IRB submission.

What if I'm just having undergrad students help me on a project for a short period of time?

Undergrad, graduate student or volunteer. One month, one week or one day. These factors have no bearing on the regulatory requirement that all persons who are engaged in human subjects be listed and reviewed by the IRB to ensure they meet qualifications for conducting human subjects research.

What if I haven't identified the staff that will help at the time of initial submission?

That's ok. You can submit with just those individuals you know today and get approved to start your research. Once the additional persons are identified, then submit an amendment to add research personnel.

NOTE: Added personnel cannot begin working on the research project until they are approved by the IRB.

What if I know who will be working on the project, but they haven't completed CITI training and I really need to get started on my research?

That's ok. You can submit with just those individuals who are compliant with investigator requirements, like CITI training, and get approved to start your research. Once the additional person has completed the requirements, then submit an amendment to add research personnel.

NOTE: Added personnel cannot begin working on the research project until they are approved by the IRB.

What does the IRB check for when reviewing research personnel?

Individuals are checked for whether they are qualified to conduct the research, have completed CITI training, and has no conflict of interest related to the research project.

How long does it take to get a personnel change approved?

Individuals who are compliant with the requirements will experience a short turn-around-time, usually 1 – 3 business days. Those applications with missing CV, training or COI disclosures will experience delays until those items are completed.

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Recruitment Materials

Frequently Asked Questions

What approvals do I need for recruitment flyers, posters, and brochures?

Flyers, posters and brochures are often used to solicit potential research subjects. These types of advertisements are usually placed in strategic locations to be viewable by targeted populations, such as bulletin boards, clinic offices, public transportation or public areas.

Before research recruitment materials can be posted or distributed, it must be IRB-approved. It also may be necessary for the investigator to obtain approval from the sites where the flyer, poster and/or brochure will be placed.

What if my advertisement is not study-specific but more general in nature?

Study-specific recruitment materials should be submitted to the IRB under the related study either during initial submission or via an amendment. Recruitment material that is more general in nature does not have to be submitted under a study. General research advertisements must still adhere to recruitment do's and don'ts.

See 800.01 Template, Advertisement – General.

What information do I need to include in research recruitment materials?

The consenting process really begins at the recruitment stage. Since these types of advertisements are visible tools of recruitment, they must present sufficient information that is accurate and balanced so that potential subjects can make an informed decision about potentially participating.

Generally, recruitment materials should include the following:

- The name and address of the clinical investigator and/or research facility.
- The condition being studied and/or the purpose of the research.
- The time or other commitment(s) required of the subjects.
- The location of the research and the person or office to contact for further information.
- A clear statement that this is research and not treatment.
- A clear statement that participation is voluntary.

Click here to download a worksheet that will help guide you in developing a recruitment plan. [Worksheet, Investigator Recruitment Plan.](#)

Click here for recruitment templates:

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800.01 Template, Advertisement
800.01 Template, Dear Subject Letter

What information cannot be included in research recruitment materials?

Generally, any advertisement should be limited to the information that a prospective subject need to be able to determine their eligibility and interest in learning more.

Advertisements should NOT:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol
- Overemphasize the benefits and minimize the risks
- Promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research
- Include exculpatory language
- Emphasize the payment or the amount to be paid, by such means as highlighted, larger or bold type.

For FDA-regulated research, the advertisement CAN NOT:

- make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation
- make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device
- use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
- Include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

See 800.01 Checklist, Recruitment Materials

Can I include the compensation amount in the advertisement?

Including the amount of compensation in the recruitment material is generally discouraged. This will be considered by the IRB on a case-by-case basis. Although compensation or reimbursement may factor into one’s decision to participate in research, it must be carefully worded to not to coerce a subject to participate.

Learn more about compensation:

- 900.01 Compensation to Study Subjects
- 900.01 Guidance, Compensation
- 900.03 Lotteries, Raffles, and Games of Chance for Participation



FAQ: Recruitment Materials			
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When should I get IRB approval for audio/video tape recruitment materials?

While the IRB will have to review a final version of the materials created, the IRB will review a draft version. Getting IRB edits on the draft version can reduce cost by avoiding reproduction for productions that do not meet approval criteria.

Department of <department name>
Texas A&M Corpus Christi

PARTICIPANTS NEEDED FOR RESEARCH IN <topic/area>

We are always looking for volunteers to take part in our research.

For more information about our ongoing research efforts,
please contact:

<insert name of contact person>

<insert name of department>

at

<phone number>

Email: <email address>

You are under no obligation to participate in any research.

Upon contacting us we will describe what research is currently ongoing and provide you with the contact information of the study team to learn more about the particular study.

Once you have all the details about the study, you may choose to or not to participate.
Participating in research is always voluntary.

<Date>

Dear <Name or subject class, i.e. Students, Faculty>,

<Institution name> is conducting a study <describe the area, i.e. in your community, in your neighbourhood, in the area of <study topic>. This study focuses on <generally state study objective> through the Department of <Department name> under the supervision of <name of PI>. As you may know, <provide a statement as to why they may care about this study>. Because you are <state why they were selected for participating, i.e. a participant in X or a student/faculty at <institution name>>, your opinions are important to this study. Thus, I would appreciate the opportunity to speak with you about this.

Participation in this study is voluntary and would involve a <insert time commitment> interview in <state location, i.e. your home or alternate location> at <convenient location>. There are no known or anticipated risks to your participation in this study. The questions are quite general (for example, <give a representative example of interview questions to be expected>).

You may decline answering any questions you feel you do not wish to answer. All information you provide will be considered confidential and grouped with responses from other participants. You will not be identified by name in any report or publication resulting from this study. The data collected through this study will be kept for a period of <insert number of years>.

You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

This study has been reviewed and approved through the Texas A&M University-Corpus Christi Institutional Research Board (IRB). If you have questions, you can contact them at 361-825-2497 or irb@tamucc.edu.

For all other questions, or if you would like additional information to assist you in reaching a decision about participation, please feel free to contact <research team contact name and contact info>.

Thank you for your assistance with this project.

Yours sincerely,

<Principal or Student> Investigator

WORKSHEET, Investigator Recruitment Plan

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The purpose of this worksheet is to aide investigators in developing a recruitment plan for the IRB. This worksheet is to be used as guidance on what needs to be included in the research protocol for recruitment. It does not need to be completed or retained. (Click box if “Yes”)

1 Who will be asked to participate?

<input type="checkbox"/>	<p>Do you know how many potential subjects are there?</p> <p>Aggregate, de-identified data. This is not research involving human subjects. When activities do not meet the definition of human subjects research, IRB review is not required to review de-identified data to determine the number of potential subjects..</p> <p>If using Protected Health Information (PHI): Consider using the Preparatory to Research Option under HIPAA to get aggregate numbers on potential subjects that could fit inclusion/exclusion criteria. When activities “preparatory to research” involve the use of PHI, IRB approval is required when activities in which an Investigator obtains and records individually identifiable health information (PHI) for purposes of planning a research proposal and/or identifying potential participants to aid in study recruitment. Investigator conducting preparatory to research activities are required to certify that:</p>
<input type="checkbox"/>	Use or disclosure is sought solely to review PHI necessary to prepare the research protocol;
<input type="checkbox"/>	No PHI will be removed from the covered entity during the review;
<input type="checkbox"/>	The PHI the researcher seeks to use or access is necessary for research purposes; and
<input type="checkbox"/>	Access is limited only to the minimally necessary information needed for the purposes of preparing a research proposal.
<input type="checkbox"/>	<p>Any barriers to participating in research that may exclude populations from participating? Example: If participating requires computer access, economically disadvantaged may not have access to computers or tablets. If yes, be prepared to discuss with IRB these barriers and any steps you have taken to minimize barriers.</p>
<input type="checkbox"/>	<p>Have you identified potential vulnerable populations?</p> <p><input type="checkbox"/> If yes, have you scientifically and ethically justified inclusion of the vulnerable population?</p> <p><input type="checkbox"/> If excluding populations, have you scientifically and ethically justified excluding populations? Example: Only enrolling men because the condition being studied only affects men. Excluding Non-English speaking persons because tools used have not been validated in other languages.</p> <p><input type="checkbox"/> Special resources required to enroll the vulnerable population? If yes, have you budgeted for these resources? Example: Money for translation of documents and time for interpreters for Non-English speaking persons.</p>

2 Who will contact potential participants?

<input type="checkbox"/>	IRB Approved: Have they completed research education requirements, COI disclosures, and been approved by the IRB to be on the study?
<input type="checkbox"/>	Training: Have been trained on the protocol to be able to answer potential subject’s questions?
<input type="checkbox"/>	Are there any non-university employees who will be contacting potential participants?
<input type="checkbox"/>	Are these non-university employees engaged in research? See Checklist Site Engagement in Research Determination.
<input type="checkbox"/>	If engaged, do they belong to an institution that holds an FWA?

WORKSHEET, Investigator Recruitment Plan

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	Lookup FWA by typing institution name at https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc
<input type="checkbox"/>	Are they getting IRB approval at their home institution?
<input type="checkbox"/>	If engaged but not part of a FWA-institution, do you have a contract in place to cover their research activities? Contact irb@tamucc.edu for reliance contract.

3 How will the potential subjects be contacted?

<input type="checkbox"/>	Will you need to use protected health information (PHI)? If No, skip these questions.
<input type="checkbox"/>	If yes, will you need to access PHI prior to approaching to consent the subject? If yes, submit a partial HIPAA waiver for pre-screening.
<input type="checkbox"/>	If yes, have you limited the pre-screening identifiers to the minimal amount in order to identify and contact persons to secure their informed consent?
<input type="checkbox"/>	Will you be using social media to recruit?
<input type="checkbox"/>	Have you considered how potential subjects will interact with the social media platform?
<input type="checkbox"/>	Have you reviewed the social media for potential privacy issues? Some social media platforms collect user information to be used for other purposes. This could adversely affect subject privacy or a notice of the site's privacy practices should be provided to the subjects to inform them of this risk.
<input type="checkbox"/>	Have you considered disabling the comment functionality on the platform? Individuals may unknowingly share personal information regarding their health or study participation on these sites, believing this information is only visible to a limited audience related to the study. In reality, the comment/post may be visible to all users of the social media platform. Allowing comments on the platform could have an adverse effect on subject privacy and potentially skew study data if other subjects can read one subject's personal experience.
<input type="checkbox"/>	Submit social media copy to IRB for approval.

**4 Advertisement Material Review, if applicable (all must be checked in order to be compliant)
All draft recruitment materials will need to be submitted to the IRB and IRB-approved prior to use.**

<input type="checkbox"/>	The application describes how the recruitment material will be used, i.e. distributed by mail, placed in patient areas, etc.
<input type="checkbox"/>	Information in the advertisement is accurate and consistent with the protocol and consent form.
<input type="checkbox"/>	Advertisement to recruit research subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.
	The name and address of the clinical investigator and/or research facility.
	The condition being studied and/or the purpose of the research.
	The time or other commitment(s) required of the subjects.
	The location of the research and the person or office to contact for further information.
	A clear statement that this is research and not treatment.
	A clear statement that participation is voluntary.
<input type="checkbox"/>	Advertisement Content:
	Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in consent or protocol.
	Does NOT promise "free treatment," when the intent is only to say subjects will not be charged for taking part in the research.
	Does NOT include exculpatory language.

WORKSHEET, Investigator Recruitment Plan

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<input type="checkbox"/>	Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type.
<input type="checkbox"/>	For FDA-Regulated research, the advertisement content:
	Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.
	Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device.
	Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
	Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
5 Will subjects be compensated for participating? (all must be checked in order to be compliant)	
<input type="checkbox"/>	Amount of payment, proposed method, and timing of disbursement is not coercive or presents undue influence.
<input type="checkbox"/>	All payments are described in the protocol including:
	Amount
	Method
	Timing of disbursement
	To whom payment will be made (e.g., subject or parents if child subject)
<input type="checkbox"/>	Credit for payment accrues as the study progresses.
<input type="checkbox"/>	Payment is not contingent upon completing the entire study.
<input type="checkbox"/>	Plans have been made for distributing payments to participants: Is Payment, Reimbursement, Tangible Property properly designated? Reimbursement is payment of the exact amount spent based upon subject providing receipt of cost associated with participation, i.e. presenting hotel room charge. *Mileage is considered payment when based upon map calculation of distance between two places. *Tangible property still requires that subject name, SSN, visit date, and address be recorded for tax purposes.
<input type="checkbox"/>	The informed consent properly advises subjects of:
	Payment method
	Maximum compensation to be paid
	Potential tax consequences
	Identifiers required to make payment: Social security number, name, visit date and address These identifiers should also be listed in the HIPAA authorization section as identifiers collected for study purposes.