A Guide to Basic Research

at

Akamai University

Office of Research Integrity

Contents

What is the purpose of this guide?

This guide describes the background of the review process at the Institutional Review Board at Akamai University. It also provides answers to the most common questions from the research community conducting research involving humans subjects. If you can't find the answer to your specific question, please contact Dr. Melinda Connor at 520-609-1765 or melinda_connor@mindspring.com.

What are the Research Compliance Services (RCS) at Akamai University

Research Integrity Office is the office that administers and supports four areas of research compliance: Conflict of Interest (COI), Responsible Conduct of Research (RCR), Research Misconduct (RMIS) and the Human Research Protection Program (HRPP). For purposes of this document, we will focus on the HRPP and specifically the Institutional Review Board (IRB) part of the review process.

What is an Institutional Review Board (IRB)?

An IRB is defined as an administrative body composed of scientists, nonscientists and community members established to protect the rights and welfare of human research subjects recruited to participate in research activities. The Akamai human studies research ethics board has one to seven member participants on the board. The number of people who will review your research will depend on the kind and type of research you are doing. Every full board review will have at least seven participants who will be selected based on their expertise and called on to do a review.

What is the Human Research Protection Program (HRPP)?

The HRPP is the Internal Review Board (IRB) which reviews all human subjects research. The office focuses on supporting research conducted by faculty, staff and students in accordance with applicable federal regulations.

In The United States:

What federal agencies oversee the protection of human subjects?

The Federal Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are the primary agencies responsible for the oversight of human subjects research in the United States of America. These agencies are under the direction of the U.S. Department of Health and Human Services (HHS). The Department of Health and Human Services (HHS) is the principal agency for protecting the health of all Americans.

For additional information regarding HHS please visit their website at

http://www.hhs.gov/.

For additional information regarding the FDA please visit their website at http://www.fda.gov/.

What is the Office for Human Research Protections?

The Office for Human Research Protections (OHRP) provides leadership in the protection of rights, welfare, and wellbeing of subjects involved in research conducted or supported by HHS.

For additional information regarding the OHRP please visit their website at http://www.hhs.gov/ohrp/.

What set of federal regulations does each federal agency implement and oversee?

The OHRP implements Title 45A – Department of Health and Human Services; Part 46-Protection of Human Subjects. (45 CFR 46)

Does 45 CFR 46 have a specific name?

45 CFR 46 is also referred to as the "Common Rule." It is called the Common Rule because several federal department and agencies have agreed to follow 45 CFR 46 in the protection of human subjects in research as a common regulation.

The FDA follows a separate and distinct set of federal regulations. Title 21, Chapter 1-Food and Drug Administration, DHHS; Part 50-Protection of Human Subjects. (21CFR 50)

In the United Kingdom:

In the United Kingdom individual ****** oversee the research in their area. Please contact the local ***** where you live to get specifics on how to apply for permission to conduct research in the UK. Be aware that while CITIprogram training is supported by the WHO and accepted by many countries as research ethics training, your particular **** may ask that you take the version supported in your area of the UK. We recommend the program which is offered at Kings College in London as a high quality program of research ethics training.

In Canada:

Canada will accept all human studies research ethics training done through the CITIprogram training at www.citiprogram.org. Most Canadian universities either use the CITIprogram or will accept it. Please note that if you are doing research at a Canadian university or with a Canadian university mentor, your mentor will need to be approved by

the office of research integrity at Akamai University and you may be asked by your mentor to carry a research study insurance policy that protects all study team members from liability. You may also be asked to provide liability insurance protection when renting a property where you will be conducting your research.

In Singapore:

Singapore will accept all human studies research ethics training supported by the WHO for research done in Singapore. As such the CITIprogram training at www.citiprogram.org with meet the requirements.

In Indonesia:

At the time of this writing (Jan 2022) Indonesia will accept all human studies research ethics training supported by the WHO for research done in Indonesia. As such the CITIprogram training at www.citiprogram.org with meet the requirements. Please confirm with your local professor or mentor that this is still applicable as a separate training program is currently under discussion at most major universities in Indonesia.

In Africa:

At the time of this writing (Jan 2022) most African countries will accept all human studies research ethics training supported by the WHO for research done in their country. As such the CITIprogram training at www.citiprogram.org with meet the requirements. Please confirm with your local professor or mentor that this is still applicable.

NOTE: Specific state laws or laws specific to your country may affect research design as well.

Why is a Human Studies Ethics Review (IRB review) necessary?

There are several historical events causing the formation of an IRB and unfortunately also current events that continue to illustrate the need for an IRB.

1932 - Tuskegee Institute study
US Public Health Service studies the effects of syphilis on African-American men. The men were given periodic examinations but the syphilis was left untreated. The subjects did not consent to participate.

1947 - The Nuremberg Code
The code was developed after Nazi experiments done during WWII. The Code is taken to be the basic principles of protection involving human subjects in research.

1948 - Guatemala Syphilis Experiment
US study which infected soldiers, sex workers and prisoners with syphilis and other STD's. The subjects did not consent to participate.

1964 - Declaration of Helsinki (Poland)
The declaration was provided to guide physicians in research involving human subjects.

1970 - Tearoom Trade Study
A study of anonymous homosexual encounters done by Laud Humphreys. Subjects were never informed of the study and were later contacted at their homes.

1971 - Stanford Prison Experiment (US)
Philip Zimbardo's study involving students put into the roles of prisoners and guards in a mock prison. After six days the experiment was ended due to the guards becoming abusive.

1974 - National Research Act (US)
The process instituted basic regulations governing the protection of human subjects in research.

1978 - Belmont Report (US)
The Belmont Report identifies three fundamental ethical principles for all human subjects research:
1. Respect for Persons
2. Beneficence
3. Justice

1991 - US Federal Common Rule adopted

1997 - Investigator Training Required in most countries
All programs and universities which receive federal monies which include human research are required to have investigators trained in Human Subjects Research in the US. By 2010 most countries around the world had implemented a similar policy though the information and training can be specific to that country.

2003 - Havasupai DNA study
Members of the Havasupai tribe had DNA collected for diabetes research. Their DNA was later used in other research resulting in information that was detrimental to the members of the tribe.

Note: All federal monies may be withheld from institutions not in compliance with the "common rule."

2019 - Updated Human Studies Research requirements
As of July of 2019 the rules changed in the US and most states in the US now have the following requirements:

1. All principle investigators and study personnel that are doing research on humans or animals must complete training in research ethics specific to the type of research being done. This includes all animal research, research involving more than

three human subjects in education, business, all social sciences, behavioral sciences, and medicine.

2. All investigators must renew this training on either a yearly or three year basis based on state and federal requirements. This a requirement for all human and animal studies research conducted within their state.

3. All investigators doing studies on animals must take training on ethical management of animal health care.

Please note that Akamai University does not currently approve genetic research on plants, animals or humans.

Common Terms in Research

Research
Research is a systematic investigation that involves a prospective plan which incorporates data collection, either quantitative or qualitative. Data analysis is conducted to answer a research question or objective that will either develop a theory or contribute to generalizable knowledge. This knowledge may be applied to populations outside of the specific study population and/or inform policy.

Animal Subject
An animal subject is a living individual that provides data to an investigator through intervention and interaction.

Human Subject
A human subject or a respondent is a living individual that provides data to an investigator through intervention, interaction and/or identifiable private information.

Project
The project would be considered to include all steps that the investigator would undertake to go from theory to publication, or the long-term process. This is commonly confused with the term protocol.

Protocol
The protocol would include logistical procedures, documents, scripts, and templates that will be reviewed by the IRB and subsequently followed by the investigator to conduct the project.

De-identified
The term de-identified indicates that the data does not contain information that would link a participant's identity with the data collected including the ID code. This includes situations where the master list still exists

Are there different categories in which the IRB can review a project?

Yes, the IRB will review human and animal subjects research within three different categories:

1) Exempt: No risk
2) Expedited: No greater than minimal risk.
Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research and is not greater than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
3) Full Board: Greater than minimal risk or does not qualify for an Exempt or Expedited category.

NOTE: Theses and dissertations are not considered class projects. They must be reviewed by the IRB. All research, even for class projects which include more than 3 humans or animals must receive an IRB review and approval.

What is Exempt Research?

1) Research conducted in established or commonly accepted education settings involving normal educational practices.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior to obtain non-sensitive data.

NOTE: Exemption #2 does not apply if:

- The participant can be identified AND it would cause them harm to be identified.
- The research involves surveys, interviews or participant observation with children.
- The research involves observation of sensitive aspects of a participant's behavior.

3) Research involving elected or appointed officials and all identifying information remains confidential for the life of the data.

4) Research involving the collection or study of EXISTING public and/or unidentifiable materials.

NOTE: ALL data to be included within a secondary data analysis protocol must exist at the time in which the research starts. If data will be added through a future primary data collection process, the protocol cannot be reviewed at an Exempt Research review level.
5) Research involving the study of public benefit or service programs.
6) Research involving a taste and/or food quality or consumer acceptance study.

What is Expedited Research?

Expedited Research involves no more than a minimal risk level.

1) Prospective collection of biological specimens for research purposes by noninvasive means.
2) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving genetics, x-rays or microwaves.
3) Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis.)
4) Collection of data from voice, video, digital or image recordings made for research purposes.
5) Research on individual or group characteristics or behavior OR research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

What is a Full Board Review?

A Full Board Review involves research with greater than minimal risk and may include vulnerable populations.

Policy Statement: Akamai University uses a rigorous standard for all research involving medical/health care processes. As such, all clinical studies and studies of medical devices, animal or human will go through a full board review. While professors may use vulnerable human populations in their research, no student without written permission from the members of their dissertation committee may conduct research on a vulnerable

population.

IRB Forms - What do you have to submit for a review?

Policy Statement: All Akamai students conducting research for courses at Akamai University and all Faculty of Akamai University conducting research which represents the University must go through the University IRB process regardless of the country of origin. If you are working for multiple organizations this may mean that you will have to be approved by more than one IRB committee.

In the appendix A of this booklet are the following forms:

1)The Project Review Template
2) Subject Consent Form
3) HIPAA
4) Conflict of Interest Form
5) Change Request
6) Adverse Event Form (Must be submitted within 48 hours of the event and no further research may be conducted until the event has been reviewed.)
7) Continuing Review Form

Policy Statement: No study subjects may be recruited until you have received your signed approval letter and your signed stamped consent. (Law in the US.)

Most students will submit the proposal for their thesis or dissertation that has been developed in prelims. Please submit the project review template and all supporting documentation by email to Melinda_Connor@mindspring.com. If applicable, the HIPAA and the Conflict of Interest form may also be submitted. (Please check with your advisor.)

Policy Statement: Please have the subject consent form (and HIPAA if applicable) reviewed by an attorney in the state or country where you will be conducting your research so that you are sure it meets local requirements.

What is a conflict of interest and why is reporting a requirement?

A conflict of interest is any situation that may have a real or perceived influence on the research results. The IRB requirement will specifically ask about any financial interest or conflict of commitment that you may have that is specific to the IRB project under review.

Are their other forms which I must submit as part of the review process?

Yes.

All studies must include the following:

1) a copy of the CITI Training completion certificate of each member of the study team. This includes anyone who will have contact with your research subjects and anyone who has access, contact or analyzes any of the study data even if that data is blinded. This can include: data entry, statistician, co-investigators, greeters, office personnel. Instructions on how to access CITI training are in Appendix B.

2) Common documents used in the study:

1. Advertisements
2. Fliers
3. Handouts
4. Bulletin Postings
5. Reminders
6. Email Messages
7. Phone Scripts
8. Invitations
9. Postcards
10. Surveys
11. Questionnaires
12. Images
13. Introductions
14. Recruitment Scripts
15. Assessments
16. Standardized Assessments
17. Grant Funding Applications or letters of receipt
18. Site Permission Letters
19. Informed Consent
20. HIPAA
21. Chart requests
22. Study Insurance approval

May I change my study design after it is approved?

Policy Statement: No study design changes are allowed after the study is approved without submitting a change request to the IRB. No study design changes may be implemented until a notice is received from the IRB granting the design change approval.

What does a study review cost?

A thesis review is $250US. A dissertation review is $500US. Faculty members review is $1000. This is significantly lower that most IRB review boards which generally charge $4000 and up.

How long does it take to receive an IRB approval?

Approval time varies depending on the number of projects under review, the quality of the project submitted and the amount and content of the revisions that were requested.

- Exempt Review typically requires two weeks for a determination.
- Expedited Review typically requires three weeks with review conducted by one member of the IRB.
- Full Board Review typically requires at a minimum one month for review by the convened IRB.

When a form is returned with a "revisions requested" status, how much time is allowed to complete the required revisions?

All forms are allowed 14 days for re-submission of revisions that are requested. However, the sooner revisions are submitted, the sooner IRB approval will be obtained.

What will I receive from the IRB that shows I have permission to go forward?

You will receive a signed, dated letter with a study number which states that you are approved to proceed. You will also receive a signed stamped consent which must be used for your consent process. Be aware that each subject must sign two copies of the consent form. One copy they will keep for their records and one copy is for your study records. Be sure to schedule your free one hour training class via skype or zoom with the IRB on how to properly consent research subjects when your receive your study approval.

What kind of data management requirements will I have to meet for my study?

All study data must be kept for 7 years and must be kept in locked file cabinets. Study data which is transported to and from a study site must be kept in a locked brief case and during transport must be kept in the trunk of the car or a fire proof safe.

Demographic data and subject number assignment lists must be kept in a separate file drawer from all other study data.

If the data is kept on a computer, the computer must be start-up password protected and all study documents must be individually password protected. Again, the study data must be kept for 7 years.

Policy Statement: Research data may not be kept on the "cloud" in any form nor may it be backed-up onto a cloud platform as neither are private or protected environments. Further, if investigators are using computers which have Windows 10 installed as the operating system the release must have been installed as a custom installation with all 24 privacy flags turned on.

Principal investigators are encouraged to back up all study data appropriately and maintain a back up copy in a fire-proof environment. Health and Human Services of the state or federal government or your countries equivalent may at any time seek to review human studies research data and cannot be refused. All investigators should keep this in mind when organizing their study data.

For questions and problems filling out your human studies application form please contact your thesis or dissertation chair or email the Office of Research Integrity, melinda_connor@mindspring.com.

Appendix A: Study Forms

These are samples. Please have a local attorney review the examples and make any changes necessary for your local area. For seperate and current copies of the forms please download the pdf's on the Office of Research Integrity web page.

Project Review Form

Project Title:

_____

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

_____

IDENTIFICATION OF PI(S)

Principal Investigator(s):	Degree(s):	Status/rank:	Department:	College:
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Faculty Advisor (if PI is a student):

_____	_____	_____	_____	_____

PI CONTACT INFORMATION

Contact phone: _____ Fax: _____
_____ _____
_____
____

Email: _____ Campus Mailing address if applicable (PO Box):

ADVISOR CONTACT INFORMATION

Contact phone: _____ Fax: _____

Email: _____ Campus Mailing address:

PROJECT START DATE: **PROJECT END DATE:**

_____ _____

SUPPORT

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

If "yes", sponsoring agency/ies:

Amount of funding: _____

NOTE: The full grant application must be submitted if the research described in your PRF is in conjunction with a grant proposal.

Verification of Human Subjects Training

All individuals conducting research involving human subjects (with or without financial support of any sponsoring organization or agency) must complete Human Subjects training. Those individuals include principal investigators, co-investigators and all other individuals involved in the conduct of research. Students and their advisors must meet the same standard as faculty and staff.

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

Name	Research Role (PI, Co-PI, Collaborator, Sub-I, Data Manager, Research Assistant, etc.)	Will this person be involved in the consenting process? *	Training Title Indicate type of training: **Biomed, SBS,** and/or **CITI-Biomed, CITI-SBS** (see definitions below)**	Completion Date(s) for each Human Subjects training listed (mm/dd/yy)
		YES NO		
		YES NO		
		YES NO		
		YES NO		
		YES NO		
		YES NO		

		YES NO		
		YES NO		
		YES NO		
		YES NO		
		YES NO		
		YES NO		

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

****CITI-Biomed**,

CITI-SBS: *Collaborative Institutional Training Initiative* – www.citiprogram.org

Author: University of Miami

Biomed: *Biomedical and Social/Behavioral Science Researchers*

Text: Protecting Study Volunteers In Research

Authors: Cynthia McGuire Dunn/Gary. L. Chadwick

SBS: *Social/Behavioral Science Researchers only*

Text: Planning Ethically Responsible Research

Author: Joan E. Sieber

ASSURANCES

If appropriate, after review by the Departmental Review Committee, please forward their opinions and comments along with the signatures on the Project Review Form to the Office of Research Integrity. Only one copy is required and will be retained for the Human Subjects Protection Program files and eventually microfilmed for a permanent record. Please provide responses to all of the following items.

1. PRINCIPAL INVESTIGATOR

By signing below, I, the Principal Investigator, assure that all other investigators (co-investigators, collaborating

investigators, involved statisticians, consultants, or advisors) are fully aware of, and concur with, the project submission and that all Human Subjects training verification information provided in this form is accurate. I agree that no procedural changes relating to the research will take place without prior review by the IRB.

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

Financial Interest Statements:

a) Do ANY of the investigators or research personnel (or relatives) serve as a speaker or consultant to the sponsor, the manufacturer, or the owner of the product or program being evaluated?

□ Yes □ No

b) Do ANY of the investigators or research personnel (or their relatives) have a proprietary interest, derive a direct or indirect benefit, hold equity or receive income annually from the sponsor, manufacturer, or owner of the product or program being evaluated?

□ Yes □ No

c) Do ANY of the investigators or research personnel (or relatives) serve in an

administrative or advisory capacity to the sponsor (e.g., Board of Directors with or without compensation)?

□ Yes □ No

If yes to ANY of the above, **attach** copy of Conflict of Interest and Commitment Disclosure Form.

_____ _____ _____

Principal Investigator (Print) Signature Date

2. SUPERVISING OFFICIAL (IF PI is a student)

I certify that (1) the resources necessary to protect human participants are available. Such resources include but are not limited to; staffing and personnel (in terms of availability, number, expertise, and experience); psychological, social, or medical services (e.g., counseling or social support services required due to research participation); psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and resources for participant communication (e.g., language translation services)
(2) I assume the responsibility for ensuring the competence, integrity, and ethical conduct of the investigator(s); (3) no procedural changes relating to the human subjects involved will be allowed without prior review by the Human Subjects Committee; (4) I am satisfied that the procedures to be used for obtaining informed consent comply with the spirit and intent of DHHS and FDA regulations; (5) I certify that the investigator(s) is fully competent to accomplish the goals and techniques stated in the attached proposal

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

_____ _____ _____

Signature Date Title

PROJECT ABSTRACT

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

1. POPULATION

a. Number of persons to be recruited for participation in the study:

b. Describe the population to be recruited and rationale for their participation (indicate age range, gender, and ethnicity). Note any special efforts to encourage the recruitment of women and/or representatives from racial or ethnic minority groups.

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

d. What are the inclusion and exclusion criteria for study participation?

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

a. Describe how potential participants will be identified and how you will respect and protect their privacy during recruitment.

b. Describe how you will contact individuals who may become participants in the study (e.g., web site, email, flyers, phone calls, advertisements).

c. Describe how the project will be explained to individuals when you recruit them for participation (include the text of advertisements, phone solicitations, etc). Include any pre-screening questions or surveys that may be used.

d. Describe how informed consent will be obtained. If the participants are minors or of another vulnerable population, explain how assent or legal consent will be secured. Include if appropriate, the steps you will take to allow sufficient time for the participant to think about their participation or time to review the consent form with family or friends, prior to consenting. If an informed consent document is inappropriate for your project, explain why and how you will ensure informed consent.

e. How will you make it clear to the recruits that their participation is voluntary and that they may withdraw at any time?

f. Describe the additional safeguards you will use to protect participants from coercion or undue influence, during recruitment and throughout the study (e.g. if the participants are students and the investigator is their teacher).

3. METHODOLOGY AND DATA COLLECTION PROCEDURES

a. Is your project evaluating an active intervention or treatment procedure (to determine whether an intervention/treatment is effective for the people undergoing it)?
   - Yes___ No___ If yes, in lay terms provide a summary of the intervention and/or treatment methods and procedures to be employed

b. What type of data collection and recording will be employed? Check all that apply and provide an explanation. (If Administrative Records are to be used, include a letter of authorization from the appropriate agencies in Appendix C. Include samples of all data collection instruments in Appendix D.)

o **___ Questionnaires/Surveys**
o ___ Observations
o ___ Videotaping
o ___ Photography
o ___ Participant observation
o ___ Interviews/Focus Groups
o ___ Records Review (medical, educational, etc.)
o ___ Audiotaping
o ___ Other (define):

c. In lay terms, provide a description of the research methods (including deception) and procedures for data collection that will be employed.

d. Describe the procedures you will use to respect and protect the research participant's privacy (physically, behaviorally, or intellectually) during the data collection process (e.g. during the interview the participant will meet with the researcher in a location away from his/her place of employment).

e. Describe when appropriate, how the research plan makes adequate provision for monitoring of data when participant safety is a concern, or identification of or support for distressed participants to ensure their safety (e.g. Participants who may self-identify for depression will be provided with referral information so they may seek professional help.)

f. Where will the project be conducted? If study is to be conducted anywhere outside your department (e.g., in another department, at an off-campus agency or organizational location), include a letter of authorization in Appendix C, or state when it will be provided to the Human Subjects Protection Office. If your project takes place off-campus but site authorization is inappropriate, explain why.

g. Are you the lead investigator of a multicenter study?
i. If yes, describe the plan for communicating the following information (relevant to the protection of research participants) among the sites involved in this study:

- Unexpected problems
- Protocol modifications
- Interim results

4. CONFIDENTIALITY OF PERSONAL IDENTIFYING INFORMATION

a. What procedures will be followed to ensure that the information obtained about them will be stored in a secure manner? (Specify how the confidentiality of data will be maintained throughout the research.)

b. What are the plans for retention and/or destruction of linkages between study data

and personal identifying information? (Specify when and how personal identifying information will be destroyed.)

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

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

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

5. BENEFITS, COSTS, COMPENSATION & RISKS

a. Benefits: i. What are the potential benefits directly to the participants, if any?

Benefits: ii. What are the potential broader benefits of the study?

b. Costs: What are the costs to the participants (monetary, time, etc)?

c. Compensation: Will monetary or other compensations be offered to the subjects? (If so, identify the amount of compensation and method of payment.)

d. Risks: i. What risks to the participants could be encountered through participation in this project (physical, psychological, sociological, financial, economic, etc)?

Risks: ii. Describe the approaches you will take to minimize these risks and/or to minimize their impact.

6. APPENDICES

Attach the following appendices to the PRF, in the order specified, labeled as

indicated, and with a table of contents identifying all appendix materials. Use titles that are consistent with those used in the text of the PRF.

A.1 Subject Informed Consent Form/Parental Informed Consent Form

A.2 Minor Assent Form

B. Recruitment Materials

C. Site Authorization Letter (for study conduct and/or access to administrative records)

D. Data Collection Instruments

E. Grant Applications

F. HIPAA documentation.

Revised: 04/10

RESEARCH PARTICIPANT CONSENT FORM

GUIDELINES FOR SUBJECT'S CONSENT FORM(S)

The written consent form must be in a language easily understood by the subject. Avoid technical terms or explain thoroughly in simple lay language if they must be used. Essentially the form should represent the subject's statement in his/her own words since he/she will sign it. The forms should be titled "Subject's Consent Form" and should contain the basic elements of informed consent. The legality of the subject's

signature is the responsibility of the principal investigator. (The following elements must be separately titled and addressed.)

(This paragraph must be used verbatim following the title - preferably in capital letters.)

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being invited to participate voluntarily in the above-titled research project. The purpose of this project is (state specifically why the study is being proposed).

SELECTION CRITERIA

I am being invited to participate because (give brief description of inclusion and exclusion criteria). Approximately (insert number) subjects will be enrolled in this study.

STANDARD TREATMENT(S)

Include a brief description of standard treatment(s) available as an option if he/she does not wish to participate in this study.

PROCEDURE(S)

If I agree to participate, I will be asked to consent to the following: (include each procedure [in simple lay terms], state time requirements, and list measurements [i.e., inches, etc., blood to be drawn {teaspoons, tablespoons, ounces}], skin biopsy [size, location]). If the study is blind or double-blind, describe the groups clearly. Subjects must be aware they will be assigned (randomized) to a group by chance, "like the

flip of a coin". Listing procedures in the consent form is adequate only if supplemented with an oral description to the subject with more detailed information to comply with the requirement for "fully informed consent".

RISKS

List the most common serious risks Project Approval Form (or the questionnaire/survey Project Approval Form). State in lay terms and include % incidence, if known, and precautionary measures to be taken. The possibility of psychological and/or social risks involved in study participation must also be stated clearly. If the study is placebo-controlled, subjects must be informed that there is a possibility that they will receive no treatment, and the consequences of this (or withholding previous treatment regimen) should be explained.

BENEFITS

A benefit is a valued or desired outcome. If there are no benefits, so state. Benefits associated with participation in research can be classified as those that accrue to the subject directly such as improvement in health status, acquisition of useful information from examination or testing, and those that accrue to society (e.g., societally important and generalizable information). Financial or other forms of compensation should not be considered a benefit to be derived from the research goals and procedures and as such, should be listed under Participation Costs and Subject Compensation.

CONFIDENTIALITY

Explain how confidentiality will be maintained. List people by category and/or by name who will have access to the data.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

It is considered unethical (in most cases) to have a research subject pay for experimental drugs and the laboratory costs involved. Please state clearly the costs the subject and/or third party payors will assume (including hospital stay). If there are no costs, so state. If subjects will be paid, state the amount (add proration for partial completion of the study). This will usually be commensurate with time lost and expenses, and must not be in amounts excessive enough to represent potential financial coercion. Specify any compensation provided to the subjects (e.g., gift certificates, training sessions, etc.).

CONTACTS [for projects involving no known risk(s) to subjects, include the following sentences]

I can obtain further information from the principal investigator _____ (name of Principal Investigator plus his/her degree, M.D., Ph.D., Pharm.D., Ph.D. Candidate, etc.) at ( )___-____. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee representative at (520) 609-1765**.**

LIABILITY (for projects involving greater than minimal risk - use this paragraph verbatim)

Side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm also may occur and require care. I do not give up any of my legal rights by signing this form. In the event that I require or am billed for medical care that I feel

has been caused by the research, I should contact the principal investigator _____ (name of Principal Investigator plus his/her degree, M.D., Ph.D., Pharm.D., Ph.D. Candidate, etc.) at ( )___-____. If I have questions concerning my rights as a research

subject, I may call the Human Subjects Committee office at (520) 609-1765

AUTHORIZATION (the following paragraph is to be used verbatim in all consent forms with two exceptions: delete words "or by the sponsor" if unfunded and no sponsor and "or affecting my medical care" if not clinical, medical treatment)

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I MAY ASK QUESTIONS AT ANY TIME AND I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT

MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, _____ OR AUTHORIZED REPRESENTATIVE OF THE

_____ DEPARTMENT. I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. **A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.**

_____
_____

Subject's Signature Date

_____
_____

Parent/Legal Guardian (if necessary) Date

_____
_____

Witness (if necessary) Date

INVESTIGATOR'S AFFIDAVIT

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

_____

_____

Signature of Investigator Date

GUIDELINES FOR SUBJECT AUTHORIZATION FORM FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

This form must be in a language easily understood by the subject. Avoid technical terms or explain thoroughly in simple lay language if they must be used. The form should represent the subject's statement in his/her own words since he/she will sign it. The forms should be titled "Authorization Form for Use and Disclosure of Protected Health Information for Research" and contain the elements required for an authorization form as designated by the Office for Civil Rights. <u>The legality of the subject's signature is the responsibility of the principal investigator</u>. (The following elements must be titled and addressed separately.)

(This paragraph must be used verbatim following the project title.)
The United States government has issued a new privacy rule to protect the privacy rights of individuals enrolled in research. The Privacy Rule is designed to protect the confidentiality of an individual's health information. This document hereafter known as an "Authorization for Use and Disclosure of Protected Health Information for Research" describes my rights and explains how my health information will be used and disclosed for this study.

PURPOSE

I am being invited to participate voluntarily in the above-titled research project. The purpose of this project is **(state specifically why the study is being proposed). (A description that relates to the need for medical information is acceptable.)**

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Provide a description of information to be used or disclosed and include reason why the information is needed for the study (access should be limited to minimum amount of information necessary to attain study goals). State how long the information will be linked to the subject's identifying information. The information should be understandable to the individual, not merely a list of elements understandable only to the research team. Terms such as lab tests, clinic visit information, X-ray reports are appropriate. Avoid other unnecessary medical jargon. This information will be used for **(describe how the information will be used.) Indicate who is providing the information (list the person/organization providing the information) to (list the person/organization receiving the information).** I have the right to access my PHI that may be created during this study as it relates to my treatment or payment. My access to this information will become available only after the study analyses are complete. **(IF the research subject's access rights are to be suspended while the study is in progress, the authorization form must include an agreement to this denial of access and that the right to access PHI will be reinstated at the conclusion of the study.)**

CONTACTS (Include the following sentences)

I can obtain further information from the principal investigator _____ **(name of Principal Investigator plus his/her degree, M.D., Ph.D., Pharm.D., Ph.D. Candidate, etc)** at ( )___-____. If I have questions concerning my rights as a research subject, I may call the Human Subjects Protection Program office at 520-609-1765.

AUTHORIZATION

I hereby authorize the use or disclosure of my individually identifiable health information. I may withdraw this authorization at any time by notifying the Principal Investigator in writing. The address for the Principal Investigator is **(insert address here.)** If I do withdraw my authorization, any information previously disclosed cannot be withdrawn and may continue to be used. Once information about me is disclosed in accordance with this authorization, the individual or organization that receives this may

rediscloseit and my information may no longer be protected by Federal Privacy Regulations. I may refuse to sign this authorization form. If I choose not to sign this form, I cannot participate in the research study. *Refusing to sign will not affect my present or future medical care and will not cause any loss of benefits to which I am otherwise entitled*. This authorization will expire on the date the research study ends. **(Other options include actual date of expiration, occurrence of a particular event, or "none", [meaning the authorization will have no expiration date].)** I will be given a copy of this signed authorization form.

_____

_____

Subject's Signature Date

_____

Printed Name of Subject

_____ _____

_____

Signature of Subject's Legal Representative (if necessary) Date

_____

Printed Name of Subject's Legal Representative Relationship to the Subject

_____ ----------

Use to request a modification to previously approved research	
IRB Project No.:	
Protocol Name:	
Investigator:	
Investigator's Contact Information:	
Alternate Contact:	
Alternate Contact's	

Information:	

Approvals Required Prior to Modifying Research			
Does this modification involve?		**Prior to initiating the research approval is required by:**	**Have you obtained approval?**
A change in use, type, or frequency of radiation, laser, or MRI	☐ No ☐ Yes	Radiation Safety Committee	☐ No ☐ Yes
The use of any biohazards	☐ No ☐ Yes	Biosafety Committee	☐ No ☐ Yes
A change to any reportable interests	☐ No ☐ Yes	Institutional Review Committee	☐ No ☐ Yes
Privacy issues	☐ No ☐ Yes	Privacy Board	☐ No ☐ Yes

Summarize the modification or attach a summary:

Update the Investigator Protocol if affected by the modifications.

Provide 1 copy of the following documents if affected by the modification:

- FORM: Application for Human Research.
- Investigator Protocol
- Research tools
- Data collection instruments (questionnaires, etc.; do not submit case report forms).
- All written materials to be provided to or meant to be seen or heard by subjects, including:
    - Evaluation instruments and surveys
    - Advertisements (printed, audio, and video)
    - Recruitment materials and scripts
    - Consent documents
- If consent will not be documented in writing, a script of information to be provided orally to subjects

Provide one copy of the following documents when they have been modified:

- Grant application
- Current product information for each investigational device
- Foreign language version of any written material to be provided to or meant to be seen or heard by subjects.

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with applicable regulations and the National Foundation for Energy Healing policies and processes.	
Investigator signature	Date

Use for both continuing review and as a final report to close a study. **If modifications are being requested, submit a separate request for a modification.**	
IRB Project No.:	
Expiration Date:	
Protocol Name:	
Investigator:	
Investigator's Contact Information:	
Alternate Contact:	
Alternate Contact's Information:	

Enrollment Status

Number of subjects enrolled:

	Since activation	Since last approval	Male	Female	Other, Unknown
Total locally:					
Total all sites:					

Number of subjects enrolled locally since activation of the study:

Caucasian	Black	Hispanic	Asian Pacific Islander	American Indian/ Alaska Native	Other, Unknown

Total number of subjects considered members of vulnerable populations:

Children	Prisoners	Fetuses	Pregnant	Students Employees	Cognitively Impaired	Other

Financial Interest Declaration						
☐	The Principal Investigator hereby affirms that ALL appropriate project personnel have submitted an ROI to the Conflict of Interest Office and *no* outside interests related to this project have been disclosed by any individual.					
☐	The Principal Investigator hereby affirms that ALL appropriate project personnel have submitted an ROI to the Conflict of Interest Office and outside interests *have* been disclosed by one or more individuals that must be reviewed by the Institutional Review Committee (IRC) to determine whether a conflict exists related to this project.					

Yes*	No	The following questions refer to all sites involved in the research:
☐	☐	Since the last IRB review, have subjects experienced any harms (expected or unexpected)?
☐	☐	Since the last IRB review, have subjects experienced any benefits?
☐	☐	Since the last IRB review, have there been any unanticipated problems involving risks to subjects or others since the last IRB review?
☐	☐	Since the last IRB review, have any subjects withdrawn from the research?
☐	☐	Since the last IRB review, have any subjects or others complained about the research?
☐	☐	Since the last IRB review, have there been any publications in the literature relevant to the risks or potential benefits research?
☐	☐	Since the last IRB review, have there been any interim findings?
☐	☐	Since the last IRB review, have there been any multi-center trial reports?
☐	☐	Since the last IRB review, have there been any data safety monitoring board reports?
☐	☐	Since the last IRB review, has there been any other relevant information regarding this research, especially information about risks associated with the research?
☐	☐	In the opinion of the principal investigator, have the risks or potential benefits of this research changed?
☐	☐	Since the last IRB review, have there been any modifications to the research?
☐	☐	Are there any problems that required prompt reporting that have NOT been submitted as required?
☐	☐	Have all serious adverse events and unanticipated adverse events in Veterans Administration (VA) research been reported as required? Check ☐ N/A if this is not Veterans Administration (VA) research.

***Attach a summary explanation or description for each question whose answer is "Yes."**

Current Protocol Status

Check all that are true or not applicable	
☐	The research is permanently closed to enrollment.
☐	All subjects have completed all research-related interventions.
☐	Collection of private identifiable information is completed.
☐	Analysis of private identifiable information is completed.
If all items are checked, the research may be concluded **Otherwise, the Human Research must undergo continuing review by the IRB.**	

Provide 1 copy of the consent documents to be used in the next approval period (See Investigator Manual for additional instructions related to these documents). If consent will not be documented in writing, a script of information to be provided orally to subjects. This may be omitted if the research is permanently closed to enrollment.

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with applicable regulations and the National Foundation for Energy Healing policies and processes.	
Investigator signature	Date

National Foundation for Energy Healing

CONFLICT OF INTEREST AND COMMITMENT DISCLOSURE

NAME: _____

DATE: _____

DEPARTMENT/ COMPANY:

_____

ADDRESS:

_____

TELEPHONE: _____

1. If your potential conflict of interest confers a benefit (pecuniary, property, or proprietary), directly or indirectly, on you or a member of your family and the benefit exceeds a remote interest provide a full description of the activities including actual valuation and method of determining stated value.

2. If your responsibilities or commitment to the work (teaching, research, service, or other activities) are or will be affected by the outside interest, please explain. All related activities must be included.

3. If your interest is with a company or other legal entity, provide:

a. Name:

_____

b. Nature of the business activity:

_____

c. Address and Telephone Number:

_____

SIGNATURE: _____

DATE: _____

Please feel free to attach additional pages to this form if the space allotted is insufficient to fully describe and to explain the potential conflict of interest.

Appendix B: Human Subjects Research Training

How do investigators complete human subjects training?

Akamai University uses the Collaborative Institutional Training Initiative (CITI), a web-based program, to provide an educational access to the federally required human subjects training curriculum at www.citiprogram.org.

Who needs to complete CITI training?

All investigators conducting human or animal subjects research are required to complete the proper CITI training course. This includes faculty, staff, students and any unaffiliated collaborators. Everyone who has access to the research subjects, everyone who has access to the raw research data, must complete human studies research ethics training.

What course is required and when?

Most Akamai investigators will complete the Research Training Independant Investigator Social/Behavioral/Educational or Biomedical BASIC course. All study team members must complete the training with a grade of 87% or better prior to submitting the IRB review request. Please include a copy of each team members CITI training completion report as an appendix to the project review submission.