TCSPP IRB Policy & Procedures Manual

The Chicago School of Professional Psychology
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1 INTRODUCTION

The IRB is charged by the Office of the President of The Chicago School of Professional Psychology (TCSPP) and the Office of the Vice President Academic Affairs with the review of all human subjects research conducted by or under the direction of university students, faculty, or staff. The purpose of this review is to protect the rights and welfare of all research participants and to ensure that research is in compliant with federal regulations, local laws and regulation and university policy.

The Chicago School has two IRB Committees: Chicago and California. The Chicago Committee is responsible for reviewing applications from the Chicago, Washington DC, Xavier University, and Online campuses. Applications from the Downtown Los Angeles and Irvine campuses are viewed by the California Committee. However, each Committee may review applications submitted by students or faculty at any TCSPP campus. Both Committees' reviews are conducted to reflect the ethical principles outlined in the *Belmont Report* and in accordance with the rules and regulations outlined in the US Department of Health and Human Services (DHHS) Code of Federal Regulations Title 45 Part 46, also known as the "Common Rule".

The Chicago School of Professional Psychology has obtained a Federalwide Assurance (FWA) from the Office of Human Research Protection (OHRP) for the Chicago IRB Committee and for the California IRB Committee. The TCSPP FWA number is FWA00017156.

2 DEFINITIONS

Research

Per 45 CFR 46.102(d), an activity is considered to be "research" if it involves a "systematic investigation designed to develop or contribute to generalizable knowledge." Activities not systematic, not designed to contribute to general knowledge, or done only for personal use (i.e. not shared with *anyone* else, including other members of the labor department) do not meet this definition.

Human Subjects

Per 45 CFR 46.102(f),research is considered to involve "human subjects" if it entails obtaining information about living individuals, either through intervention or interaction with the individuals; or if the research involves the use or receipt of *individually identifiable* information originally obtained in a context in which the individuals could reasonably expect privacy.

Non Human Subjects

In order for a project to require IRB review, it must both be “research” and involve “human subjects.” If upon submission, the IRB staff finds that the activity does not constitute human subjects research, a letter stating that the activity does not require IRB review or approval will be issued.

The IRB staff must be consulted prior to implementing changes to the research An amended version of the IRB application must be completed and submitted for review. The IRB will determine whether the research now involves human subjects as a result of the changes.

3 IRB MEMBERSHIP

Meetings

The Chicago Committee meets twice a month while the California Committee meets once a month. Additional meetings may be scheduled by each committee when necessary. While meetings can be held, no Committee decisions will be made without the necessary quorum and without the vote of at least one non-scientist member. If a quorum fails for any reason, no further actions are taken until quorum is restored.

Members

The IRB Committee is made up of staff and faculty from each TCSPP campus, representing a broad range of Psychological disciplines and includes at least one non-scientific member, and one member who is unaffiliated with TCSPP.

Non-members and guests may attend a convened meeting if upon request.

Chair

The Chair of each IRB Committee is appointed by the TCSPP President based upon the recommendation of the Faculty Council. The term of membership is two years.

Appointments

IRB members are appointed by the TCSPP President based upon the recommendation of the Faculty Council. Each department must have representation on the IRB Committee. The term of membership two years.

Education

All IRB Members are required to complete Human Subjects Protection Course via the CITI Program website. IRB Members must complete both the Social Behavioral Researchers and the IRB Members modules every two years. In addition, all new members must complete the IRB Training course conducted by the IRB Director or Associate Director.

4 PRINCIPAL INVESTIGATOR

4.1 ELIGIBILITY

Faculty

All faculty members are eligible to serve as ~~Lead~~ Principal Investigator (PI).

Adjunct Faculty

All individuals appointed as adjunct faculty members within TCSPP are eligible to serve as Principal Investigator with documented approval of their Department Chair.

Students

All students within TCSPP in good standing can serve as Principal Investigator on research studies involving human subjects, provided the research is being conducted as part of completion of their dissertation or thesis program. Students wishing to perform research that is not associated with the completion of a dissertation or thesis program must obtain a faculty sponsor to oversee the research prior to IRB review.

4.2 TRAINING

All Principal Investigators whether student or faculty, must complete the CITI Human Subjects Protection Training for the Social & Behavioral Research learner group prior to submitting their application for IRB review. Principal Investigators and research assistants must receive at least a score of 80% on each applicable module.

In addition, all Dissertation and Thesis Chairs must also complete the course prior to their student submitting an application for review. The IRB reserves the right to also require other research personnel included on the application to complete the CITI course based upon their level of contact with research subjects.

4.3 RESPONSIBILITIES

Although the IRB Committee and investigators have different roles in the conduct of research, they have a shared responsibility to ensure the protection of the research participants. The Principal Investigator is responsible for the overall conduct of the study. As such they must possess sufficient knowledge of the research topic and knowledge of the basic principles of *The Belmont Report* to conduct and oversee the study. The principle of beneficence requires investigators to design ethical research, protect human subjects from unnecessary risk, and make continuing assessments of the risk benefit ratio. In regards to the principle of respect for persons, the Principal Investigator is responsible for ensuring that the informed consent process is carried out and the subject's privacy is protected. Lastly, the Principal Investigator is

responsible for ensuring that all members of the research team understand the study and act according to the ethical principles that govern research. The Principal Investigator must take direct responsibility for the activities performed during the study by him/her or the research personnel.

General responsibilities include, but are not limited to:

- Ensuring that anyone having direct contact with the subjects or access to subjects' data is listed on the IRB Application and has received the appropriate training. Examples of direct contact with subjects and access to subjects' data include obtaining consent from subjects, administering questionnaires and surveys, conducting ~~clinical~~ interventions, and performing data analysis.
- Providing the IRB with the necessary information to conduct the review of the study by completing the IRB application included in the IRB electronic system.
- Ensuring that no research activities are initiated until an IRB approval notice, exemption notice, or non-human subject notification has been received.
- Obtaining the appropriate informed consent from subjects as necessary (see the informed consent section).
- Performing research procedures as described in the IRB approved application.
- Implementing research modifications only after IRB approval of the addendum has been received.
- Reporting to the IRB, in writing, all issues of non-compliance, deviations, adverse events, unanticipated problems, and complaints that occur during the course of the research within 5 working days of knowledge of the event.
- Maintaining confidentiality of all research records.
- Ensuring timely completion and submission of all materials necessary for continuing renewal, if applicable.
- Responding to all correspondences from the IRB within a timely manner.

Dissertation/Thesis Chair Responsibilities

- Review all initial IRB applications completed by their students and approve/submit their application to the IRB for review.
- Supervise the student researcher during the conduct of their research study.
- Report to the IRB, in writing, all issues of non-compliance, deviations, adverse events, unanticipated problems, and complaints that occur during the course of the research within 5 working days of knowledge of the event.

5 PREPARING AN IRB APPLICATION

5.1 THE SUBMISSION PROCESS

All human subjects research conducted at TCSPP must be submitted to the IRB for approval prior to initiation of the research. All applications must be submitted via the IRB

Electronic Submission System. The IRB application and submission procedures are periodically revised to ensure that the IRB has the necessary information required to perform a complete review.

Application Contents

A complete application will include the following documents:

- *The electronic Questions & Answers (Q & A) Form*
  The Q & A form is designed to highlight areas of particular interest to the IRB in their consideration of a study. As such, the form must be completed in its entirety and provide an accurate description of the research project. Furthermore, information should not be copied directly from the dissertation proposal.

- *CITI Completion Certificate*
  A copy the CITI Completion Certificate for the researcher, Dissertation/Thesis Chair, and any other personnel conducting research must be submitted to the IRB. A copy of the certificate can be downloaded from http://citiprogram.org/. The certificate is valid for two years and must be renewed prior to the expiration date.

- *Supplemental Materials*
  Materials that will be used with research participants may include any or all of the following as applicable to each study: recruitment documents (e.g., advertisement), consent and/or assent forms, data collection forms, surveys, questionnaires, interviews, debriefing script, etc.

- *Documentation of permission or approval from external site(s)*
  When research procedures, including recruitment, will take place outside of TCSPP documentation from the site granting you permission to conduct research must be submitted to the IRB.

Any application missing the documents noted above will be deemed incomplete returned to the Principal Investigator.

5.2 Informed Consent

In keeping with the ethical principles set forth in the *Belmont Report* which require that subjects, to the extent that they are capable, be given the opportunity to choose what shall or shall not happen to them, the IRB must consider the consent process proposed for each study. The consent process should consist of a dialogue between the subject and the researcher during which the subject is encouraged to ask questions about the study and or procedures prior to agreeing to participate. **Therefore, simply giving the subject a consent form or reading an oral script does not constitute informed consent.** The requirements for informed consent will depend on the nature of the research. Multifaceted studies may require more than one method of consent. All applications submitted to the IRB are required to include a description of the

consent process to be used. There are three methods by which this requirement can be addressed:

A. Waiver or Alteration of Consent
The IRB may approve a procedure in which consent is not obtained or alters some or all of the elements of informed consent (e.g., informed consent will not be obtained or at least one element of consent not be disclosed to participants). This may be appropriate for studies using archival data collection or studies that may involve deception. The IRB may approve a waiver or alteration of consent provided that the research meets the following criteria.:

- The research involves no more than minimal risk to the participants
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

B. Waiver of Consent Documentation (e.g., oral consent, online consent, etc.)
A waiver of consent documentation may be requested when a signature documenting the consent process will not be obtained. Studies using this method obtain consent through means other than in writing, such as verbally, online or through audio or video recording. A document similar to a written consent form is either read to (via an oral consent script) or provided electronically to the participant. The participant will indicate their decision either verbally or electronically. The IRB may grant a waiver of consent documentation if the research meets one of the following criteria.

- Criterion 1 – The principal risks are those associated with a breach of confidentiality concerning the participant's participation in the research, and the consent document is the only record linking the participant with the research.
- Criterion 2 - Study participation presents minimal risk of harm to the participant and the research involves no procedures requiring consent outside the context of participation in a research study.

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C. Written Consent
Written consent refers to obtaining the participant’s or their legal representative’s signature on a consent form. The consent form should be used as a tool to discuss the research study with the participant. The subject should be given adequate time to read the consent form and to have his/her questions about research answered by the researcher before signing the consent form. The signed consent form provides a record that the consent process took place. Electronic signatures are not allowed.

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Elements of Consent

The IRB has prepared a consent form template, which includes all of the elements of consent as described in the Federal Regulations (45 CFR 46.116). This template must be used to create all consent forms (e.g., written, online, verbal, etc.). The consent form template is available on the IRB website. The consent form should be typed in a 12-point font and should be written in a language that can be understood by a person having a tenth-grade reading level.

Non-English Speaking Subjects

If non-English speaking subjects will be enrolled in research, a translated version of the English language consent must be prepared and submitted. In addition, the qualifications of the individual who translated the document must be described.

Subject Who Cannot Read or Write

The written consent form may be read to the subject or their representative if the subject cannot read or write. The consent form should document the means by which the subject communicated their agreement to participate. An impartial third party should witness the consent process and sign the consent document.

Prisoners

If prisoners will be enrolled as study subjects, the consent form should include a statement to inform the prisoner that their decision to participate will have no effect on the charges pending against them, their prison sentence, or their release from custody.

Forbidden Language in Consent forms

Consent forms may not include language through which the subject is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

5.3 ADVERTISEMENTS

The IRB must review and approve the exact wording and graphic appearance of all advertisements used to recruit subjects. Copies of all advertisements (flyers, newspaper ads, internet, emails, or other materials) must be included with each application. Advertisements to be used to recruit research participants must contain the following information:

- Identification as advertisement for research
- Condition under study/the purpose of the research
- A summary of the eligibility criteria
- The anticipated time commitment
- Location of the research
- A description of the benefits or payment to the subject if applicable*
- The name of the person to contact for further information

* A***dvertisements may not emphasize the amount to be paid; you may not use large or bold type when indicating amount to be paid.***

5.4 Recruitment of TCSPP Students, Faculty and Staff

Requests to recruit TCSPP students, faculty or staff via their TCSPP email address will be processed as follows:

Internal Request

The IRB will approve internal request to use the TCSPP directory to recruit students, faculty, and staff for participation in TCSPP research provided the recruitment material was submitted as part of an IRB approved research study. The advertisement must include the required information noted above. Recruitment emails will be sent from the TCSPP research email account and will contain the contact information of the Principal Investigator for interested participants. Requests will be sent only once on a designated day. Additional approval from the TCSPP Office of Institutional Research may be required. Instructions on how to use the TCSPP directory can be found on the IRB website.

External Request

The IRB will approve external request to recruit TCS students, faculty, & staff in research studies provided the request is received in writing and is accompanied by proof of IRB approval. The advertisement must include the required information noted above. Recruitment emails will be sent from the TCSPP research email account and will contain the contact information for the Principal Investigator for interested participants. Requests will be sent only once on a designated day.

5.5 Research with Special Population

Federal regulations require special precautions be taken when enrolling subjects who are classified as vulnerable populations. This includes but is not limited to the following populations.

5.5.1 Children

Per 45 CFR Subpart D the IRB is required to consider the risks and discomfort in relation to the benefits to the child and/or to society as a whole prior to granting approval for studies involving children. The defined categories of approvable research involving children are as follows:

- Research not involving greater than minimal risk
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject
- Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Research with children may be granted expedited approval if the IRB determines the study is minimal risk to the subject and it falls into an appropriate expedited category.

Child Assent/Parental Consent

Generally, all research enrolling individuals under the age of 18 will require written consent of the minor's parent or legal guardian. Consent must be provided by at least one parent/legal guardian, except in instances where the research presents more than minimal risk and offers no direct benefit to the subject. In such instance the consent of both parents will be required unless one parent is deceased, unknown, incompetent or not reasonably available.

The IRB may waive parental consent if the study is enrolling a population of children for which parental or guardian permission is not a reasonable requirement to protect the subject (for example, neglected or abused children), provided an appropriate mechanism for protecting the child is in place

Additionally, the IRB must determine if appropriate provisions have been made to obtain the assent of the minor if they can reasonably be consulted. This assent is an indication that the child has agreed to their participation in the research study. The IRB may waive the assent requirement if the child cannot reasonably be consulted due to age or condition and the requirements for a waiver have been met. If the IRB determines that the assent of minor is required, research that will not directly benefit the child may not proceed without the assent of minor. A separate assent form or an oral assent script can be prepared for this purpose. The assent form or assent script must explain the study to the child in a language they can understand.

5.5.2 Wards of the State

Wards of the State may not be included in research that is greater than minimal risk and likely not to directly benefit the subject unless it is related to their status as wards or is conducted in schools, camps, hospitals, institutions or similar setting in which the majority of children are not wards. Please contact the IRB office for more information.

5.5.3 Prisoners

The TCSPP IRB will consider research proposals that intend to enroll prisoners as participants. As defined by the federal regulations, a prisoner means an individual involuntarily confined or detained in a penal institution and encompasses individuals sentenced to such an institution under a criminal or civil statue; individuals detained in other facilities by virtue of statues or commitment procedures which provide alternative to criminal prosecution or incarceration; and individuals detained pending arraignment, trial or sentencing [45 CFR 46.303(c)].

The research must fall into one of the categories noted below.

- It is a study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

- It is a study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

Location

A copy of a letter from the institution where the subjects are incarcerated or IRB approval (if appropriate) must be included with the IRB application. Alternatively, if an institution request that the study be approved by the TCS IRB prior to their consideration, then a letter of support from an individual in authority at that institution must be included with the IRB application.

Recruitment

The procedures for the selection of subject must be fair to all prisoners and free from arbitrary intervention by prison authorities or prisoners.

Informed Consent

Written informed consent must be obtained from all participants. The consent form must be written in a language that is understandable to the subject population. The consent form must include a statement to inform the prisoner that their decision to participate will have no effect on the charges pending against them, their prison sentence, or their release from custody.

Benefits

Any benefits that may accrue to the prisoner should not be of such a magnitude that his or her ability to weigh the risks of the research against the value of the potential benefits is impaired.

Risks

The study must present no more than minimal risks or inconvenience to the prisoner subject and must be equal to the risks that would reasonably be accepted by non-prisoner participants.

Review Requirements:

The prisoner representative member of the IRB Committee must review all studies that intend to enroll prisoners as research participants. The prisoner representative will review the initial submission, addendums, and continuing renewals. Additionally, addendums request to add prisoners as a study population will be reviewed by the prisoner representative and subject to the above requirements.
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5.6 USE OF ARCHIVAL/EXISTING DATA

Investigators may wish to use archival or existing data. Archival data is defined as data that is in existence at the time the study proposal is submitted to the IRB for review. This data may include but is not limited to information obtained from client records, database information, or test results.

Research using only archival data is considered a retrospective study. To ensure that only retrospective data will be used, the Investigator should provide the IRB with dates in which the data was originally collected. Additionally, the IRB application must describe the information that will be culled from the archival data set including permission from the original researcher to access this data. To help determine the review category and appropriate consent method the researcher should clarify whether or they will have access to information to which could be linked to the subject.

5.7 After Submission

Upon receipt of a new IRB application, the IRB staff reviews it for completeness. The IRB staff will notify the Principal Investigator and their Dissertation/Thesis Chair (if applicable) regarding any incomplete applications or any issues that need to be resolved prior to consideration by the reviewer and/or committee.

6 Functions of the IRB Committee

6.1 Review of New Applications

The IRB Committee considers the entire application as a whole to ensure the requirements for approval have been meet.

Requirements for Approval

Per 45 CFR 56.111, the IRB must determine that the following requirements are satisfied in order to approve a research study. These requirements must be satisfied for research eligible for exempt review.

i. Risks to subjects are minimized. To make this determination, the IRB considers whether or not the study procedures are consistent with sound research design and whether or not the procedures unnecessarily expose subjects to risk.
ii. Risks to subjects are reasonable in relation to anticipated benefits, if any to subjects and the importance of the knowledge that may be expected to result. The IRB considers only the risks and benefits that may result from the research, as opposed to the risks/benefits of procedures or treatment that potential subjects would receive even if they were not participating in the research.
iii. The selection of subjects is equitable. In making this determination, the IRB must take into account the purpose of the research as well as the setting in which the study will be conducted. Furthermore, the IRB must determine whether enrollment or lack of enrollment of vulnerable populations is appropriate.
iv. Informed consent will be sought from each prospective participant or their legally authorized representative. This requirement may be waived provided it meets the regulatory requirements for a waiver or alteration of informed consent (see Section III).
v. Informed consent will be appropriately documented. Copies of signed written consent forms should be included in the study records, securely housed by the investigator for a minimum of five years.

vi. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
vii. Where appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data including.
viii. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguard have been included in the study to protect the rights and welfare of these subjects.
    a. Where some or all of the subjects are expected to be children, the study fulfills all regulatory requirements
    b. Researchers must describe measures taken to protect confidentiality, including where records will be stored, who has access to records, how and when records will be destroyed.

Application Status

After review, a letter will be sent to the Principal Investigator and their Dissertation/Thesis Chair (if applicable) to describe the status of the application.

i. Upon receipt of Notice of Exempt Determination, Expedited Approval, Full Approval, or Non-Human Subjects Determination the researcher may begin the proposed study.

ii. Request for Modifications
The investigator may not begin the proposed study until the requests stipulated in the letter have been addressed and one of the letters noted above has been issued All documents revised in response to these issues must be uploaded in the IRB Electronic System and if requested, accompanied by a memo detailing the changes to the study.

.Any responses received after 60 days may require review of the entire application.

Any revised applications that the IRB Member Reviewer feels requires further discussion by entire committee will be considered at a convened IRB meeting.

No research may be started until all issues noted in the letter have been addressed and a formal approval letter has been issued.

iii. Defer
The application has been reviewed at a convened IRB meeting. However, additional information must be provided in order for the Committee to make a determination of risk to participants. The response to the Committee's concerns and the revised application must be reviewed at a convened IRB meeting.

iv. Rejected
The IRB may reject a study if the study poses severe or unnecessary risks to the participants and the revisions needed would significantly change the study design or procedures. If an application is rejected any intention to conduct, a revised version of the study must be submitted as a new application.

6.2 Level of Review

Exempt

Certain applications may qualify for Exempt review. These studies involve minimal risk to the participants and fall into one of the categories below as described in the federal guidelines. The requirement for approval must be satisfied for research that is eligible for exempt review. **Please note that institutional policies require that the IRB or its delegates make the final decision regarding whether research qualifies as "exempt." Researchers may not make this determination.**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests, surveys, interviews or observation of public behavior unless (1) information is recorded in such a manner that the subject can be identified directly or through identifiers; (2) any disclosure of the subjects' responses outside the research could place the subject at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research involving the use of educational tests, surveys, interviews or observation of public behavior that is not exempt under category B if (1) the human subjects are elected or appointed public officials or candidates for political office or (2) a federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of **existing data***, documents, records pathological specimens, or diagnostic specimens if the sources are publically available or if the information is recorded by the investigator in a manner that subjects cannot be identified directly or through identifiers linked to the subjects. ***Existing data is defined as materials that are "on the shelf" at the time the research is submitted to the IRB.***

5. Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine (1) public benefit or service 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 method or levels of payment for benefits or services under those programs.

6. Research involving taste and food quality evaluation and consumer acceptance studies (1) if wholesome foods without additives are consumed or (2) 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 safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If complete, these studies will be reviewed by IRB staff and do not require consideration by the full committee. The investigator will receive written notification of the IRB decision regarding their application.

Expedited Review
The Federal regulations (45 CFR 46.110) provide that certain types of research may be considered for review through an expedited process. In order to qualify for expedited review statements 1 and 2 must be true and the study must fall into one of the six categories listed below.

1. The research activity poses no greater than minimal risk to the subjects **and**;
2. The identification of the subjects and/or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal **and**;
3. The project falls under one of the six expedited categories listed below.
    i. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from (a) healthy, nonpregnant adults who weigh at least 110 lbs; (b) other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency of collection. *For these subjects, the amount drawn may not exceed the 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.*
    ii. Prospective collection of biological specimens for research purposes by noninvasive means. For example hair/nail clippings, external secretions, saliva, mucosal skin collected by buccal swab.
    iii. Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example: (a) physical sensors that are applied either to the surface of the body; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, ultrasound, Doppler blood flow, and echocardiograpy; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
    iv. Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis).
    v. Collection of data from voice, video, digital or image recordings made for research purposes.
    vi. Research on an individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Studies that meet the requirements for Expedited Review will be reviewed by a single IRB member and do not require the consideration of the full committee.

Full Committee Review
Any study that involves greater than minimal risk or does not meet the requirements for Expedited or Exempt review will be considered by the committee at a convened IRB

meeting with the majority of IRB members present. The researcher and their Dissertation/ Thesis Chair (if applicable) will be notified if their application requires review by the full committee. All studies that require full review will be assigned to a single reviewer who will present the study to the Committee for discussion. Studies are not assigned to reviewers who are the Principal Investigator, Dissertation/Thesis Chair, Readers, or faculty who are in the same department as the Investigator.

The Committee will discuss the study until a consensus for approval, request for modifications, defer, or rejection is reached. Investigators and their Dissertation/Thesis Chair (if applicable) will be notified in writing of the Committee's decision.

6.3 Addendum Requests

Any revisions to an approved research studies must be submitted to the IRB for review. These changes may include modifications to any of the following:
• research design
• subject population
• consent form (written or oral script)
• recruitment procedures
• data collection materials (i.e., questionnaires, surveys, etc.)
• advertisements

Investigators wishing to amend their study must complete the Addendum Request Form in the IRB electronic submission system. The completed form must explain the desired changes and provide a rationale for those changes. A revised copy of all applicable documents (consent forms, advertisements, questionnaires/survey) should also be submitted for review=.

Completed Addendum Request Forms will be reviewed by the IRB staff or designee. The IRB staff will notify the Principal Investigator and their Dissertation/Thesis Chair (if applicable) regarding any issues that need to be resolved prior to IRB review. Addendums that reflect simple or administrative changes that do not increase the risks to subjects will be reviewed by the IRB staff and an approval notification will be issued. Addendums that represent a significant change in study design or increase risk to study participants will be considered by the Committee at a fully convened IRB Meeting.

Investigators and their Dissertation/Thesis Chair (if applicable) will be notified in writing of the IRB's decision regarding the addendum request. **Research modifications described in Addendums may not be initiated until IRB approval has been obtained.** The IRB office must also be notified of proposed changes to Exempt and Non-Human Subjects research.

6.4 Continuing Renewal Request

The IRB grants a 12 month approval p for research proposals. The federal regulations require that all active studies receive IRB review no less than annually. This review is required if the

enrollment of participants and/or the collection of study data will exceed the expiration date . As a courtesy, the Principal Investigator will receive email renewal notifications 60 and 30 days prior to the study expiration date.

Researchers requesting to renew their study must complete the Continuing Renewal Request form describing the progress of the research. In addition, the researcher should also submit a copy of the approved consent form(s), recruitment materials, and questionnaires/surveys for review. These documents must be submitted at least 30 days prior to the study expiration..

Completed Continuing Renewal Request forms will be reviewed by the IRB staff. The IRB staff will notify the Principal Investigator and their Dissertation/Thesis Chair (if applicable) regarding any issues that need to be resolved prior to IRB review.

The IRB Chair or designee may grant expedited approval of Continuing Renewal Request provided the renewal falls under one of the categories listed below.

• The research was originally reviewed and approved under expedited procedure and continues to fall into one of the expedited review categories listed above in Section 6.3.

OR
Continuing review of research previously approved by the convened IRB as follows:

- where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- where no subjects have been enrolled and no additional risks have been identified; or
- where the remaining research activities are limited to data analysis;

Renewal requests that do not fall into one of the above categories will be considered by the Committee at a convened IRB meeting. Investigators and their Dissertation/Thesis Chair (if applicable) will be notified in writing of the IRB's decision regarding their renewal request.

Failure to submit the Continuing Renewal form or respond to the renewal notification email prior to the expiration date will result in automatic expiration of the study until a new application can be submitted and approved.

Reporting Requirements

Any occurrence of noncompliance, deviations, unanticipated problems, adverse events and complaints by subjects must be reported to the IRB office. to the IRB in ~~writing~~ Every complaint received by the IRB is taken seriously and will be thoroughly investigated.

Investigation
When a report is received the Investigator will be immediately instructed to discontinue all research activities(if applicable) until the investigation is complete. The IRB Chair, Institutional Official, Academic Dean, Department Chair and Dissertation Chair (if applicable) will be notified. An examination of the complaint along with the purpose of the study, the consent form, method

of recruitment, and all other study related materials as necessary will occur to determine the level of seriousness. The Principal Investigator is required to submit documents that the IRB deems necessary to complete this examination. Based upon this evaluation the following steps will be taken.

All reports will be evaluated and investigated by the IRB Director or Associate Director and IRB Chair to determine the level of seriousness. If necessary, the report may be presented to the committee to determine the level of seriousness.

Serious Noncompliance

All incidents determined to be serious will be presented to the committee and the following steps will be taken.

1. The IRB committee will discuss the incident to consider the potential risk to participants as well as whether or not the incident reflects continuing non-compliance and determine a corrective action plan..
2. The corrective action plan will be sent in writing to the Investigator, Department Chair, Dissertation/Thesis Chair as appropriate.
3. The appropriate regulatory agencies will be notified of the incident, as applicable.
4. Documentation of the incident, the investigation, and the resolution will be maintained within the appropriate IRB file.

Non-Serious Issues

If an incidence is deemed to be non-serious in nature, the following steps will be taken.

1. The IRB Director or Associate Director and IRB Chair will recommend a corrective action plan.
2. The corrective action plan will sent in writing to the Investigator and their Dissertation/Thesis Chair, as appropriate.
3. Documentation of the incident, investigation, and the resolution will be maintained within the appropriate IRB file.

7 INTERNAL SURVEY RESEARCH

All internal survey research proposals related to TCS ES operational activities and studies for internal management, including but not limited to research conducted for program evaluation, quality assurance, quality improvement, fiscal or program audits, and marketing studies will be reviewed by the OIR IRB representative. The OIR Representative will review the study to ensure it meets the appropriate requirements for IRB Exemption (Section 6.2) particularly making sure that the information collected is not recorded in a manner that the subject could be identified directly or through identifiers; and that any disclosure of the subjects' responses outside the research could place the subject at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. If OIR determines that the research proposal is exempt from IRB review, the Office of Institutional

Research will proceed with the review as described in the OIR Internal Survey Policy. The Investigator will be notified that the study is exempt from IRB review and will be processed according to the OIR Internal Survey Policy. If the proposal does not meet the requirements for IRB exemption, the Office of Institutional Research will advise the applicant to submit an application to the IRB for review.