Institutional Review Board
Application Packet
For research beginning after January 21, 2019

Introduction
Taylor University is committed to the protection and ethical treatment of human subjects in the research process. To fulfill this commitment, Taylor University established the Institutional Review Board (IRB) to review ALL research conducted by or on Taylor University constituents. Taylor University’s IRB is federally registered with the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). This registration allows Taylor’s IRB to provide Federal Wide Assurances (FWA) for research projects involving human subjects. Taylor’s registration number is FWA00016004.

Changes have been made to the Common Rule that impact how Taylor University faculty, staff, and students conduct research involving human subjects. These changes have been incorporated into the Revised Common Rule, also known as the Final Rule, which is scheduled to go into effect for research beginning after January 21, 2019. For complete details, refer to https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html.

The following terms are drawn from the citiprogram.org and the hhs.gov websites.

“Clinical trial” means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. The definition of clinical trial should be used for determining which studies require posting of the IRB-approved consent form used to enroll subjects.

Written or In Writing includes electronic formats. The definition does not preclude the possibility that consent forms could be in media other than paper or electronic formats and still meet the requirements of the Common Rule.

The term Vulnerable (to coercion or undue influence) is not included as a definition but is updated as a criterion (46.111) for approval of research. The Final Rule no longer includes pregnant women, handicapped and physically disable individuals as examples of populations potentially vulnerable to coercion or undue influence. The Final Rule uses the term “individuals with impaired decision-making
ability” to replace “mentally disabled persons”. The vulnerability of the subjects in research studies should be considered as a function of the possibility of coercion or undue influence.

**Deception** is not included in the definitions section of the Final Rule but under 46.104(d)(3)(iii) it specifies that “authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research in”.

**Generalizable knowledge** is undefined and unaddressed in the Final Rule. *Taylor University is required to define what standard is used and consistently apply this definition across all processes and documentation.* This includes the thought that the results are intended / expected to be applied to a larger population beyond the site of data collection or the population studied.

**Practically** appears in the consent waiver and alteration sections of the revised rule. It is undefined but is recommended to be interpreted as impracticable to perform the research not impracticable to obtain consent due to financial or administrative burdens, without the waiver or alternation.

**Key Information** is undefined but is an important regulatory term. Key information must be prioritized by appearing at the beginning of the informed consent and be presented first in the consent discussion. According to the Final Rule’s preamble, a brief description of five elements at the beginning of the consent form, and informed consent process, would encompass the required key information. The five key elements are:
1. The fact that consent is being sought for research and participation is voluntary.
2. The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research.
3. The reasonably foreseeable risks or discomforts to the prospective subject.
4. The benefits to the prospective subject or others that may reasonably expected from the research.
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

**Broad Consent** is a new concept presented in 46.116(a) and (d) which addresses elements of consent for the storage, maintenance, and secondary research use of private information or identifiable biospecimens (blood, cells, etc.). It involves seeking prospective consent to unspecified future research. Broad consent may be obtained only for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

**Secondary Research Use** is not defined in the regulations but is referred to as re-using (for research purposes) identifiable and non-identifiable information and biospecimens that are collected for some other “primary” or “initial activity” (such as from research studies other than the proposed research study). The information or biospecimens that are used for secondary research would generally be found by the investigator in: records, archives, information systems, databanks (in the case of information), or tissue repositories. There is no requirement that the information and biospecimens must be pre-existing at the time that the investigator begins a research study.

The definition of “human subject” now references “information and biospecimens” (replacing “data”) and adds obtaining, storing, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens as trigger events. 46.102(e)(1)(i) clarifies that investigators may “obtain”
(possess) information and biospecimens without triggering the human subject definition until they use,
study, or analyze the information or biospecimens

All principal investigators must complete the CITI certification for Social and Behavioral (or
Biomedical) Human Subject basic refresher course. A copy of the certificate must accompany this
application.

To access CITI training:

- Go to https://about.citiprogram.org/en/homepage/
  - If you have never used CITI click register in the upper right corner of CITI home
    page. Proceed to step 1.
  - If you have used CITI before log in and go to Taylor University courses then add a
course. Skip to Step 7.

- Step 1 - Select Taylor University (your organizational affiliation)
- Step 2 - Enter your personal information (first and last name, email address)
- Step 3 - Create a username and password, and a security question
- Step 4 - Continue answering questions regarding gender, etc.
- Step 5 – the answer is No
- Step 6 – must enter TU email address, department and role in research (i.e. student
  researcher – undergraduate)
- Step 7 - check social and behavioral human subjects – basic course

Review and Approval process
All proposals reviewed will be classified into one of eight categories as established by OHRP. Six of the
eight are detailed below. The other two are omitted from this document because they involve federal
agents (category 5) or are unchanged from the pre-2019 rule (category 6). A brief description for each
category follows. For more detailed information, please visit the OHRP web site at

EXEMPT:
Category 1: Research in Established or Commonly Accepted Educational Settings - research is not likely
to have adverse impacts on students learning required educational content or assessment of educators
who provide instruction.

EXEMPT with LIMITED REVIEW:
Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior - exemption as long
as one of the three criteria is met:
  1. Information obtained is not identifiable
  2. Disclosure outside of the research would not put subjects at risk of harm
  3. Information obtained can be identifiable but the IRB has done a limited IRB review in keeping
with 46.111(a)(7), which relates to there being adequate provisions for protecting privacy and
maintaining confidentiality.

Research could be exempt that is any of the following: (1) Not Identifiable, (2) Does not pose any risk if
there is disclosure (regardless if identifiable or not), OR (3) Does not pose any risk if there is limited IRB
review in keeping with the 46.111(a)(7) criteria. The Final Rule revised this category to include visual or
auditory recording as research methods. Surveys also cannot include collection of biospecimens or
interventions, as those additional activities would disqualify the research from this category. When the
research is subject to Subpart D and includes children, Category 2 still does not allow surveys or
interviews or the observer participating with children (public behavior observation without intervention is permitted).

**Category 3:** Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects (New Category). Benign behavioral interventions are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing” (HHS 2017). An example provided is having subjects solve puzzles under various noise conditions.

**Category 4:** Secondary Research for Which Consent is Not Required. This category covers secondary research uses of identifiable private information or identifiable biospecimens. Category 4 is exempt and does not require informed consent if at least one of the following criteria is met: (1) Use of publicly available identifiable private information or identifiable biospecimens, (2) information recorded by the investigator in such a way that the identity of the subjects cannot be readily, ascertained, and the investigator will neither contact the subjects nor re-identify subjects, (3) research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA (4) analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

**REQUIRED LIMITED REVIEW:**

**Category 7:** Storage or Maintenance for Secondary Use for Which Broad Consent is Required (New category) This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis. The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.

**Category 8:** Secondary Research for Which Broad Consent is Required (New category) Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent. Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

*The three determinations (exempt, expedited, and full) are still applicable; however, some changes have been made.*

**Exempt** – The proposal is reviewed only by the chair and determined that it is exempt from further review. Although a research project may be exempt, based on the categories above, limited review may be needed.

**Limited Review (previously termed as Expedited)** – The proposal is reviewed by two members of the IRB. In a limited IRB review, an IRB must conduct a review and make certain determinations as a condition of exemption. For example, that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” (46.111(a)(7)).
Full – The proposal is reviewed by the full IRB. Proposals that would require full review include, but are not limited to the following:

- Research involving populations subject to undue influence or coercion (including children)
- Research that exposes subjects to more than minimal risks
- Research that is particularly private or sensitive in nature

Regardless of the level of review, the IRB considers the following issues about your research:

This list is drawn from the National Institutes of Health IRB protocols.

1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.
3. Subject selection is equitable.
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.
5. Informed consent is obtained from research subjects or their legally authorized representative(s).
6. Risks to subjects are minimized.
7. Subject privacy & confidentiality are maximized.

It is the goal of the IRB to complete the review process within one week of submission, however, this may not be possible for proposals that require a full review. It is extremely important that all information is provided that is requested. Incomplete proposals will be returned and will delay the review process.

Submission

To submit a proposal to the IRB, you must complete and submit a complete research proposal that includes the following:

- Name of the Primary Investigator and all secondary investigators
- If you are a student conducting the research, you MUST list and have approval from a sponsoring faculty member.
- Description of the project’s
  - Goals
  - Design
  - Hypotheses and/or research questions
  - Location
  - Procedures and
  - How the data will be obtained
- Description of participant population(s)
- Description of how the data will be analyzed and disseminated
- Identification of Risks to Participants
- Attach a copy of the Informed Consent form
- Attach complete copies of any interview or questionnaire instruments that will be used
- Attach copy of NIH certification

Instructions
To submit a proposal application to the IRB:

- Complete all sections of this proposal application by editing the document with Microsoft Word®.
- Print off and sign the assurances section (page 3). If you are a student conducting the research you MUST have a faculty sponsor sign this form. Scan the signed form and save as a .pdf, .tif or .gif file type.
- Review IRB check list to ensure you have addressed all areas of the proposal requirements
- E-mail the complete proposal and all associated files (including all protocols, consent forms, cover letters, etc. and assurances signature page) to IRB@taylor.edu.

Proposals will be reviewed in the order submitted. Once the review is completed, you will receive notification from the IRB indicating if the proposal was approved and the level of review.
Request for IRB Review of Research Involving Human Subjects

Taylor University institutional policy and federal regulations require that research projects involving human subjects be reviewed to consider:

1. The rights and welfare of the individual(s) involved
2. The appropriateness of the methods used to secure informed consent
3. The balance of risks and potential benefits of the investigation

All research involving human subjects should complete this application. Please send this form with any supporting documentation to IRB@taylor.edu. Questions may be directed to IRB@taylor.edu.

Section A: Applicant Information and Assurances

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Researcher Assurance: IF THIS APPLICATION IS SUBMITTED ELECTRONICALLY (THROUGH TAYLOR UNIVERSITY’S BLACKBOARD SYSTEM) THIS PAGE DOES NOT NEED TO BE SIGNED BY HAND. PLEASE TYPE RESEARCH NAMES AND DATE. THE ELECTRONIC SUBMISSION WILL SERVE AS YOUR CERTIFICATION AND AGREEMENT.

I certify to the following:

1. The research will not be initiated until written approval is obtained from the IRB.
2. I have completed the appropriate training for human subjects protection through CITI or other appropriate program.
3. The proposed research includes only those activities described in this application.
4. I will obtain prior written approval for modifications to this project, including but not limited to changes in procedures.
5. I will report to the IRB any unanticipated problems and adverse effects, as well as my findings during the course of the study that may affect the risks or benefits to the subjects.
6. I agree to keep records of IRB approved documents and to retain research data with appropriate confidentiality.
7. I understand that this research is subject to continuing review and approval by the IRB.
8. The information on this application is correct.

______________________________________________ Date __________________________
Researcher #1

______________________________________________ Date __________________________
Researcher #2

______________________________________________ Date __________________________
Researcher #3

______________________________________________ Date __________________________
Researcher #4

Faculty Advisor Assurance: (Student research only includes graduate students)
I have examined the proposal, and I assume the roles and responsibilities required to oversee the conduct of this research, prevent harms to subjects and foster benefits to the subjects. I will report any significant and relevant changes in the research proposal, adverse events, or incidents to the IRB. I have also received certification for human subjects’ research and can confirm that the students have received appropriate certification.

____________________________________  _______________________________  __________________
Faculty Name (print)    Signature    Date

Instructions:
If this submission is not being completed using Taylor’s Blackboard system: Once signatures have been obtained, please scan this page and submit it with the completed application to IRB@taylor.edu.
Section B: Project Description

Briefly, but completely, answer the following questions. Please keep the use of technical phrasing and/or jargon to a minimum. Explain in terms or phrases that may be unclear to those who would be reviewing your material and who are not in your field. [*Please type your information into this Word document. Simply keep typing and use as much space as needed*]

You MUST respond to ALL questions

1. Describe the project’s
   a. Goals
   b. Design
   c. Hypotheses and/or research questions,
   d. Location (Where will the study be conducted?)
   e. Procedures, and
   f. How data will be obtained

2. Describe your participant population(s). Include (a) age, sex, and approximate number (b) inclusion/exclusion criteria if any. (c) method of recruiting, and (d) inducement to participate.

3. Describe how data will be analyzed and disseminated.

4. Describe security procedures for privacy and confidentiality. Describe how all data collected will be handled and stored—and when, if ever, forms, or identifiers will be destroyed such that the participants’ confidentiality or anonymity will be protected.

**IF THIS PROPOSAL IS USING EXISTING DATA or DATA SETS SUCH AS NSSE OR HERI ONLY YOU MAY STOP HERE. ALL OTHERS COMPLETE QUESTIONS 5-7 AND THE INFORMED CONSENT FORM.**

5. Identification of Risks to Participants. Remember there are always risks, even if it is exposure to the normal risks of everyday life.
   a. Please describe any foreseeable risks (physical, emotional and social) to the participants. Include any methods or devices that will be used to limit participant risk. Describe any distress that might be caused by the research. If distress is a possible outcome, describe the planned procedures for debriefing the participants after the research is conducted.
   b. If you would like to request a waiver of written informed consent, please explain how the use of written consent would impede the research or needlessly jeopardize the participant’s confidentiality. Explain how you will guarantee that oral consent has been
secured. Researchers proposing to use oral consent must provide a copy of the consent document that will be read to participants.

c. Please describe the consent process by explaining when and how the participant’s consent will be obtained. Describe additional steps that will be taken to ensure the participant’s right to withdraw without penalty at any time and to guarantee their privacy and ensure confidentiality. Attach the consent form to this application. If participants include minors (under 18) or other populations who may not be able to give consent for themselves, describe how parents/guardians will be informed of the study and give their consent. If the research is part of an in-school or institutional study, what will teachers, officials or administration be told about the study, and how will their permission be obtained? (See sample consent form).

6. Describe how medical services will be provided if the subject suffers adverse health effects as a result of the research and who will bear the cost.

7. Attach complete copies of any interview or questionnaire instruments (including printouts from Survey Monkey or Qualtrics) that will be used.
Section C: Information / Informed Consent / Broad Consent Checklist

Complete an Information sheet, Informed Consent, or Broad Consent document. Categories refer to the HHS.gov categories referenced at the beginning of this document. The forms are available under the resources section of the Blackboard IRB Organization.

- An Information sheet is for exempt studies ONLY (category 1)
- An Informed Consent for exempt / expedited studies (categories 2-4)
- A Broad Consent is for studies involving biospecimens or personal information that may be included in future studies (categories 7-8)

For all studies, the following information is required:

A statement explaining the purpose of the research

A statement of the expected duration of the subject’s participation

A description of the procedures to be followed

A description of any reasonable foreseeable risks or discomforts to the subject, including invasion of privacy

A description of any benefits resulting from the research, either to the subject or others

A statement that informs the subject of his/her right not to be a subject in a research project that is also a teaching exercise

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

A statement informing the subject about how his/her anonymity will be guarded, e.g., that their confidentiality will be protected by assigned code numbers, be limitations of who has access to data, by data storage in locked cabinets, by locked computer files, etc., and, if relevant, noting the possibility that the Food and Drug Administration may inspect their records

A statement that the subject’s participation is voluntary, and that his/her refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

If written informed consent is required, a place for the subject to sign and date the form and a statement that the copy of the signed consent form will be given to the subject for his/her records

A statement describing the anticipated circumstances under which the subject’s participation in the research may be terminated by the principal investigator, without regard to the subject’s consent
For research involving more than minimal risk, an explanation that medical treatment is available if injury occurs, along with an explanation of what that treatment consists of, and where further information may be obtained. Additionally, the explanation should clarify whether compensation is available to cover injury–related expenses. [This is only to be used in research involving more than minimal risk. Consult the IRB for any changes to default language, such as when compensation is available]

A statement that identifiers might be removed and de-identified information or biospecimens used for future research without the subject’s consent; OR that the subject’s information or biospecimens will not be used or distributed for future studies, even if the identifiable information is removed

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subject and under what conditions that would occur

A statement that subjects do not waive legal rights by signing this form

If the subject is a minor or is not capable of giving consent, a statement of parental/guardian responsibility in consenting to the subject’s participation in the study with a place for the parent/guardian to sign and date the form in addition to the participant’s signature

The name, address, email, and telephone number of the principal investigator of the research project, and his/her affiliation with Taylor University. If the principal investigator is a student, the name, email and telephone number of the faculty advisor is also required

A statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to Taylor University’s Institutional Review Board at IRB@taylor.edu or the Chair of the IRB, Susan Gavin at 756-998-5188 or ssgavin@taylor.edu
Section D: Application check list

The following elements must be included (if applicable) in submitted proposals to be evaluated by the Institutional Review Board:

- Completed proposal application (Section A)
- Completed AND signed assurances page (page 4). Please scan the signed document for electronic submission
- Completed project description (Section B). Be sure to answer ALL applicable questions. If items are left blank, it may delay the processing of your submission
- Appropriate participant consent form (Section C)
- Letters of permission – e.g. Conducting research at another institution or work place environment or providing permission to use a survey instrument or other copyrighted material.
- Copies of ALL instruments to be used including cover letters or introductory emails.
- Copies of CITI training certificates.