Institutional Review Board Policy and Procedure

Table of Contents

Purpose

Bryan College's faculty carry out its mission to "Educate students to become servants of Christ to make a difference in today's world" in many ways including; teaching and learning in the classroom and in campus and community service. Bryan College faculty, staff and students also participate in research to contribute in their respective fields, empowering them to 'make a difference' and to better understand the meaning of 'today's world'. A trend of increased research activity at Bryan College is expected to continue as the college has expanded its offerings to include Engineering, Nursing, and Doctoral programs. The Christian values that guide all activities at Bryan College align well with generally accepted ethical principles applying to the treatment of research Human Subjects (45 CFR 46.102.2).

The Institutional Review Board (IRB) (45 CFR 46.101.g) at Bryan College (the institution per 45 CFR 46.102(f)) has been established to protect the autonomy and well-being of Human Subjects who are invited to voluntarily participate in research conducted by Bryan College faculty, staff and/or students (45 CFR 46.101.a). In order to comply with 45 CFR 46.101.2 the IRB, its chair or a member appointed by the chair, shall evaluate all research conducted by Bryan College faculty, staff, and/or students, as well as all research utilizing Bryan College faculty, staff, and/or students as Human Subjects.

The IRB Committee has the authority to approve such research with or without requiring modifications to research design and/or content or to reject research outright. Following modern conventions, the IRB and its members will refer to and apply ethical guidelines contained within the Belmont Report and 45 CFR 46, as they are applicable, including: Respect

for autonomy through informed consent and rights of refusal to participate; valuing the minimization of risk of harm over the benefits of data (45 CFR 46.111); and procedural justice. Rather than attempting to interpret the regulations concerning research in this document, Bryan College relies on the IRB chair and the IRB committee members to follow these regulations as they are in the most informed position to do so. All explanation and instruction within this document is made on the basis that the IRB chair and the IRB committee members are acting in accordance with 45 CFR Part 46 and are using that document and its supplements to inform their consideration of research for classification and review. Sub-sections of the 45 CFR regulations are noted within this document to help guide researchers in the preparation or revision of their applications and to guide the IRB Chair and IRB committee members in their review of those applications. Within 45 CFR Part 46, many references to related subsections are important and the researcher is advised to do their due diligence in preparing their application to conform to all applicable sections and sub-sections, not only to those noted in this document.

Committee Formation

The IRB is a committee established by the Academic Vice President /Provost (AVP), the Chief Academic Officer at Bryan College. As the Chief Academic Officer, the AVP has the authority to reject research proposals outright, but does not have authority to override the rejection of research proposals by the IRB. The IRB is a committee independent of other college committees. However, the IRB may at times rely on input from other committees and individual staff, faculty, and outside Subject Matter Experts (SMEs) to inform their decisions

when research proposals reach outside the IRB committee members' expertise. Each IRB Chair and IRB committee member will receive training through the Collaborative Institutional Training Initiative (CITI) relevant to their position on the committee.

Committee Membership

The AVP will appoint an IRB Chair, five IRB committee members- including one scientist, one non-scientist, and one member unaffiliated with Bryan College- and at least two alternate members. Alternate members will replace an absent IRB committee or a member who is a) recused from an application made to the IRB due to a conflict of interest; b) general involvement in the research being reviewed; or c) because no member may participate in the review of or vote on their own research. In appointing the IRB chair and IRB committee members, the AVP will ensure that "the IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall therefore include persons knowledgeable in these areas." (45 CFR 46.106.a). Each member will serve two-year terms in a manner that attempts to maintain the aforementioned diversity of membership for representation. In order to maintain continuity, the chair will serve a three-year term. If they are willing and if, upon the judgment of the AVP their continued membership is beneficial and aligns with the need for diversity of membership, members may serve multiple and consecutive terms.

Committee Function and Operations

Meetings will be held at least once a month when the committee has business, including; consideration of applications for approval, addressing changes in roles or membership, and discussing and revising internal policies and procedures – extra meetings may be added at the discretion of the AVP and the IRB Chair (45 CFR 46.108).

Before meetings begin, the IRB chair will confirm a quorum of the members in attendance, noting any alternates that will be acting as voting members and the reason for those alternate votes (for example, the absence of a member or the recusal of a member due to a conflict of interest in an application).

During the meetings, each application for IRB approval will be handled separately, with discussion pertaining to the application, evidence, and any modifications required for approval prior to a vote (45 CFR 46.109). In the absence of sufficient information, the committee may invite Subject Matter Experts or request additional information from the researcher. This may be done during the meeting (for example, by inviting a readily available Subject Matter Expert into the meeting or by calling the researcher to ask a question, etc.) or the application may be postponed for review at the next meeting so that the information may be obtained prior to the next meeting. Minutes should reflect these efforts and identify the presence and reason for the presence and modality of communication of anyone outside the committee membership. Further guidance for best practices in the keeping of IRB minutes can be found on the HHS.gov website here. During the meetings, the IRB Committee will be apprised of any IRB Exemptions

and Expedited Review of research that were approved by the IRB chair or appointed member since its last meeting.

A simple majority of the quorum of voting members, including any voting alternates, will be required to approve, approve with required modifications, or reject a proposal. The Department of Health and Human Services offers guidance here on setting conditions for modification of research through conditional approval. Committee members are advised to review these best practices and use them as applicable. Minutes will be kept in accordance with 45 CFR 46 (defined later in the IRB Records section of this document).

Relationship to Institutional Effectiveness

Bryan College is dedicated to Institutional Effectiveness (IE), an effort which often includes surveying students/faculty/staff and results in the collection and storage of data. IE staff are trained to differentiate between the simple surveying of students and research by the 45 CFR 46 criteria. IE staff defer research-related requests for surveys to the IRB. IE staff may consult with the IRB chair to make this determination in case of uncertainty. It is expected that, as allowed by 45CFR 46.104.d.2, much of the testing and use of testing data by instructors and IE Staff as well as surveying of students by an instructor within their own class will be exempt and thus will not require IRB application.

Research Review Process

All researchers will apply to the IRB before contacting Human Subjects or beginning data collection using the Application for IRB Review. Only complete applications will be reviewed.

Incomplete applications will be returned to the researcher with an explanation of what information was missing or insufficient and an invitation to reapply with a complete application. If the researcher is a student, a faculty member must sign the application, agreeing to supervise the research in accordance with the approved application and required modifications.

Prior to IRB approval, researchers are forbidden from: Contacting subjects directly; collecting subject data; or using subject data. After receiving IRB approval, researchers are forbidden from modifying the research or performing the approved research outside of the approved time period. Researchers identifying the need to modify the research may submit a new application and must not continue the research until the modified research design is approved by the IRB. Specifically, research approved based on an application that did not involve Human Subjects but which has changed to require Human Subjects must be suspended until the researcher reapplies and is approved for the use of Human Subjects (45 CFR 46.119). Researchers identifying the need to extend the duration of the research beyond the approved time period may apply for an extension.

To avoid any confusion as to the status of an IRB proposal, researchers should only consider their research approved when they have completed the required CITI Principal Investigator Training and have received their approved application, signed by the IRB chair, including the time period in which the research may be conducted.

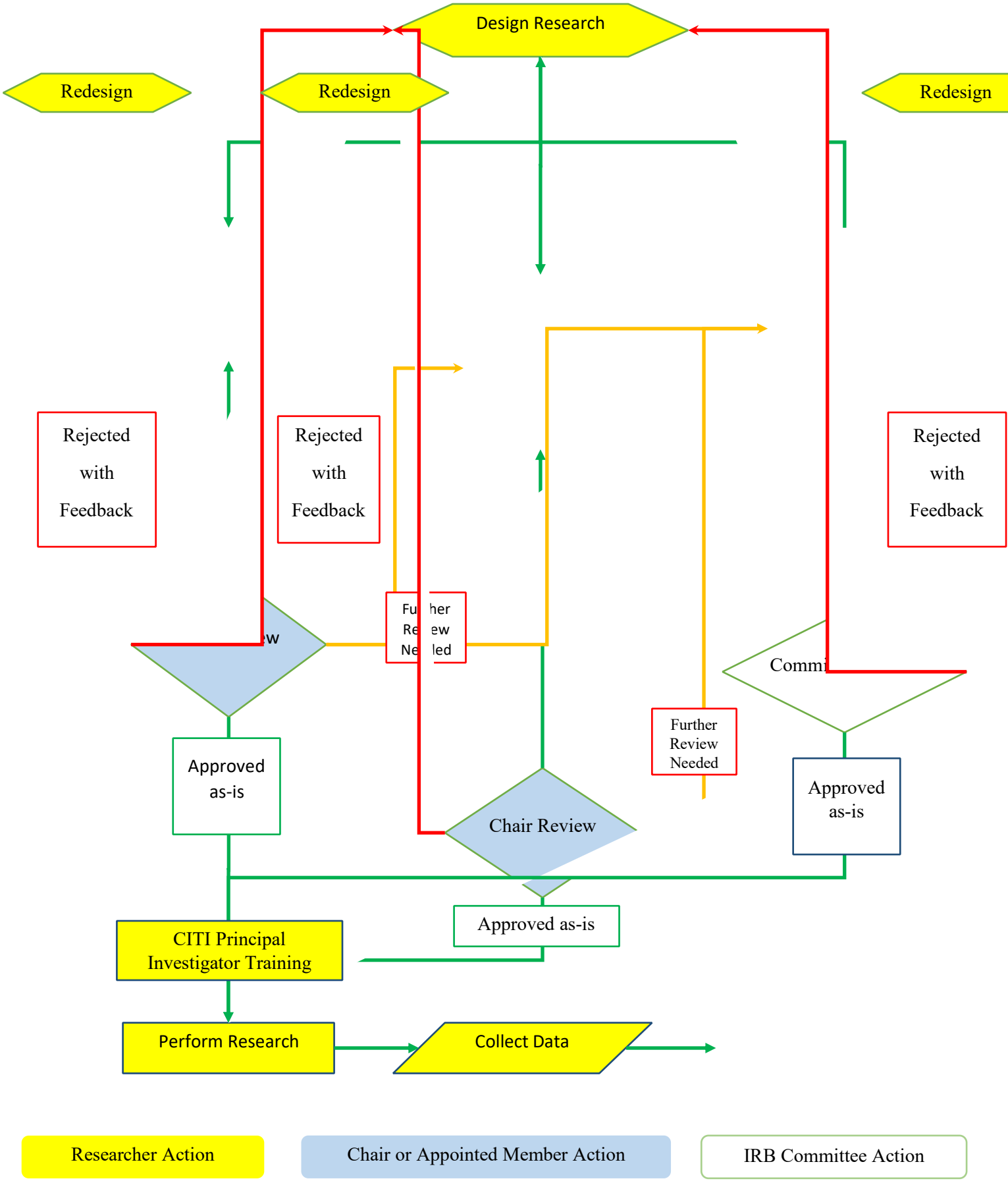
It is likely that IRB approval is not required for the following: student evaluation of faculty within a course; faculty survey of students within their own courses for discussion in class; or supervisor/administrator survey of their own faculty; faculty research outside of Bryan College.

Researchers are advised to complete the IE or IRB Exemption approval process to ensure that is the case.

External Research Performed by Bryan College Faculty

Research performed by a Bryan College faculty member outside of the College (using Human Subjects elsewhere) and outside the faculty member's role at Bryan College does not require IRB approval from Bryan College but is subject to the Faculty Handbook and approved Conflicts of Interest policies. However, if IRB approval is required for research conducted at another institution, it is likely that institution will require the Chief Academic Officer's approval or IRB approval from Bryan College in order to approve the research at that institution (45 CFR 46.114). Thus, an Application for IRB Exemption and good communication with the AVP is advised.

Flowchart on next page


Design Research
Redesign
Redesign
Redesign
Rejected with Feedback
Rejected with Feedback
Rejected with Feedback
Approved as-is
Further Review Needed
Chair Review
Further Review Needed
Approved as-is
Approved as-is
CITI Principal Investigator Training
Perform Research
Collect Data
Researcher Action
Chair or Appointed Member Action
IRB Committee Action

Research Complete

Review

For

Exemption

Full Review

Expedited

Review

Review of Applications for Exemption

In order to avoid researchers continuing with their research under the false assumption that their research was exempt from the IRB review process and in order to expedite the review process, Bryan College allows researchers to apply for exemption using the Application for IRB Review form (included as an Appendix to this document) as allowed in 45 CFR 46.104.

Upon receipt of an Application for IRB Exemption, the IRB chair will confirm receipt of the application with the researcher and enter the application into the IRB log. Review by the IRB chair or an IRB committee member appointed by the IRB chair is required for IRB Exemption (45 CFR 46.110). The IRB chair may either review and make a decision to approve, deny, or approve with modifications or the IRB chair may delegate this to a member of the IRB committee. Upon review:

1) If the Application is approved as-is, the researcher will be free to proceed with the assurance that their work is not subject to IRB approval once they receive their application signed by the IRB chair or the appointed IRB Committee member and for the following five years. The research may only be conducted as indicated on the Application for IRB Exemption and may not be modified. If the researcher wishes to

perform similar but modified research, they must reapply using the appropriate application to request the appropriate level of review;

2) If the IRB chair or the appointed committee member determines in review of the information included with the Application for IRB Exemption that the researcher's work is subject to IRB approval, the IRB Chair or appointed IRB committee member must then determine whether the research is subject to expedited or full review and proceed accordingly.

Review of Applications for Expedited IRB Review

Upon receipt of an Application for Expedited IRB Review of Research, the IRB chair will confirm receipt of the application with the researcher and enter the application into the IRB log. The Chair will then appoint an IRB committee member to perform the expedited review of research, noting which of the categories noted in 45 CFR 46.110 qualifies the research for Expedited IRB Review. The appointed IRB committee member may request further information from the researcher, confer with the IRB Chair in making determinations and may ask for revisions to the research design before approval. Research approved by the Expedited IRB Review is subject to IRB Policies and Procedures. During the Expedited investigation, the appointed IRB committee member may determine that the research requires a Full IRB Review of Research, in which case the application will be placed on the IRB committee's agenda at the next scheduled meeting by the IRB Chair.

Review of Applications for Full IRB Review

Upon receipt of an Application for Full IRB Review of Research, the IRB chair will confirm receipt of the application with the researcher and enter the application into the IRB log. Prior to the next scheduled IRB Committee meeting, the IRB Chair will confirm completeness of the application. If complete, the IRB Chair will place the application on the agenda and share the application with the committee for review prior to the meeting; if incomplete the, IRB chair will return the application to the researcher, inviting the researcher to reapply with a complete application.

The application and all associated information and materials will be considered by a quorum of voting members (including any alternates that are voting). The IRB committee may, during that meeting; vote to approve as-is, require modifications, or deny the application; request more information from the researcher; or invite Subject Matter Experts to inform their decision, referring to 45 CFR 46.112). The Department of Health and Human Services offers guidance here on setting conditions for modification of research through conditional approval. Committee members are advised to review these best practices and use them as applicable. If the IRB Committee requires modifications, the researcher must confirm modification by resubmitting the application to the IRB chair. The researcher may not begin the research without approval of the re-submission review. Upon approval of an Application for Full IRB Review, the researcher may begin their research within the constraints of the approved application. The IRB may suspend or terminate IRB approval of research if they determine the research has exceeded the constraints of the approved application, referring to 45 CFR 46.113.

Informed Consent

The Bryan College IRB Committee will require, review, and retain Informed Consent documents in compliance with 45 CFR 46.116. A sample Informed Consent document will be provided as an example of what an Informed Consent document could contain related to a ~~fairly~~ simple research design, noting that the actual required content will vary based on the researcher's actual research design. The researcher is responsible for preparing and submitting an Informed Consent document specific to their research that includes the elements required in 45 CFR 46.116 as part of their application for IRB Expedited and Full IRB Review ~~to be reviewed by the IRB~~. Further guidance on the preparation of Informed Consent statements can be found on the HHS.gov website here. The researcher is responsible for collecting, storing, and, if required by the IRB, sharing Informed Consent documentation with the IRB (45 CFR 46.117).

Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects

Some researchers may submit applications for IRB review which lack detail in the treatment of Human Subjects - usually due to grant funding requirements, these proposals should be noted as such by the researcher upon application and will be reviewed by the IRB in accordance with 45 DFR 46.118.

Data Security

As part of complying with regulations protecting the privacy and autonomy of human subjects, Bryan College requires that the researcher prepare, include with their application for Expedited

IRB Review or Full IRB Review, and maintain a data collection and storage plan that conforms to 45 CFR 46. Typically, hard copies of survey responses should be stored in a locked cabinet and electronic copies in a password-protected file location. Unless the Human Subject has specifically authorized identifiable data use (for example, in mixed methods studies where the respondent is named and quotes or survey responses are paired with the individual's name), the researcher should make every effort to store responses in such a way that individual data are not able to be associated individual Human Subjects.

IRB Records

In compliance with 45 CFT 46.,115, the Bryan College IRB will maintain:

> "(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
>
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
>
> (3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not be required as described in §46.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

(8) The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records related to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed or electronic form. . All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner." – 45 CFR 46.116.

Appendix I -Revision History

Date	Revision	Reason and Description for Change
		Established Policy and Procedure Initial Issue approved by …
		Formation of Initial Committee Added names, titles, affiliation and rationale for membership
		Forms and documents Revised and Approved by the Initial Committee

Appendix II - IRB Application

I. Applicant(s)/Researcher(s):

Provide the Name and Title for each individual responsible for the research being presented for IRB review in this application. If the primary researcher is a student, include a faculty research supervisor. If there are multiple researchers, indicate the role(s) of each researcher. If one researcher is primary and the others are secondary, indicate the primary researcher.

Name School Title Role Primary

II. Reason:

Indicate the reason for the research. For example, a student may be performing research for an assignment, to complete their degree or to participate in the Bryan College Undergraduate research project.

III. Describe the goal of the research, including the research problem and the research question and null hypothesis.

IV. Describe the research design/methodology, including procedures (a chronological and hierarchical list of steps to be taken) with dates.

V. Describe and include text, pictures, attachments of methods (types of interventions, surveys, questionnaires, tests, etc) and instructions to Human Subjects.

VI. Describe the population and the sample population of the research.

VII. Describe the sampling procedure of the research, indicating the rationale for choosing that sampling method for the population described above.

VIII. Identify the likelihood of involvement of Human Subjects from special populations (such as pregnant, incarcerated, or minor participation) and explain what special care has been taken to minimize risk to those potential Human Subjects.

IX. Identify and explain any known risks to the Human Subjects, including the perceived likelihood of a Human Subject encountering each negative consequence of participation.

X. Explain the care that has been taken in the research design to minimize each risk identified above.

XI. Explain any known/anticipated/possible benefits, direct, indirect, immediate, or latent to the Human Subjects.

XII. Explain the care that has been taken in the research design to make the benefits above equitable among Human Subjects and to minimize the impact of the benefits above on the results of the research.

XIII. Explain any known/anticipated/possible benefits to the sample population, population and/or society in general.

XIV. Explain how Human Subject data will be stored, including measures that will be taken to protect anonymity, confidentiality and access to data. (e.g. The data will be stored in an encrypted folder…, The Google form will be password protected, etc…)

XV. If relevant, disclose the funding source of the research and provide a summary of how the funding will be allocated to perform the research.

XVI. Utilizing the Sample Bryan College Informed Consent form and the requirements in 45 CFR 46.116, prepare and provide an Informed Consent statement to be used in this research.

XVII. Indicate the level of application for IRB Review being sought for this r esearch and provide rationale, referring to the relevant sub-section of 45 CFR 46.104 and/or 46.110:

The Bryan College IRB suggests that researchers use the decision chart provided here to make this determination

If it meets the criteria of 45 CFR 46.104.(?), etc.(*indicate the sub-section(s)*)

_Expedited This research meets the criteria of 45 CFR 110.(?),etc.(*indicate the sub-section(s)*)

_Full IRB Review Exceeds the conditions for Exempt 45 CFR 46.104 and 45 CFR 46.110

XVIII. List the step (above – I, II…XVII) supported by each piece of evidence included outside of this application template, including its type, title, location, and format (examples follow):

Step	Material type	Title	Location	Format
IV.	Timeline	Research Timeline	Attached	.xls
V.	Questionnaire	*Theory XY Questionnaire*	Attached	.pdf
V.	Video	Funniest commercials ever	www.123.com	.mp4
V.	Questionnaire	Survey questions	http://…..	Google Form
XVI.	Informed Consent	Informed Consent	Attached	.doc

XVIV. Signatures:

By signing this document, I affirm that all information provided in this document, supporting material (listed above) and discussions with the IRB Chair and Committee are true and, if approved, I accept responsibility for ensuring the research described above will be carried out as approved by the Bryan College IRB.

Copy and paste the list from I. (above) and add signatures.