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Board membership

The Rhodes College Institutional Review Board (IRB) membership composition must meet or exceed federal regulations. Specifically, the IRB must be minimally comprised of five individuals. Of these five individuals, one must be a scientist, one must be a nonscientist, and one must be unaffiliated with the College. Federal regulations require gender and professional diversity. To address these regulations, the Rhodes College IRB consists of six members. Three positions will be filled by faculty members, of which one will fulfill the role of IRB chair. Two positions will be filled by staff members, of which one will be affiliated with Student Affairs. The final position will be filled by an individual unaffiliated with the College. The Dean or an Associate Dean of Academic Affairs will be invited to serve as a non-voting, ex-officio member of the IRB.

New members will be identified by the IRB chair in consultation with the Dean of Academic Affairs and will be submitted for review by the Faculty Governance Committee. In selecting new members, consideration will be given to the expertise represented across disciplines while intentionally ensuring gender and racial diversity in the composition of the board. Members are appointed to a three year term with the possibility of serving two consecutive terms.

Board function

The Rhodes College IRB is tasked with reviewing all research affiliated with Rhodes College that involves work with human participants. In reviewing these research proposals, our mission is to ensure all steps are taken to protect the rights and welfare of individuals who participate as subjects in human research activities.

Research is defined by the Office of Human Rights Protection as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

As a secondary purpose, the Rhodes IRB seeks to ensure that the College and members of its research community are compliant with the ethical standards and regulations governing human subject research.

IRB authority

Rhodes College has a Federal-Wide Assurance through which we have committed to the Department of Health and Human Services (DHHS) to comply with federal regulations regarding research involving human participants. Specifically, we are committed to ensuring research involving human participants that is affiliated with Rhodes College is consistent with the principles outlined in the Belmont Report and DHHS regulations 45 CFR Part 46. Our FWA provides the Rhodes IRB with the authority to review, approve, require modification in, or disapprove research activities affiliated with the College.

The Rhodes College IRB will convey decisions and requirements for revisions in writing. Investigators have the option to appeal to the IRB in the case of disapproval or request for

modification(s). Furthermore, no committee or official can approve an investigator to undertake research involving work with human participants that has not been approved by the Rhodes College IRB.

Meetings

The IRB will normally convene six full-board meetings per semester and three full-board meetings each summer. The primary purpose of these meetings will be to review proposals that require full-board review. Review of full proposals will only occur in convened meetings of the IRB. A secondary purpose of these meetings will be to provide a summary of all exempt and expedited applications that have been received and approved electronically by email. Full-board votes require a quorum of IRB members. At least one member comprising the quorum must be a nonscientist. Deliberations and discussions of protocols involving conflicting viewpoints will be documented in meeting minutes.

Pre-meeting distribution of materials to the IRB

The IRB chair will provide the following materials at least three days prior to the meeting:

1) Agenda
2) Protocols and supporting documents for review
3) Minutes from previous meeting
4) Summary of exempt and expedited reviews
5) Other materials for consideration

Meeting Minutes

The primary purpose of IRB meeting minutes is to document the justification for the IRB's decision on each protocol reviewed. Any identifying information associating opinions or votes to a particular member of the IRB should be avoided. Meeting minutes should be reviewed and approved or modified at the subsequent full-board meeting. Finally, minutes will be retained for three years, and protocol-specific records will be retained for three years following completion of the research.

Meeting minutes should include:

1) Attendance
2) Conflicts of Interest/Recusals
3) Actions taken by the IRB
    a. Vote (including the number of members for, against and abstaining)
    b. Justification for requiring change or disapproving research
    c. Summary of discussion and debate on any protocols
    d. Documentation that all requirements for approval are met
4) Report of the chair on all exempt and expedited review activities

Records and documentation

All records, documentation, and minutes will be stored on a password-protected server. Access will only be granted to individuals currently serving on the IRB and the Dean of Academic Affairs. Additionally, a summary report will be delivered to the Dean of Academic Affairs annually by the IRB Chair.

IRB Member Training

IRB members will receive CITI training upon joining the board. Additionally, all IRB members will complete a review of procedures and policies at the first full board meeting each year.

Chair duties

The chair is responsible for the following duties:

1) Organize annual training for IRB members
2) Verify that all reviews are correctly categorized as exempt, expedited or full-board upon receipt
3) Review all exempt applications
4) Review all expedited applications and assign reviews to at least one additional reviewer
5) Prepare and distribute all materials relevant for full board meetings
6) Combine and deliver all reviewer feedback with the IRB decision to the PI in a timely fashion
7) Notify PIs when a protocol is approaching the deadline for renewal or closure
8) Write the annual summary of the IRB's activities for the dean of Academic Affairs

Member duties

IRB members are responsible for the following duties:

1) Complete CITI training for IRB members
2) Complete Rhodes IRB training annually
3) Attend IRB meetings of the full board
4) Provide timely feedback on expedited reviews
5) Provide feedback on full board reviews during IRB meetings

Conflicts of interest

IRB members must identify any conflicts of interest and immediately recuse themselves from voting on any related protocols. In instances in which the chair discloses a conflict of interest, the appointed faculty member of the IRB with the most seniority (i.e., longest serving member of the IRB) acts as Chair for that protocol.

Consultants and Expert Advice

The IRB may retain the expertise of others to facilitate the review of a protocol as necessary. Although consultants may participate in full-board meeting discussions, they will not be allowed to vote.

Requests from non-Rhodes Principal Investigators

The Rhodes IRB will only review protocols that have a Rhodes affiliated Principal Investigator (PI). Studies that make use of Rhodes facilities or involve systematic recruitment of Rhodes students, staff or faculty (through a Rhodes official or any Rhodes sanctioned student organization) for the sake of conducting research (e.g., an internet-based survey) must be approved by the Rhodes IRB. In turn, this requires a Rhodes PI (or co-PI) for all studies being conducted on the Rhodes College campus or with members of the Rhodes College community as research participants.

Multi-site studies or reviews

Studies involving two or more investigators at different research sites may be approved by the IRB affiliated with either site. Rhodes College IRB is willing to accept the approval of the other college's IRB if an Individual Investigator Agreement or IRB Authorization Agreement is completed and submitted by the Rhodes co-PI with the original IRB application submitted to the other site. If Rhodes College IRB review is required, all procedures and policies are applicable (e.g., use Rhodes IRB application forms, submit documentation of ethics training for all on-site and off-site research team members, etc.).

Auditing investigators

The Rhodes IRB reserves the right to audit investigators or individual studies for establishing compliance with federal regulations. Moreover, audits will verify whether or not studies are being conducted within the limits of the IRB approved protocol. Routine audits may occur when the IRB selects an investigator or specific protocol for review. Alternatively, audits may be conducted when complaints or concerns are reported to the IRB about a particular protocol or PI.

Reporting Unanticipated Problems and Adverse Events

Principal investigators are required to report unanticipated problems and adverse events promptly after their occurrence. PIs should use the appropriate form and submit their report no more than five working days after the incident is reported to the investigator. A separate report must be filed for each incident. Upon receipt of the report, the IRB chair will convene a panel to review the incident, and the panel will decide what corrective action will be required, which may include (but is not limited to) modifications to the project or termination of the project entirely. Severe incidents will be reported to Dean of Academic Affairs and the OHRP as required by federal regulations.

Unanticipated problems are regarded as "unanticipated problems involving risks to subjects or others" (HHS regulations at 45 CFR part 46) and have been further specified by the OHRP as "any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research

protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized."

Adverse effects are defined as: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. However, some examples of such incidents that are not limited to biomedical research include (but are not limited to): physical or emotional harm, a breach in confidentiality or privacy, and any problem that increases the risk to participants' rights and safety.

For more information, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q1

Investigator Responsibilities

Investigators must commit to protecting the rights of human participants, and in doing so, PIs commit to the following:

1. Applications will clearly demonstrate compliance with IRB and federal guidelines for ethical research with human participants.
2. Research team members will be fully trained to conduct research ethically with human participants, and evidence of training will be submitted to the IRB.
3. All incidents involving unanticipated problems or adverse events will be reported within the specified timeframe.

Maintaining Records

All records pertaining to approval of the original protocol, amendments, and continuing reviews, as well as all signed consent documents, must be maintained for three years beyond closure date of the study based on federal guidelines. However, research records for protocols subject to HIPAA regulations must be securely retained for six years following closure of the study. These records must be available

for review or audit by the IRB throughout the duration of the study and for the three years following closure of the study.

Protocol submission, continuation, and revision

Principal Investigators (PIs) are responsible for understanding the procedures for submitting a proposal to the IRB, and in turn, they take full responsibility for the submitted proposal, all research activities associated with the research study, and all subsequent actions that must be taken to maintain IRB approval of their studies. Students may not serve as PIs.

Each application should clearly state the study's objectives, scientifically sound methods, research implications, and detailed consideration for the risks to which participants will be exposed. Specifically, the PI must clearly address the following items in each submitted protocol:

1. How does the proposed study satisfy ethical standards set forth within the PI's discipline and in the broader context of the Belmont Report?
2. What risks may be encountered by participants? How are risks minimized in the proposed design?
3. Are all members of the research team qualified to conduct the proposed research?
4. Have all research team members completed (and submitted proof of) an ethics training course that has been approved by the Rhodes College IRB?
5. Does the PI (and research team) have access to facilities and resources for successfully and ethically completing the research project?
6. Does the PI (and research team) have sufficient access to the participant population? Will the sampling procedure and data be adequate to meet the study's objectives?
7. If deception is used, is it justified? How will participants be debriefed?

It is expected that applications will always be submitted with documentation of the procedures used to obtain informed consent and will be submitted with the following documents when relevant:

1. All research instruments (e.g., surveys, questionnaires, interview scripts/questions, sample stimuli, debriefing forms, advertisements, phone call scripts, email solicitations, etc.)
2. IRB authorization agreements from other institutions (in the case of multi-site studies)
3. Letters of support for access to resources, venues, etc. that are not directly managed by the P.I.
4. Evidence of Rhodes College IRB approved ethics training (if not already on file) for each member of the research team
5. If conducting research in a classroom setting (with minors), signed letters from the principal and classroom teachers providing consent for students to participate in the study.

Please note that additional documentation may be required based on the nature of a given study. The above list is not designed to be exhaustive. Instead, this list is designed to give examples of the documentation necessary to demonstrate that the proposed study is feasible and is likely to satisfy the objectives of the proposed study.

See section on Amendments for a discussion of the procedures involved in modifying an existing protocol.

See section on Continuing Reviews for a discussion of the procedures involved in extending the study beyond the IRB approved duration.

Review Procedures

There are three levels of review: exempt, expedited, and full. All research projects involving human participants must undergo review regardless of level. IRB approval is good for up to one year minus one day. However, the IRB reserves the right to shorten the period of IRB approval for studies involving high risk. All expedited and full-board review research must undergo "continuing review" each year (at minimum). The data for continuing review is set by the IRB at the time of approval, and again, this period of time is influenced by the amount of risk involved in the study.

Although PIs indicate the level of review required for their projects when submitting their applications, the ultimate authority in categorizing studies as exempt, expedited, or full rests with the IRB.

Exempt Reviews

To be considered an exempt study, the proposed project must satisfy one or more of the following criteria:

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

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior that result in minimal risk, **unless** the information is obtained and recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under item (3) above; **if** the human subjects are elected or appointed public officials or candidates for public office; **or** 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** these sources are publicly available, **or** if the

information is recorded by the investigator in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.

6. Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the USDA.

The IRB chair will review all exempt applications and verify their exempt status. If one or more of the above criteria are not met and sufficiently justified, the application will be returned to the PI, and a request for an expedited or full application will be made. Please note that exempt status does not apply to research involving vulnerable populations (except research involving children and educational tests/observations), studies that record identifiable data with any level of risk, or studies that involve deception.

Expedited Reviews

Expedited studies will be reviewed by the IRB chair and one other member of the IRB. If there is disagreement between reviewers that cannot be resolved or if there is sufficient concern about the nature of the study, the application will be forwarded to full board review. Evaluation of the application will center on criteria generated from the Belmont Report. A list of studies that require expedited review can be found here.

Full Board Reviews

Studies that do not qualify for exempt or expedited review will be forwarded to all IRB committee members for full board review. Consideration for full board reviews will only occur in a convened meeting at which a quorum has been met. The application must be approved by all members present at the meeting. Otherwise, the application will be provisionally accepted or rejected. Any concerns voiced in this meeting will be forwarded to the PI and should be addressed through a revision to the application, a letter addressing IRB concerns, or both of these options. In instances that the protocol was provisionally accepted, the PI's response will be considered by the chair of the IRB. If the response satisfactorily addresses the IRB's concerns, the protocol will be approved. If the response does not comprehensively address the IRB's concerns, the protocol will be returned to PI for further modification. In instances that the protocol was rejected by the IRB, the revision and PI response will be forwarded to the entire IRB for consideration at the next meeting.

Amendments for protocols

Amendments to protocols with IRB approval can be made by resubmitting the approved electronic application with tracked changes. The proposed changes included in the amendment may be implemented upon approval. The project will retain its original approval expiration date and will not be adjusted based on the approval date of the amendment.

Amendments will be considered with expedited review if the proposed changes will not result in increased risk to participants AND if the study has had no unanticipated problems or adverse effects. Amendments will be considered with full review if the proposed changes increase the risk for participants OR if the study has had an unanticipated problem or adverse effect.

Continuing Reviews

Continuing reviews will be conducted at least once per year but may occur more regularly depending on the level of risk involved in research procedures. Similar to amendments, continuing reviews should be submitted by tracking changes on the original application if the PI wishes to make any modifications (e.g., increasing the sample size). If no changes are requested at the time of renewal, the original application should be submitted and accompanied by a note that no changes to the original protocol are requested. Note that continuing reviews should be submitted (and must be approved by the IRB) before the current IRB approval expires or the PI risks having to suspend research activities.

Closure Reports

Principal investigators should complete a closure report when all activities associated with a protocol have been completed. Specifically, a project is deemed completed when:

1. All interventions and interactions with participants are completed
2. Data collection is completed
3. Analysis and maintenance of identifiable data is completed.

Changes in research personnel

Changes in research personnel should be submitted using the amendment procedure. Evidence of ethics training should be submitted for new research team members if it is not already on file with the IRB.

Informed consent

Investigators must obtain documented informed consent from each participant involved in IRB approved protocols unless the IRB has granted a waiver of consent or an alteration as allowed by federal regulations. Please note that the IRB cannot grant a waiver of informed consent if the Family Education Rights and Privacy Act (FERPA; 20 U.S.C.§ 1232g; 34 CFG Part 99) or the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104-191, 110 Stat. 1936) is applicable.

A waiver of consent allows PIs to dispense with documentation of informed consent. Instead, the participants are provided with the same information contained in a consent document (either in written or verbal form), but a signed document is not required. Waivers of written consent may be granted for some or all research participants if either of the following criteria is met:

1) the research procedures involve no more than minimal risk such that the potential harm or discomfort associated with the procedures will not exceed the harm or discomfort experienced in daily life
2) a signed informed consent document would be the only record of an individual's participation in the study AND there is sufficient risk with a breach in confidentiality that warrants the waiver of signed consent.

Ethics Training for Research with Human Participants

All individuals engaged in research involving human participants must complete an ethics training program approved by the Rhodes College IRB. Training must be completed by all members of the research team before the project application will be considered by the IRB. The College provides training in the protection of human research participation (PHRP) through the Collaborative Institutional Training Initiative (CITI). However, the IRB will accept training through other approved outlets so long as documentation of completion is provided.

Acceptable PHRP ethics training will review the Belmont Report, federal regulations related to research with human participants, and issues for consideration when managing risk involved in human participant research. Additional training may be required by the Rhodes College IRB when relevant to the particular research question being addressed, the utilized method, or the research population (e.g., HIPAA, special populations). Researchers must obtain a minimum of 80% correct across CITI module quizzes to successfully complete ethics training.

Ethics training (or the appropriate CITI refresher course) must be completed every three years.

Researcher and College Conflicts of Interest

Conflicts of interests (e.g., funding source, a conflict of conscience) must be declared in the initial IRB application. If any conflicts of interest arise after initial approval of the study, these conflicts must be declared to the IRB within two weeks. To address any concerns regarding a PI's conflict of interest, the IRB may require PIs to state their conflicts of interest on consent forms, to modify procedures, or may reject the proposal if sufficient safeguards cannot be put in place to protect the integrity of the study.

The Rhodes College IRB maintains its authority to reject research proposals that the College wants approved as a means of protecting against an institutional conflict of interest. Although the College cannot insist that a study be approved that was otherwise rejected by the IRB, the College may further restrict or decline a project than what was approved by the IRB with sufficient justification. In

the spirit of the IRB, the justification for further restricting a study must be accompanied by a list of modifications that will be necessary for eventual approval.

Research by Students

Projects undertaken by students that are federally defined as "research" involving work with human participants must be reviewed by the Rhodes College IRB. Specifically, "research" is defined by the OHRP as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Even in instances in which IRB approval is not required, the expectation is that members of the Rhodes community will conduct all research activities with adherence to the highest ethical standards. Students may not serve as the Principal Investigator on any study. Thus, a Principal Investigator must be identified to guide the development of the IRB application, review the proposal, and provide oversight of the project.

Course-based Research

Course-based research may occur in various forms and for a variety of reasons. Projects that are conducted within the context of a class and are not intended to contribute to generalizable knowledge do not require IRB approval, unless they involve vulnerable populations or greater than minimal risk. Nonetheless, the Rhodes College IRB expects all necessary steps are taken to conduct such research activities ethically (including, but not limited to: obtaining informed consent, preserving anonymity where possible, minimizing risks). Ethics training is available for all members of the Rhodes community, and it would benefit all individuals engaging in research with human participants to complete this training regardless of whether or not the study requires IRB approval. Additionally, acquiring IRB approval prior to data collection allows for future publication or presentation of the data if such occasions arise.

If course-based research involves vulnerable populations, greater than minimal risk, or will be disseminated in any form beyond the classroom for which the project was assigned, it must be approved by the IRB. This includes (but is not limited to) local conferences and symposia (e.g., URCAS, public symposia for senior seminar projects), regional conferences, and national/international conferences.

Faculty-supervised, independent research

Whether research is conducted independently through a research practicum course, through a volunteer opportunity, or as partial completion of an honors thesis, it almost always will need IRB approval. These forms of research are designed to contribute to generalizable knowledge, and as a result, they meet satisfy the federal definition of "research."

Incentives and Compensation

Although incentives and compensation may be provided for participation in a given study and expenses incurred due to participation in a given study (e.g., travel expenses), compensation and incentives (e.g., gift cards) must be limited in their scope to avoid unduly influencing individuals to

participate in the research project. With this in mind, the IRB considers the value of the compensation or goods given for participation in a study while concurrently making several other considerations (e.g., the complexity of the procedure, socioeconomic considerations). PIs are encouraged to keep the following guidelines in mind when making decisions about participant incentives and compensation.

1. Participants must be informed of the types, amounts, and timing of compensation during the consent process.
2. Compensation Amounts
    a. The amount of compensation cannot be so large that it can exert undue influence.
    b. There is no set standard for what is considered "reasonable" compensation.
    c. Typically, $10-$20 per hour is considered acceptable. However, the scope of the procedures will be considered when evaluating compensation procedures.
3. Compensation cannot be contingent upon completion of the study procedures. Therefore, PIs are encouraged to include a procedure in which compensation is prorated. In some instances a prorated procedure will not be viable (e.g., a study which involves a single, 30 minute session with $5 compensation). Otherwise, researchers may wish to consider compensation for 30-minute increments, 60-minute increments, or for each session of a given study.
    a. Compensation must be awarded (even if it is partial compensation) if a participant withdraws from a study.
    b. Compensation should not be withheld across multi-session studies, and instead, compensation should be awarded at the end of each session.
    c. Bonuses for completing all sessions of a multiple-session (e.g., longitudinal) study may be awarded if the bonus is reasonable and amounts to a small percentage of the overall compensation earned from participation.
4. Lotteries
    a. Information about compensation awarded through lotteries requires explicit disclosure of procedural details.
    b. PIs must disclose in recruitment materials and consent materials:
        i. The amount of compensation
        ii. The estimated odds of winning
        iii. Individual who will draw the winner
        iv. Individual who will observe the drawing
5. Performance-based compensation
    a. Performance-based compensation must be clearly justified based on extant literature within the PIs field.
    b. PIs are responsible for reporting guaranteed compensation (e.g., for time and travel)
    c. PIs may report the additional potential compensation during the recruitment process if the full range of potential compensation is disclosed (i.e., the PI may not recruit for the study by emphasizing only the maximum amount of potential compensation). Otherwise, the PI may wait to disclose potential earnings until the consent process.

Data Security

Principal Investigators must provide and adhere to a plan for maintaining participant privacy and the confidentiality of their data. This is true regardless of whether data are collected, stored, and/or shared electronically or on paper. The level of caution that must be taken will depend on the risk involved in the study. For example, storing data on a password protected computer may be acceptable when data are de-identified but may be insufficient if the data contain sensitive information. Thus, the first step when designing a data security plan is to comprehensively assess the risk involved. This assessment should consider every element of risk from the type of data collected (e.g., are the data identifiable or sensitive in nature) to the devices used to collect and store the data (e.g., is it a portable device? If so, what happens if the device is lost or stolen?).

To facilitate the creation of a data security plan the PI should make the following considerations (note that this is not an exhaustive list, and the IRB will consider the unique elements of each individual application):

1) Timeline for de-identifying data (if applicable)
2) Storage location and security procedures for data before and after being de-identified
3) Separate storage of de-identified data and any keys for re-identification
4) Research team member access to identified vs. de-identified data

Technology-based considerations

1) Data encryption at the time of collection
2) Sufficient password strength
3) Secure data sharing procedures (e.g., emailing is generally not a secure procedure, and texting sensitive information is never a secure procedure)
4) Secure data storage when using Cloud-based platforms
5) Malware and virus protection software
6) Timeline of transfer from a portable device to a secure system

Even if your project is not supported by a National Institute of Health (NIH) grant, it is important to consider their requirements related to securing identifiable data from section 2.3.12 Protecting Sensitive Data and Information in Research:

> "Recipients of NIH funds are reminded of their vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known

and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act."

Finally, it is important to note that the current section outlines considerations and guidelines pertaining to data security and maintenance consistent with federal guidelines. The nature of a particular study may warrant additional considerations. For example, sharing data with international collaborators may invoke more specific actions or expectations with regard to data storage and sharing than those set out in the current policy.