Institutional Review Board - Human Subjects Research
Tips for Completing IRB Forms

• Principal Investigators for ALL research projects (except class projects) must complete the IRB Protocol Application coversheet and the IRB Protocol Application and include all supporting documents.

  PLEASE NOTE that all research involving human subjects (including research that uses archival data or protected health information) MUST SUBMIT A SIGNED, COMPLETED RESEARCH PROTOCOL APPLICATION. APPLICATIONS MUST BE APPROVED BY THE IRB PRIOR to subject recruitment and/or data collection.

• EXEMPT and EXPEDITED requests require an additional checklist to be completed. The appropriate checklist should be included with the protocol application.

• If uncertain of which type of review is most appropriate for the research project, review the checklists to determine if the research project fits one of the categories, review the IRB Policies and Procedures document, or ask for assistance from the IRB representative from the appropriate school/college.

• Full Board review protocols MUST be submitted by the first working day of the month to be considered for review.

• Complete the application coversheet in full. Many are returned because of lack of signatures, incomplete addresses, or lack of a title. Complete each line in total. Researchers MUST use their Maryville contact information for participant recruitment and research communication. Researchers may include additional contact information as well.

• Many protocols are returned because they are incomplete and inconsistent. Be sure that all sub-parts of all questions are answered completely (if a particular sub-part does not apply, indicate N/A) – this is particularly necessary for mixed methods studies where each question’s sub-parts may apply differently to different components of the study (e.g., risks vary for survey vs. face-to-face interview so risks for each aspect of the study should be noted separately). Also be sure that the details noted in each question are addressed consistently and completely in the Informed Consent document.

• The higher the risk, the more explanation needed about the proposed study. Remember to give the Board COMPLETE explanations of methodology. ANSWER ALL questions as listed in the IRB Research Protocol document. If an item does not apply, simply note N/A, but do not skip it

• Many protocols are returned because the informed consent does not meet the guidelines. Follow the directions carefully. PLEASE use the sample template and make sure the content included in the Informed Consent document is consistent with the content throughout the protocol.
• For all protocols, please provide one (1) copy of all documents submitted electronically – Preferably in a WORD document. Be sure to include all materials (recruitment documents [flyer/script], survey[s], data collection sheets, consent documents, human subjects education certificates for all researchers, permissions to collect data off-site) with the copy. Incomplete protocols will be returned un-reviewed.

• It is the responsibility of the Principal Investigator to secure all appropriate copyright releases for use of instruments (for research purposes) included in the research protocol. Do NOT assume instruments are in the public domain just because they are available on the internet.

• Use the IRB Reviewer’s Checklist at the end of the packet to be sure the researcher(s) have responded to all items. This is the document that reviewers use when evaluating protocols. For students, it is recommend to ask a colleague in an appropriate program to review the protocol using the checklist to assess for clarity and consistency prior to submission for IRB review.

Complete protocol application packets MUST include one (1) copy of all listed materials submitted ELECTRONICALLY:

☐ Application cover sheet with electronic signatures – PDF format
☐ IRB Research Protocol application including Consent/Assent Form(s) on Letterhead – WORD format
☐ Exempt or Expedited Checklist (if necessary/appropriate) – PDF format
☐ Appendices – format of choice
  o Subject recruitment document(s) – flyer, script, etc.
  o Research instruments (questionnaires, data collection sheets, observation sheets, interview questions, etc.)
  o CITI Certifications of Human Subjects protection training/education for ALL researchers (including faculty advisor, if Principal Investigator is a student)

When saving the documents to be included in the application packet, please use the following naming conventions: Last Name of Principle Investigator – Last Name of Faculty advisor (if applicable), Type of Document, and Date. For example:

Allen – Gocial Application Cover Sheet 1.21.2019 (PDF)
Allen – Gocial Exempt Checklist 1.21.2019 (PDF)
Allen – Gocial Appendices 1.21.2019 (format of choice)

All documents must be submitted electronically (preferably in no more than three to four separate files to the Administrator of the Maryville University Institutional Review Board, Dr. Kimberly Allen at irb@maryville.edu.
The IRB research protocol must address each of the following questions completely and thoroughly. Please download this application into a **WORD document** and type directly into the spaces provided. **Handwritten applications will not be accepted.**

The research protocol application must provide the IRB with the information necessary to make judgments regarding the criteria for approval. Remember that the Board is composed of individuals who may not be acquainted with the concepts associated with the research discipline. Define operational terms specific to the research protocol. It is important that **each question and all of its subparts** be thoroughly completed. There is no word limit per question and its subparts. If a subpart does not apply to the study, indicate “N/A;” do not simply delete that subpart. If the IRB receives insufficient information to make adequate judgments, the protocol review will be tabled followed by a request for more information. This could significantly delay the IRB review and approval process.

**NOTE:** All items in **Green** are merely tips for completing each question – please delete these tips as each question is completed. If the question does not apply, delete the tips and insert “N/A – Not Applicable”. Aspects of the protocol that are highlighted in **Yellow** are meant to provide guidance and stress the information being sought in that subpart of the protocol. **Please do not delete the questions or change the numbering of the questions.**

**Required Application Sections:**

1. **What is the purpose and significance of this study?**
   a. Explain the purpose and/or research questions/hypotheses of the study.
      - Using a 2-3 sentences, be brief yet descriptive and explain the purpose and significance of the study.
      - Include a purpose statement. Why is the researcher conducting the study? The purpose of this study is to...
      - Include Research Questions/Hypotheses. What does the researcher hope to learn by conducting the study?
   b. Indicate how the purpose of the study relates to previous research by including a **brief review** of the literature. It is especially important to indicate how experts in this area have previously studied the topic/construct so that the multidisciplinary Board has a clear indication of the appropriateness of the intervention. If the design is highly experimental, a more exhaustive literature review is required.
      - **BRIEF review, no more than 250 words**
      - Share a literature review including the theoretical construct and suggested design that provides the foundation for the proposed study.
      - Be sure to include appropriate references for key studies cited in this section. IRB does not need all of the project’s references, just those that are cited in the application.
2. Who will be the participants in this study?
   a. Identify all participant groups (e.g., teachers, college students, elementary school students, district administrators, pediatric patients, patients, caretakers).
      • For this part of the question, identify the general characteristics of participants (e.g., college presidents, student athletes for all team sports, parents of HS seniors, patients with a particular diagnosis).
   b. For each participant group, describe the basic characteristics of potential participants (e.g., anticipated number of subjects, age range, gender, racial/ethnic background) and indicate any special criteria for including or excluding individuals from participation (specific diagnosis necessary, etc.). If the researcher will exclude individuals with certain criteria (e.g., under 18, too many falls in 3-month period), indicate HOW the researcher will determine whether or not the participants meet the inclusion or exclusion criteria (e.g. inclusion/exclusion items at the beginning of questionnaire).
      • Give as much detail possible here regarding these categories as this area affects the IRB reviewers’ ability to provide protections and information for informed consent.
      • Age range = In particular, note whether participants will be over 18 – also note the upper age limit of your proposed participants (Note: HIPAA has special restrictions for patients 90+ years of age).
      • Inclusion = Think about the defining characteristics that are important for all of the participants to have – share those.
      • Exclusion = Think about the characteristics that disqualify prospective participants from inclusion (e.g., people who are not native English speakers, students who have transferred to the institution, Presidents who have been on the job less than 6 months, patients who have not yet begun treatment, patients who have completed treatment, patients with a contraindicating diagnosis, patients with an allergy to latex).

Recommended formatting

Inclusion Criteria
The participant must:
1. Be 18-20 years of age
2. Have completed.....
3. Have attended ..... 
4. Be enrolled as a ..... 
5. Diagnosed with....
6. Agree to be audio-recorded for....

Exclusion Criteria
Participants may not:
1. Be 90 years or older
2. Be a....
3. Have a contraindication of....
4. Have achieved more than....

The researcher will determine whether or not the participants meet the inclusion or exclusion criteria by.....
c. If this research involves vulnerable populations (e.g., children, the mentally disabled, prisoners) or others who cannot fully give informed consent, justify their inclusion in this research study.
- Anyone under 18 is considered to be part of a vulnerable population.
- Provide a few words about why vulnerable populations are included. In many cases, these groups are the focus of the research => that’s OK; these populations just require greater protections, so the IRB needs to know vulnerable populations will be part of the study and why.

d. Describe any relationship that currently exists between the researcher and potential participants (e.g., teacher-student; OT-patient; nurse-patient; administrator-teacher) and how that relationship will be delineated for purposes of this research.
- The greatest concern here is the perception of coercion and/or an authority’s expectations for participation. This authority could be a teacher, therapist, nurse practitioner, etc.
- The IRB is looking for how the researcher mediates any potential conflict of interest between the work done every day and the work done to conduct the proposed research.
- The researcher must delineate role and relationship and how the researcher will safeguard participants’ autonomy.
- Clarify that while some aspects of the classroom or job are required (e.g., must attend faculty development program), participants may choose not to include their DATA in the project.

3. How will potential participants be identified and recruited?
   a. Describe how the researcher will gain access to potential participants/participant groups, how participants will be contacted, and what information will be given to them as part of the recruitment process.
   - Is there an intact group to reach? How will the researcher gain access to the members of the group?
   - Make sure that to check with the organization or group about HOW the researcher can legitimately use membership lists (e.g., sending letter/e-mail, posting flyer, phone calls)
   - Information to be shared is typically a more basic list of information included in informed consent document.
   - Researchers who own or work at a medical clinic must still adhere to HIPAA regulations when accessing patient files for the purposes of research (See HIPAA Authorization Form and Waiver of Authorization Request Form.)

   b. If participants will be compensated in any way (monetary, gifts, course credit), indicate the nature of the compensation and the source of the funds to be used.
   - Any kind of incentive (drawing for a gift card, cash, prizes, extra credit, pizza for a focus group, etc.) should be noted here.

   c. Attach copies of all materials in the appendices that will be used to recruit participant (e.g., letters, advertisements, announcements, script).
   - If a flyer is posted where people will call or e-mail to participate in the study, include the flyer and a script used for those who respond so that the communication is consistent.
   - A script is also necessary if there is a verbal recruitment conversation (such as at a conference booth asking participants to take an anonymous survey).
   - The script could include setting appointments, special instructions, etc.
   - A copy of a SAMPLE recruitment flyer is available in the IRB section of the portal.
d. If participants will be identified and/or assessed through a cooperating institution/agency/school/business or other location (not Maryville University), provide documentation that the study has been reviewed and approved by the appropriate official, ethics committee or IRB of the institution.

- Typically the necessary documentation is an approval letter from the IRB at that location.
- Check on whether the organization has some type of IRB process (do this sooner rather than later) – some processes take up to two months.
- Depending on the participant population, a separate IRB review may not be necessary.

e. If participants will be selected from a school, hospital, or other organization, and that location DOES NOT have a separate IRB process, provide documentation that the study has been reviewed and approved to be conducted at that organization.

- Typically this is a letter of support from the organization.
- Note – not all organizations will allow use of their participants – or they may want Maryville IRB approval before they give the researcher their final letter. The IRB administrator will work with the researcher on this timing issue. However, it is important that SUPPORT for the project to be conducted and data to be collected at the location is included at the time the protocol is submitted for review.
- Note: If the PI is also owner of a clinical site, support for such access should also be provided by any clinic co-owners or supervising physician.

4. What methodology will be used to answer the research question(s)? Please describe all interventions, treatments, assessment procedures, or other sources of data that will be used / collected in the study. [The reviewer should be able to follow the proposed procedure exactly from the response to the various parts to this question.]

a. Describe what each participant (or group of participants) will be asked to do, including any interventions or educational programs, and all testing, observation, interviewing or laboratory procedures utilized to collect data. If observing or interviewing participants, please explain how all data will be recorded (video/audio recordings, field notes, etc.). Note the expectations for participants’ total time engaged in the study for data collection.

- Be specific here. Thinking about the process in small specific steps helps with logic and inclusion of all necessary information about the design and its potential impact on the participants.
- Include survey, focus groups, interviews (recorded or not), activity of some kind.
- If the project uses mixed methods, be sure to include specific methods for each aspect of the study.
- Note how data will be recorded => on-line survey, checklist, observation data sheet, etc.
- Ideally, data collection sheets should use codes (not names)
- If creating and using an electronic survey, the Maryville connection to Qualtrics (rather than Survey Monkey) MUST be used for this purpose.
- Be realistic about the amount of time each participant will need to be available to participate in the project.
- Demographics?
  - Where possible, use categories/ranges, not blanks (especially if there’s a group where few are expected)
  - Put demographic questions at the end of the protocol/survey unless needed to verify inclusion/exclusion criteria.
Recommended formatting

This research project will be achieved by conducting the following steps:

Step One:
Step Two:
Step Three:
Step Four:

b. If the research is being conducted in an applied setting (hospital, school, clinic, business) distinguish between programs or procedures already in place and those being added for this study.
   - Start with “normal operations”, then make it clear what is unique to the research and how that may differ from “normal operations”.

c. If this project is qualitative or an oral history project involving semi-structured or unstructured interviews or observations, provide a detailed description of the nature and scope of these procedures. This description should include the purpose of the interviews or observations plus information about where and by whom they will be conducted, the skill or training level of those conducting the interviews, how long the interviews will be, the type of information to be gathered and general areas to be covered, and sample questions or behaviors to be observed.
   - Focus groups are also included here
   - Location matters – private office / in the home / public space / conference room
   - Work to balance purpose and sensitivity of information collected with the location where data will be collected.

d. If archival data (data already collected for other purposes and on file) will be used for any portion of this study, the nature of the data archive should be described and the specific data to be accessed for the present study should be indicated. If the data are publicly available, state this. If not, describe how the researcher will gain access to these data and provide documentation of authorization to do so. If the project requires access to protected health information, indicate how the researcher will be meeting the expectations of the HIPAA Privacy Rule. Also note whether the researcher is seeking a Waiver of Authorization and if so, be sure to include the “Waiver of Authorization” form with the protocol.
   - Access and authorization are key components here
   - Example: Test scores, parents’ income, number of on-line courses taken and grades in each, previous diagnoses, number and dates of previous visits to nurse practitioner, participation in a health screening
   - If archival data was collected by the researcher, but for another purpose (e.g., health history), authorization to utilize that information for this project will come from participants directly, but you still need access to the data – how will you get it? (If the PI is also owner of a clinical site, support for such access should also be provided by any clinic co-owners or supervising physician.)
   - Note whether data will be de-identified when it is provided.
e. If **deception** is to be involved or if information is to be withheld from subjects, explain why this is necessary and describe procedures for **debriefing** participants.

- Sometimes the researcher may need/want to be circumspect regarding purpose of study or to be very vague to avoid biasing participants’ responses – that’s OK, but if saying one thing when the purpose is really something else, then need to be sure to debrief participants.

f. Attach copies of all instruments that are being used for the purpose of the study (e.g., tests, surveys, observations recording sheets, interview questions, laboratory reporting sheets, data collection sheets, debriefing materials). For all instruments not specifically created for this study, indicate whether Maryville owns the instrument or provide documentation (i.e., specific copyright release) of permission to reproduce or use the instrument in your research.

- Sometimes as simple as e-mail permission from instrument’s creator
- If the researcher creates an instrument, be sure to include the questions and response options (not just the questions) – if the instrument is adapted from an existing instrument, then cite the original instrument on the new instrument.
- If using Qualtrics, please use your Maryville account to create the questionnaire and include an active link for review. Please do not select “prevent ballot box stuffing” during the review.

5. **What are the potential risks to participants and what will be done to minimize these risks?**

a. Discuss any physical, psychological, social/economic, or legal risks that might result from participation in this research and assess the likelihood and seriousness of these risks. If methods will be used which create risks, explain why these methods are being used. In particular, note if pregnancy status or participation in other medical research creates a risk if this information is not disclosed by participants.

- Again, be specific here – include such things as potential for discomfort with the nature or content of the questions, potential breach of confidentiality, potential for embarrassment, etc. (as appropriate to the study)
- Be clear about cases where there is an inherent relationship (esp. a power differential)
- It is rare that a study has NO risks, so think broadly here about the potential for risks.

b. For each risk identified, describe actions that will be taken to minimize risk. In particular, note if there are alternative treatment options that might be available to minimize risks.

- Tie specific actions being implemented to minimize specific risks – e.g., To minimize risk of breach of confidentiality, all data are being coded; To maintain privacy, all interviews are being conducted in private, secure location and participants will choose a pseudonym
- Indicate how the power differential or relationship will be clarified and mediated

6. **What are the potential benefits and do they outweigh potential risks to the participants?**

a. Discuss any benefits to participants and to society that can reasonably be expected to result from this study.

- Be VERY cautious about promising potential benefits to individuals, but when appropriate, include them here
- OK to share how you hope the results will benefit educational / health care programs or whatever else the study is designed to help you understand
b. Explain why any risks are reasonable in relationship to these anticipated benefits.
   - Hopefully, risks are very minimal and can be mediated fairly easily, so that potential benefits will offset those risks.
   - This question should always have a response if ANYTHING is noted in 5a above.

7. What procedures will be used to protect the anonymity and confidentiality of subjects?
   a. Explain how data will be recorded and stored during the research, indicate who will have access to data, how data will be reported (e.g., class, report to organization’s officials, professional meeting, journal, doctoral cohort), and what will happen to data at the conclusion of the project.
      - For most people, the minimum is sharing a public report of the results to other students and faculty in fields directly related to the proposed study.
      - Indicate if the researcher plan to present the data on another campus, in a poster session, or other professional presentation at Maryville or at a conference.
      - Note HOW data from a particular location will be described (e.g., teachers from a Midwestern, suburban school district; nurse practitioners with specialty in nephrology) so that individuals and/or institutions are even less likely to be identifiable.
      - Ideally, where possible, data should be reported in aggregated form.
      - Note how data will be discarded (hopefully shredded, deleted from all drives) and at what point in time post-collection (one year, etc.). Original data may not be retained indefinitely, although it may be retained in a coded database.
      - Ideally, data are stored on password protected electronic devices.
      - Any informed consent documents or lists with participants’ identities (as tied to coding) should be stored separately from the actual coded data and from the signed Informed Consent documents and this should be noted. Please note that signed informed consent forms must be securely retained for 3 years following the conclusion of the study.
      - The IRB likes two levels of secure protection for the data (e.g., stored on a password protected computer maintained in a locked office).

b. Explain any limits to confidentiality (e.g., reporting requirements such as knowledge gained of child abuse, or thoughts of suicide/homicide are revealed).
   - This is typically a concern only in cases when sensitive information is being collected and participants have a presumption of confidentiality for information they are sharing with researchers.
   - If this is an issue for the research project, make a note of the circumstances under which confidentiality may be broken and to whom information would be shared (For example: Observing teachers in a classroom on pedagogy or talking with patients about a treatment area, but notice a student or patient who appears to be abused – need to break confidentiality as the researcher in the project to protect their safety.)
   - Ideally, the researcher is taking great care with the procedures to minimize this need.

c. If audio-recording or video recording is involved, describe how recordings will be stored and what will be done with them at conclusion of study (destroyed/deleted; stored for a period of time then destroyed/deleted; archived for further study).
   - It is typical that original audio recordings are destroyed immediately after being transcribed and verified against the original.
   - It is also typical that original recordings or digital files are destroyed not later than 3 years following the conclusion of the data collection.
d. If Internet or Web-based surveys are used, describe procedures for guaranteeing confidentiality.
   • Ideally, IP addresses are not being collected so that confidentiality is more likely to be maintained.
   • It is possible that a web-based survey would include the use of IMPLIED consent rather than Informed Consent. **If so, the first page of the study would include the Informed Consent template** with a statement at the bottom that says, “By clicking the ‘NEXT’ button and completing the survey in whole or in part, you acknowledge that you are at least 18 years of age and that you are participating in this survey voluntarily based on the information presented to you. Please e-mail the principal researcher at _____________ if you have any questions.”
   • If creating and using an electronic survey, be sure to use the Maryville connection to Qualtrics (rather than Survey Monkey) for this purpose.

e. If data are being collected anonymously, describe procedures for ensuring that no information that can identify participants is collected.
   • Be sure that data are anonymous and not just confidential.
   • Make sure that demographic categories are broad enough that any given participant is not identifiable from his/her responses to those categories.

8. What procedures will be used to obtain informed consent?
   a. **Describe the process involved in obtaining consent (e.g., when, where, and by whom consent will be secured, how information about the study will be communicated).**
      • Be specific here about the steps taken to collect informed consent from the prospective participants.
      • Be sure to note if / how different procedures will be used for a mixed methods study.
   
   b. If an oral consent procedure will be used, explain why this is necessary and attach a copy of a script that will be followed in obtaining oral consent.
      • This should be used only in very rare circumstances, but may be appropriate if working with people who may not be able to read or write.
      • This might also be used if recruiting participants at a health fair booth or something similar and need to keep participants anonymous, so are seeking implied consent.

   c. If you are requesting waiver of certain elements of informed consent, indicate this and explain why this is necessary.
      • In some cases, if using “Implied Consent,” the researcher may be seeking to waive the requirement of a signature acknowledging consent. This is OK, just articulate that here and why it is appropriate for the proposed study.
      • It is most appropriate to use Implied Consent with a survey where it is important to maintain anonymity. Once the researcher collect a signature on an Informed Consent document, participants are no longer anonymous.

   d. If participants are members of a vulnerable population, or are vulnerable because of their relationship with the researcher, explain what special procedures will be followed to ensure informed and voluntary consent. (Please indicate if using implied consent.)
      • This is particularly important if using minors or participants over whom the researcher has a particular relationship (e.g., in a class or therapeutic or care-giving relationship).
• Principle of autonomy is at stake here and the IRB needs to be sure people are truly volunteer participants.
• In some cases, it may be appropriate for a third person to obtain and hold copies of the informed consent documents – this should be relevant to the study.

e. If participants are minors between 7 and 17, outline procedures for ensuring their assent to participate. Outline procedures for obtaining parental/caretaker consent.
• It does not matter in what order parental consent and minor assent are obtained, but both are needed. When in doubt, obtain parental consent first.
• It should be clear how and by whom procedures will be explained/presented to minors and that the assent document is in a language/format that they can understand (i.e., age and cognitive-capacity appropriate).
• If using a broad age range of minors (e.g., 7-15), it may be appropriate to use two different assent forms (one for younger children and one for older children) since they have different levels of cognitive abilities.

f. If deception is involved, explain how this will affect informed consent.
• This should be tied to response in Q.4e.
• As closely as possible, information should be shared with potential participants so they understand what they are expected to do as participants in the research. Nature of the deception should influence degree of debriefing involved, and participants should be reminded that they have the right to remove their results from inclusion in the study.

g. Attach copies of all consent and assent forms that will be used. Be sure to follow specifications for information to be included and format to be used in Informed Consent document.

Attachments: The following documents are typically required for all protocols – Please PROVIDE A LIST/LABEL for all Attachments - such as Appendix A, B, C, etc. with a title, so they are easy to recognize. Include the following types of documents (if applicable):
- Copies of all subject recruitment documents (flyer, e-mail, script, etc.)
- Copies of all research instruments or interview / focus group questions or data collection sheets
- Copies of all permissions needed to conduct research off-site
- Copies of Informed Consent and Assent documents
- Copies of Human Subjects Training/Education Certification for ALL researchers
Informed Consent

Informed consent is a significant component involved in the review of institutional research that utilizes human subjects. The following are the items which **MUST** be included in the forms (or scripts) for informed consent. Final informed consent and assent documents must be submitted with this application. It is **HIGHLY recommended** that the applicant use the template provided later in this document as a guide. Place informed/implied consent on letterhead.

- Title of the research project included at the top of the form
- Investigator’s name(s) and position(s) – Student investigators should also indicate that they are “working under the direction of ...” and list the name and title of their faculty advisor. If data are being collected at a particular site where the Investigator also has a relationship, that job title should be disclosed in this first paragraph as well.
- Informed consent should be on Maryville letterhead if Maryville is the only institution “approving” the project. Logos from cooperating agencies/institutions may also be included, if appropriate.
- Explanation of purpose and justification of research (noted from Q.1 of protocol)
- Description of what subjects are asked to do through their participation (noted from Q.4 of protocol)
- Explanation of the amount of time participation will take (noted from Q.4 of protocol)
- Description of risks and how risks are being minimized (noted from Q.5 of protocol)
- Description of alternative treatment (if applicable) (noted from Q.5 of protocol)
- Statement of pregnancy status (if applicable) (noted from Q.5 of protocol)
- Statement of nonparticipation in other medical research (if applicable) (noted from Q.5 of protocol)
- Description of benefits to subject/society (noted from Q.6 of protocol)
- Declaration and explanation of confidentiality or anonymity (noted from Q.7 of protocol) (Detail how the researcher will guarantee confidentiality and under what circumstances, if any, the researcher is required to break confidentiality.)
- Statement of how the results will be shared (publication, presentation, report to organization’s officials) (noted from Q.7 of protocol)
- **If applicable, give instructions for how participants may receive a copy of the final report.**
- Explanation that individual test results might not be shared with participant if the tester/researcher is learning a technique/diagnostic procedure and is thus not certified to provide/share results (typically only required with student research). Possible language may be: “diagnostic feedback will not be provided, as this research serves as a training exercise for the researcher.”
- Phone number of researcher (and faculty advisor for student researchers) who will answer questions
- Name and phone number of Chair of Maryville’s IRB (currently, Dr. Robert Bertolino at 314-529-9659)
- Statement of liability in case of injury, if injury is possible; Statement referring subjects to IRB in case of injury. (If project does not involve physical risks, these lines are not necessary to include.)
- Statement of research integrity and name and phone number of Maryville’s Research Integrity Officer (currently, Dr. Kimberly Allen at 314-529-6685)
- Statement that subject has read and understands consent form
- Statement that subject has received copy of the consent form
- Explanation of voluntary participation and withdrawal without penalty
- Statement regarding use or non-use of de-identified data for future research studies
- Line for participant to sign and date the consent/assent (each page should have lines to be initialed and dated by participant)
- Statement that a stamp will appear on consent form indicating approval of the project by the Maryville University IRB.

One (1) copy of all materials [signed application cover sheet, IRB Research Protocol, consent/assent forms, Exempt or Expedited Checklist (if necessary/appropriate), subject recruitment document(s), research instruments, off-site approvals, certifications of Human Subjects protection training for all researchers] must be submitted ELECTRONICALLY to the Administrator of the Maryville University Institutional Review Board, Dr. Kimberly Allen at irb@maryville.edu. Please note submission deadlines/guidelines vary depending on the level of review required for the IRB Research Protocol. No applications will be reviewed unless complete and signed material is submitted.

**INFORMED CONSENT**

Sample Template

These instructions include a template for a consent form. The template includes the elements of the form the researcher must create. It is suggested that you use the language of the form.

- The consent form **should be on Maryville University letterhead** (or possibly dual organizations’ letterhead if a co-sponsored study).
- The **title of the study** should appear at the top of the page.
- **All pages should be numbered with a place for the participant’s initials and date at the bottom of EACH page** (except the final page since the participant’s signature will appear there – this requirement is waived if using Implied consent).
- The language of the form should be **simple and understandable** to a layperson. Avoid the use of discipline-specific jargon or technical terms.
- All consent documents MUST include the final four paragraphs below about questions being directed to IRB chair and ethics concerns directed to Research Integrity Officer.
- Include the final statement signifying IRB approval.
- Possible wording is in italics. **Language that is bolded should be completed.** [Note: Upon completion of this document, it is best to remove the formatting with exception to bolded items for emphasis.]

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You are being asked to participate in a project conducted through Maryville University (and if applicable—any cooperating institution) by (name and position of researcher – if appropriate, also include relationship with any cooperating institution/organization/agency) [if student researcher, include that you are “working under the direction of my faculty advisor, Dr. _____, Assistant/Associate Professor of __________.” and include his/her title]. The University requires everyone who agrees to participate in this project to provide signed consent to do so. [If using implied consent, simply omit the word “signed” in this sentence.]

Purpose
The overall purpose of this research is to (describe your purpose)

Participation
Your participation will involve (be specific about tasks participants are expected to complete)

The amount of time of your participation will be (be specific – 1 hour, two 20-minute sessions)

Risks
This research study may include some risks or discomfort which would involve (explain discomfort: mild headache; possible disappointment at test result; potential breach of confidentiality; potential for embarrassment, etc.).

To minimize risks, researcher will employ the following safeguards (be specific about protections)

Benefits
The possible benefits for you from this research are (may include indirect or direct, but do not list if not tangible. You may say We do not promise you will receive benefits from this study. You should also note here if there are any incentives being provided for participating in the research.)

An alternative treatment to the one offered by this study might be (list alternatives, if applicable – often there are no alternative treatments except not to participate).

To maintain confidentiality about your personal records the researcher will (indicate how data will be coded, stored, identifiers removed, how long it will be retained, and how it will be destroyed when appropriate).

Initials ________  Date __________

Dissemination

The results of this study will be (printed in a doctoral project; shared with my research advisor; shared as a poster session at a local conference; shared with school district administrators, etc.)

The data collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

[or select the following statement if using broad consent]

Additionally, de-identified data collected from this study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

[The following four paragraphs are required with very minimal modifications.]

Questions

If you have any questions regarding this study, or if any problems arise, you may call the researcher, (name) at (phone number) (or the researcher’s faculty advisor [name] at [phone number]). You may also ask questions, state concerns regarding your rights as a research subject, or express any feelings of pressure to participate by contacting: Dr. Robert Bertolino, Chair of the Institutional Review Board at Maryville University, (314) 529-9659.

Integrity

Maryville University recognizes its federally mandated responsibility to ensure that research be conducted in an ethical and scholarly manner, respecting the rights and welfare of all the human participants. Any research misconduct including but not limited to fabrication, falsification, or plagiarism in proposing, performing and reviewing research, or in reporting research results, should be reported to Dr. Kimberly Allen, the Research Integrity Officer at Maryville University at (314) 529-6685.

Maryville University investigators, and their colleagues who are conducting research, recognize the importance of your contribution to the research studies which are designed to improve (therapeutic care; educational learning environments – insert whatever is appropriate given the purpose of your study). Maryville University investigators and their staffs will make every effort to minimize, control, and treat any complication that may arise as a result of this research. Research involving physical tasks or other health-related treatments need to add, if applicable: If you believe you are injured solely as a result of the research question being asked in this study, please contact the principal investigator or the Chair of the Institutional Review Board. Maryville reserves the right to make decisions concerning payment for medical treatments for injuries solely and directly related to your participation in the research.

By signing this form, you acknowledge that you are at least 18 years of age, that you have read and understand this form, and that you have had an opportunity to ask questions about the research project. You are voluntarily agreeing to participate in a study based on the information presented to you. You may choose to withdraw at any time without prejudice or penalty. You will receive a copy of
this form, which will include the name and phone number of the researcher and the IRB at Maryville University, should you have any questions.

[Alternate to this final paragraph if seeking implied consent may be “By returning the survey(s) completed in whole or in part, you acknowledge that you are at least 18 years of age and have read and understand this form, and that you have had an opportunity to ask questions about the research project. You are voluntarily agreeing to participate in a study based on the information presented to you. You may choose to withdraw at any time without prejudice or penalty. You may print a copy of this page, which includes the name and phone number of the researcher and the IRB at Maryville University, should you have any questions.” Please note, a participant’s signature is not required, and initials and date are not needed on each page. Researcher should still sign the form.]

___________________________________________________  ______________
Subject / participant’s signature      Date

_______________________________________  __________________  ______________
Researcher’s signature      Date  Phone Number

The date approval stamp on this consent form indicates that the project has been reviewed and approved by the Maryville University Institutional Review Board.
NOTE: This document is used by members of the IRB to verify that protocols contain all necessary elements and documents for approval. It is HIGHLY recommended that you ask a trusted colleague or fellow student to review your protocol to make sure that all required elements are included.

Maryville University—Institutional Review Board
IRB Reviewers’ Checklist

Principal Investigator: __________________________ Protocol # ___________________

Sponsor of Research (if required): __________________________ Date reviewed by full Board (if necessary) ______________

<table>
<thead>
<tr>
<th>Approval</th>
<th>Protocol Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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</table>

Application cover sheet is completed, signed and dated including signature by Dean or program director.

If applicable, Exempt or Expedited category sheet and checklist are completed.

Purpose of research and significance are clear; brief review of literature is included which helps reader understand research. (Q1)

Population is identified and justified. Participation section is complete; selections justified. Inclusions and exclusions are identified and verified. Influence of power differential (if present) is identified and mitigated (Q2)

Procedures for identifying and recruiting potential participants are clear and complete. Appropriate recruiting materials are attached. Information about incentives is clear. (Q3)

If applicable, cooperating institution has granted approval of study; IRB approval is attached. (Q3d)

If applicable, participating agency, school, hospital, clinic or other facility has granted approval of study and permission for data to be collected at that location; letter granting permission is attached. (Q3e)

Methodology section is complete and clear. The interventions or treatments and their assessments are clearly explained and justified. Data to be collected or retrieved is outlined. (Q4)

Copies of all instruments are attached. Copyright releases and permission for use of each instrument has been granted. (Q4f)

Risks and benefits are clearly and thoroughly described and assessed with strategies provided for minimizing risks. It is clear there are minimal risks with this study. (Q5-6)

Procedures outlined for maintaining anonymity and/or confidentiality, data security procedures are clear and appropriate, data destruction procedures are clear and appropriate, and protocol for dissemination of results is clear and appropriate. (Q7)

Procedures outlined for obtaining informed consent are clear and appropriate. (Q8)

Supporting materials are attached as required.

Human Subjects Certification of Education attached for all researchers.

Informed Consent (if necessary)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Consent Form Elements (see pages 9-10 of the Policies document)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Form is on Maryville University letterhead (if Maryville is only institution approving the project; if not, then letterhead of home institution of principal investigator)</td>
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<td>Investigator’s name and position are included (and that of faculty advisor, if student researcher)</td>
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<td>Explanation of purpose and justification of research</td>
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<td>Clear description of what subjects will be asked to do through their participation</td>
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<td>Description of risks and minimization of risks is clear</td>
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<td>Declaration and explanation of confidentiality or anonymity and any limits to maintaining confidentiality (i.e., threats to self or others must be disclosed)</td>
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<td>Description of benefits to subject/society is clear including incentives if applicable</td>
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<td>Description of alternative treatment, if applicable</td>
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<td>Statement of pregnancy status (if applicable)</td>
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<td>Statement of nonparticipation in other medical research (if applicable)</td>
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<td>Phone number of researcher who will answer questions</td>
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<td>Statement of liability in case of injury</td>
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<td>Statement referring subjects to IRB in case of injury</td>
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<td>Statement that subject has read and understands consent</td>
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<td></td>
<td></td>
<td>Statement that subject has received copy of consent form</td>
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<td>Explanation of voluntary participation and withdrawal without penalty</td>
</tr>
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<td></td>
<td>Line for participant to sign and date the consent/assent form (Initial and date additional pages)</td>
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<tr>
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<td></td>
<td>Consent form (and/or assent form) is written in language participant can understand.</td>
</tr>
</tbody>
</table>

I have reviewed the enclosed protocol and recommend the following action:

|     |     | Full Approval |
|     |     | Contingent Approval (explain clearly on back what needs to be done) |
|     |     | Tabling (give explanation on back) |
|     |     | Denial (give explanation on back) |

______________________________  ___________________
Signature of Reviewer     Date