Completing the forms for a research proposal

Advice from the Research Participants Protection Program -

IRB at Malone University

First steps:

1) Go to www.malone.edu and scroll to the bottom of the page.
2) Click on “Directory”; then, click “Offices & Services”.
3) Select “Research Participants Protection Program" or "Institutional Review Board” in the left side of the navigation tree.
4) Click it and scroll down when you get to the IRB page.
5) Select the “IRB Handbook and Training” and complete it, or find the same materials in Section I of the IRB Forms. Submit training page with forms or via Google Form.

4) Send it through campus mail to Dr. Lauren Seifert, Chair, HRC/IRB, or scan it and send it as a .pdf file to LSEIFERT@malone.edu

Completing the IRB forms

- At the same website that is mentioned in the previous slide, download the IRB forms.
- If this is your first proposal for this project, keep all pages through Section C.
- **Discard Sections D - H, or keep copies of them for later use.** Sections D - H are for renewals, methods changes, reporting adverse events, etc.

Starting the IRB forms

- Keep the instruction pages beside you, or open them in a separate window on your computer.
- Begin Section A. Fill-in all information, and include an email address for EACH RESEARCHER and for your faculty supervisor (if applicable).
- There is additional space after the reviewer page, if you need more space for researchers' contact information.

Ending Section A

NOTE: Once you've completed the entire set of forms (Sections A, B, and C) and have completed the certification (previous slides), then be sure to sign Section A and date it. If you have a faculty supervisor, s/he must sign and date it, too.

You should probably wait to sign and date until you have completed the entire set of items in Sections A, B, and C.

If you believe that your project will be exempted once its status is verified, you may submit Sections A & B, your completed training form, AND a complete description of your research methods. If Section C is needed, you will be contacted to supply it.

Section B

- If you are NOT doing biomedical research, then your responses to Items 1-3 of Section B will most likely be “no”.
- If you will withhold information from or deceive subjects, then you must respond “yes” to Item 4 and a full committee review will be required.
- Continue on with Section B items.

Read each Section B item

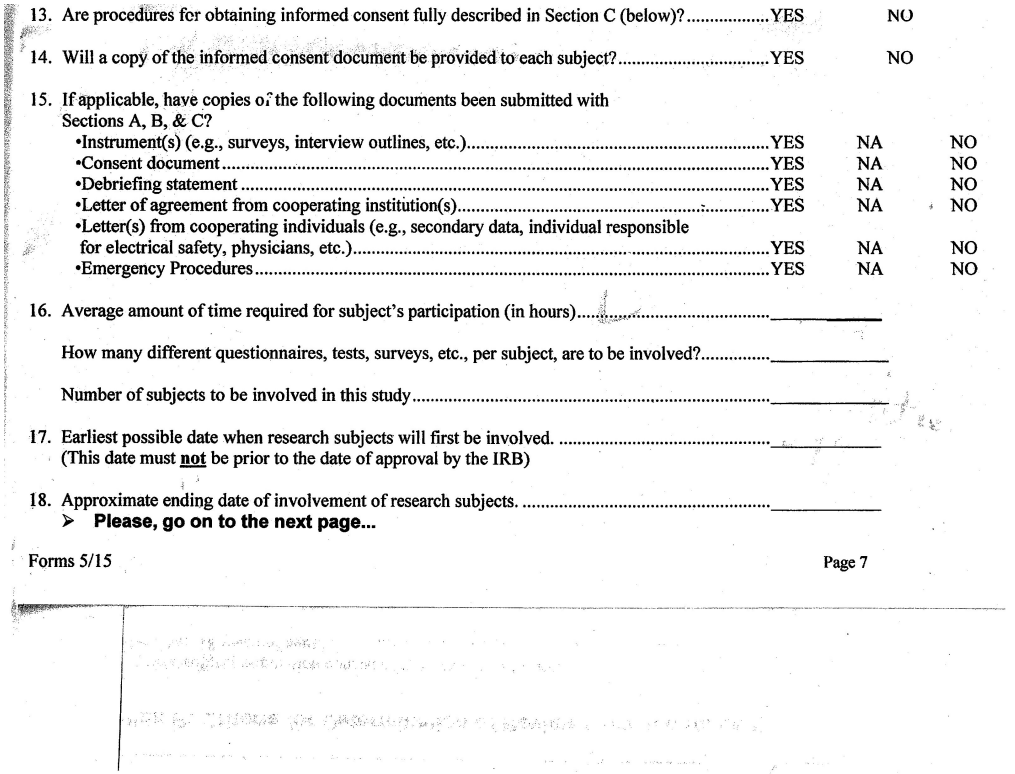
and answer it.

When responding to Item 9, ONLY answer “yes” if the population being mentioned is the **focus** of your research.

If some persons fitting the description might be included, but are not targeted for inclusion, respond "no" to Item 9.

Section B continued

- Item 15 is a vital part of the research proposal and it must be accompanied by the appropriate documentation.



13. Are procedures for obtaining informed consent fully described in Section C (below)? ..... YES NO

14. Will a copy of the informed consent document be provided to each subject? ..... YES NO

15. If applicable, have copies of the following documents been submitted with Sections A, B, & C?
    - •Instrument(s) (e.g., surveys, interview outlines, etc.) ..... YES NA NO
    - •Consent document ..... YES NA NO
    - •Debriefing statement ..... YES NA NO
    - •Letter of agreement from cooperating institution(s) ..... YES NA NO
    - •Letter(s) from cooperating individuals (e.g., secondary data, individual responsible for electrical safety, physicians, etc.) ..... YES NA NO
    - •Emergency Procedures ..... YES NA NO

16. Average amount of time required for subject's participation (in hours) ..... _____

    How many different questionnaires, tests, surveys, etc., per subject, are to be involved? ..... _____

    Number of subjects to be involved in this study ..... _____

17. Earliest possible date when research subjects will first be involved. ..... _____
    (This date must **not** be prior to the date of approval by the IRB)

18. Approximate ending date of involvement of research subjects. ..... _____

➢ **Please, go on to the next page...**

Forms 5/15 Page 7

Section B Item 15

- Any survey, questionnaire, interview, or focus group must have instructions, and a copy of the items/instrument must be included.

- If an instrument is copyrighted, then a researcher must include a letter or email of permission to use the instrument.

More:

- In studies meeting the federal definition of human research, informed consent must always be obtained from research participants, but it might not always be signed informed consent. Regardless of the way you obtain consent, the document must be included in your proposal.
- For anonymous surveys, informed consent is implied and **is part of the instructions for the survey.** There is no signature from the participant. Sample survey instructions are provided in a later slide.

More:

- Here is an example of instructions for an anonymous (no names collected) survey that provides appropriate informed consent:

- My name is XXX, and I am working with Professor XXXX at Malone University. We are interested in people's perceptions of Malone University Dining Hall food selections. This survey is anonymous. So, please, do not put your name on it. Also, the survey is voluntary, and you may stop at any time without penalty. This survey is for persons 18 and older; do not take the survey if you are under 18. The survey is estimated to take about 10 minutes to complete. There are no anticipated risks of this study, and a benefit might be that we provide Malone U. with a better understanding of student food preferences. If you have any questions about this survey, please, contact my professor [name and email address here] or the chair & coordinator of the IRB/Human Research Committee, Professor Lauren Seifert at LSEIFERT@malone.edu By completing and returning this survey, you give your permission for your responses to be included in my survey analysis. Thank you!

SAMPLE CONSENTING INSTRUCTIONS for an anonymous survey that is minimal risk (no more risk than everyday life)--

Hello, my name is XXX and I am conducting a survey as part of COURSEXXX at Malone University. I am interested in XXXX and wonder whether you would be willing to take part in an anonymous survey about XXXX?

It's voluntary and should only take a few minutes of your time; you may stop the survey at any time without penalty. This survey is for persons 18 and over; do not take it if you are under 18.

There are no estimated benefits or risks of taking part in this study, but you might have questions about it. If so, please, feel free to contact my supervisor, XXX at XXX. You may also contact the Malone University chair & coordinator of our research ethics program, Lauren Seifert at LSEIFERT@malone.edu or at 330-471-8558 with your questions.
Thanks for participating!

SAMPLE CONSENTING INSTRUCTIONS for a survey or focus group that is not anonymous but is still no more risk than everyday life (minimal risk).

Hello, my name is XXX and I am conducting a survey/focus group as part of COURSEXXX at Malone University. I am interested in XXXX and wonder whether you would be willing to take part in my study about XXXX?
It's voluntary and should only take a few minutes of your time; you may stop the survey at any time without penalty. Please, do not take part if you are under 18 years of age.

While study participation is not anonymous, I will not use your name in any report or presentation about my study results. There are no estimated benefits or risks of taking part in this study, but you might have questions about it. If so, please, feel free to contact my supervisor, XXX at XXX. You may also contact the Malone University chair & coordinator of our research ethics program, Lauren Seifert at LSEIFERT@malone.edu or at
330-471-8558 with your questions.
Thanks for participating!

The previous instructions

contain the key elements of informed consent for an anonymous survey:

1) A description of the study
2) Names of the researchers
3) A description of the time required
4) Statements about anonymity and risk
5) A statement about possible benefits
6) A statement about voluntary participation and freedom to leave/stop without penalty
7) Contact information for supervisors and the HRC/IRB committee
8) A statement of “implied consent”: “By completing and returning….”

At the end of Section B

Be sure to fill in the appropriate information for Items 16, 17, and 18.

The IRB uses these responses to estimate possible influences of the study on subjects' with respect to their time commitment and the effort required of them.

Section C is required, too, UNLESS you have provided a *complete* description of your study , sampling, methods, & procedures and are fairly sure that your study will be exempted from additional review.

Section C, Item 1, should be a paragraph or more that describes your study.

Section C, Item 2, should be a description of the subjects you will seek. What are the required characteristics? Section C, Item 3, should explain how you will seek subjects. Be specific.

In Item 3, if an outside entity/agency/organization is involved, then include a letter from an administrator there which provides permission for you to seek/test subjects. Section C, Item 4, must provide a detailed

Section C continued

Section C, Item 5, should be a list.
Section C, Item 6, should describe procedures for obtaining consent. It can include your instructions or should refer to an attached page that is your instructions or your consent form.
If you need to obtain signed consent, then build a consent form from the sample on the same website that has the HRC/IRB proposal forms.
Section C, Item 7, should describe risks to participants. If you believe there are none, then say so.
Section C, Item 8, should identify any possible benefits for the individual participant. If there are none, then say so.

Section C continued

Section C, Item 9, should include the things you will say to the subject(s) at the end of the research session. If the study has risks, then debriefing should address those. For example, you might compose a page or a ½-sheet that will go to each subject with contact information for your supervisor and for the HRC/IRB chair. In addition, you might provide helpful information or a list of helpful websites that provide support or more information about the topic.

As an example, when participants took part in a survey about college and stress, the researcher provided a debriefing page that included a number of reputable websites with information about stress and coping.

Section C, Item 10, should mention whether participants can ask questions during or after the study.

Section C, Item 11, should list ALL safeguards (e.g., informed consent, voluntary participation, giving subjects a blank copy of the consent form, giving subjects a debriefing page).

Section C, Items 12 & 13…

are also required. So, do not leave them blank.

Who are the experts who have provided you advice in planning this project?

What are at least 2 resource readings that would help reviewers understand this research area? These should be scholarly articles &/or books.

Having completed

- Sections A, B, and C, OR expecting exemption and having completed Sections A & B with inclusion of a document that describes all sampling, methods, and procedures.
- And having attached all needed documents as described in the previous slides…
- if you are a student, give all of completed forms and proposal attachments to your faculty supervisor. After s/he approves them, you both should sign and date them.
- Make copies for yourself.

To submit your completed forms

email the scanned forms as a .pdf or .jpeg file to

LSEIFERT@malone.edu (no files bigger than 15 MB, please)

- or send hard copies with NO clips, staples, or folds to RPPP/IRB Chair&Coordinator,

Professor Lauren Seifert Malone University

2600 Cleveland Ave., NW

Canton, Ohio 44709

- Best wishes for your success!