Orientation to Navigating the IRB process at UM-D: Helpful Suggestions and Hints

Caleb J. Siefert, Ph.D.
University of Michigan – Dearborn
Version 1.3 – Sept. 6th, 2016

Important Caveats: 1) This document is intended for students at the University of Michigan-Dearborn who are seeking to complete a thesis or run a research study with human participants during their time at UM-D. The information may not be applicable to students working at other institutions. 2) This document is intended solely for the use of students in the IREP lab. It may not be accurate for students working in other labs. 3) It is common for IRB forms to change. Students should always download forms from the UM-D IRB website: https://umdearborn.edu/research/696470/. 4) This document DOES NOT cover every possible study type. You will **always** need to contact Dr. Siefert and have him look over our IRB prior to submission. 5) You should always defer to the IRB at UM-D. Study requirements typically change faster than I can change this document. Thus, you should defer to IRB staff.

Introduction: This form does not cover everything. Specific studies have specific needs. Still, there are a number of things that are very consistent across studies. You can consider the information below as a possible template when completing your IRB. Ultimately, however, you and I will have to go through your IRB line by line to ensure that it is correct prior to submission.

Before You Start the IRB: Getting Your Proposal and Materials in Order

There are a number of things you need to do before you can even begin to fill out the IRB. Here's a list of the most important.

1) **Complete Peers Training**: You can't do anything on IRB until this is done. Complete training here: http://my.research.umich.edu/peerrs/

2) Create and Upload a Curriculum Vitae to eResearch: You will need my Vitae uploaded. You will need to quickly make one for yourself. Do not spend endless hours doing this. Essentially this is a glorified resume that highlights your research experience. For many students, this will be limited to classes you have taken related to research. You can download a Template here: https://umdearborn.edu/research/691920/.

3) Obtain CVs for ALL Study Team Members: You will need a CV from me and every other person working on the study. These DO NOT need to go in your proposal, but they do need to go into your IRB.

4) Start your Research Proposal: Your Research proposal will need to have an Introduction section (where you provide background information), a present study section (where you describe why this study is needed and state your hypotheses), a Methods section (which should include subsections for Participants, Measures/Materials, and Procedures), and a Data Analytic Plan section (see #12 and 13 below)

5) Finalize your Inclusion and Exclusion Criteria: In the Methods section of your proposal will be a sub-section entitled "Participants." Here you should do three things: 1) State where you plan to recruit

participants from (i.e., the recruitment population), 2) State the demographic data you will collect and refer the reader to the Appendix with the Demographic form, and 3) report all inclusion requirements and exclusion criteria. You'll need to cut and paste the inclusion and exclusion criteria into 5.3 of your IRB application.

6) **Finalize Your Forms & Research Measures**: As part of your proposal, you'll need to include ***all forms*** in separate appendices. This means you will need to have your consent form, demographic form, all self-report forms, all debriefing forms, and all advertisement/recruitment materials included as appendices in your proposal. You'll also be uploading each of these documents separately as part of your IRB. You need to upload them in "final form" (meaning what they will look like when the participant actually sees the document). The MOST important form to finalize is the consent form. To see information on making a consent form, go to: https://umdearborn.edu/research/10501/

7) **Finalize Your Study Scripts**: Scripts refer to anything the researcher will read or say to participants. In research we want things standardized. Thus, you should write out how you plan to give instructions. These "Scripts" should be titled and included in your proposal as appendices. You will also need to upload these to the IRB. The most common scripts are for introducing the study, explaining tasks to participants, and de-briefing participants.

8) **Finalize Your Order of Events Sheet**: As part of your proposal, you'll be writing a Procedures section as part of the Methods. The goal of this section is to explain in a step-by-step manner what will occur during a study session. I require my students to include as part of their IRB a list of events. The first event should always be to complete informed consent with the participant and to allow the participant to ask questions. Write what happens next (e.g., Partiicpants will complete the study demographic form [See Appendix III]). Then write what happens next (e.g., Participants will complete the Experience in Close Relationships Inventory [ECR; See Appendix IV]). Keep going until the final step which should always be something like: Participants will be informed that the study is over, thanked for their participation, and will be read/given the study debriefing form (See Appendix X).

9) Create a SONA Page for Your Study (if you are not recruiting participants via the university subject pool, skip this step): You should sign into SONA (https://umd-umich.sona-systems.com/Default.aspx?ReturnUrl=/) using either a researcher login OR PI login. Click on "Add New Study" from the menu at the top of the page. Select the option that is right for you (almost everyone will use the Standard Study option). Add you study name. The Brief Abstract should be one sentence about the study. In the detailed abstract you should: 1) list the purpose of the study (generally), 2) describe what the participants will do in the study (e.g., describe the kind of self-report measures they will fill out and/or tasks they will complete), 3) inform them of the time it will take to complete the study, 4) inform them of any risks and/or costs related to participation, and 5) inform them of how many SONA credits they will earn for participation. IF there are specific things you need participants to do or NOT do, put this in both the "Detailed Description" section the "Preparation" section.

10) Study advertisement/Recruitment Materials: For studies that use the UM-D Subject pool only, you will need to simply take a screen shot of your SONA page (for PC, do this by pressing shift + CTRL + Print

Screen), paste it into a PowerPoint slide, and save it. You'll then upload it in the appropriate section of the IRB application. See the example at the bottom of this document.

Any ads, flyers or information used to recruit subjects. This should include brief summary of the study, the time required, brief summary of what participation entails, risks/benefits, and any incentives (if offered). Keeps this both as a separate doc (you will need to upload it) and attach it to your proposal as an appendix. If you are using subject pool, then you will need to have a paragraph that shows what you will say on SONA. If you are using data from another site, you *may* need their recruitment materials (check with me).

11) Select Study start and end date: Your study starts with data collection, but it does not end there! Your study does not end until you are no longer analyzing data and/or writing data up. My advice is to select an end data one year from when you start the study This will allow you to collect data, enter it, check it, analyze it, prepare it, and ultimately present it.

12) Finalize Your Research Proposal document. Your proposal should have five sections: **Introduction** (i.e., background information and support for your hypotheses), T**he Present Study** (include your *goals* and *hypotheses* in this section), **Methods** (broken into a *participants* subsection [who are the participants going to be how will you get them; what demographic information will you collect; what are the rule in/rule out criteria for participation]; a *Measures* subsection [list all self-report and/or or coding/rating measures in the study; see examples below]; *materials* subsection [OPTIONAL; only appropriate for some studies; this section discusses any technical materials you plan on using for any reason (e.g., EEG; MRI; biometric monitoring system; computers for displaying stimuli; programs for displaying stimui); a Tasks section [OPTIONAL: only appropriate for some studies; tasks include performance-based measures, like lexical decision tasks, Stroop tasks, dot orientation tasks; puzzle solving tasks, memory recall tasks and so on]; a *Procedures* subsection [what will happen when in terms of data collection, data storage and data analysis]), finally you will need a **Data analytic plan** (this will be a description of how you will do the statistical analyses to investigate your hypotheses).

Your proposal document also should have:

***** Your demographic data collection form as an appendix.

***** Each respective measure you plan to use as an appendix.

* All stimuli (of any kind) or scripts you plan to use as an appendix.

* Consent form(s) as an appendix and separate doc (you will need to upload)

* Any material (written or scripts) to solicit subjects as an appendix and separate doc (see below, point 6)

Ultimately, you will have to upload all of these documents to the IRB.

13) Second Reader Approval & Defense: Honors students doing a Thesis and Graduate students doing a Thesis are required to have a second reader in addition to their faculty advisor. After you get approval from Dr. Siefert, you should set up a meeting with your advisor (i.e., Dr. Siefert) and your second reader to discuss your study. You will need to provide the second reader with your written research proposal ***one week prior to this meeting***. They will review and then we will have to meet to ensure that everyone is happy. If everyone agrees to move forward at the meeting, you may submit your IRB.

The Actual IRB:

Once you've done all the 10 steps above, defended your proposal, and obtain Dr. Siefert's approval, you can start on your IRB form. Every form is going to be different. There are, however, some basic things that are likely to be true across several different types of studies. *Note the appropriate IRB will always be Dearborn.*

1. **Application Type**: Unless I tell you otherwise, you should enter "Standard, non-exempt research project" in 1-1.1 for application type.

2. Department (Question 1-2.3). For this question, you will enter Dbn CASL-Psychology.

3. Scientific Merit. Unless your study is a collaboration with another university or research group that finished an IRB already and/or your study is part of a federal grant, you should check "no" for 1-2.6. Every student I have worked with to date has needed to select the "No" option.

4a. Study Team Primary Investigator: If you are filling out the IRB, then you are the primary investigator and I am the faculty advisor. In many cases, though you will be filling out the IRB, I will be filing the IRB on your behalf. You should ask me which option is right for you.

4b. **Study Team**: This is me, you, ***and anyone else working directly on the study*** (e.g., collecting data; entering data; analyzing data). Everyone on the study team must have completed PEERS training prior to engaging in any aspect of the study. Equal collaborators are "co- investigator." Everyone else is a "research staff" (e.g., other students in the lab) with some rare exceptions.

5. **Faculty Advisor**: Enter me. I will have to "approve/accept" my role. If you have a second reader, make you will have to include them as well. ***Be sure to check the box allowing me to edit the IRB proposal.***

6. **Data management plan**: The vast majority of studies done in my lab **WILL NOT** require this type of plan. This DOES NOT mean we don't need a plan for managing, storing, and housing data. This section refers to very specific types of data that require specific types of management. We will fill out information related to more "regular" data management later in the IRB. So go ahead and check the

7. **Sponsor or support**: This section refers to funding. Only include funding from the University or from grants you obtain. Most of you will not have this. As such, you will often check the box in 2.8 (i.e. check here if the proposed study does not require external or internal sponsorship or support).

8. **UM Study Functions:** For Performance Site detail (3-1.2). You will need to search using "univ" in the search tab. This will bring up many options. Select Univ of Mich Deaborn.

Assuming you are collecting data here (if you are not, contact me to review what you should click on), you should click on Recruitment, Interaction, Primary or secondary analysis; and storage. If you are doing an experiment or a quasi-experiment that involves an intervention (and typically a control group or control period), then you also need to click on Intervention. You should check with me if you think you need to check this box.

If your study involves interviews or more extensive open ended "qualitative" questions, then you will need to also check Qualitative research.

The site will be engaged in the conduct of research.

9. **Performance Sites**: If you are collecting data via subject pool only then the only performance site is the University of Michigan-Dearborn (UM-D). If you are collecting data at any other site (or if anyone from another site is helping you with data analysis) then you need to include this site *in addition* to UM-D. This tends to be rare for students. You will need to check on "Yes" for 3-1.5.

10. **Office Review (Question 3-1.7)**: For almost all of you, this will be N/A. This is only of use if you are collaborating with another institution to collect or analyze data. If this is the case, you will need to specify steps taken by that institution (almost always IRB approval by that institution).

11. **Research Design**: The answer in response to 5.1 is almost always "No". Even if you've written a proposal, this is a "No." This question is asking about protocols used in medical research and grant research.

12. Study team experience. You should include a paragraph on yourself that contains what you've done to familiarize yourself with research. For example:

(Your Name) is a Senior at the University of Michigan Dearborn. the conclusion of the Fall 2010 semester, she has completed a semester of intensive study related to the present research. She has completed the PEERS training course. She has completed coursework in research methods and design, as well as statistics (include all classes related to research directly (e.g., research methods) or indirectly (e.g., for a study looking at a clinical issue, you might include Abnormal Psychology). Her direct experience in research is limited to the present study. At

Then include a paragraph about me. I may improve this, but for now you can go with:

Dr. Caleb Siefert is an assistant professor at the University of Michigan Dearborn. Dr. Siefert has been a primary investigator on over 30 studies. He has also served on the research team or as a research consultant for over 100 studies. He will supervise the organization of the present study, ensure that proper protocols are utilized, supervise data collection procedures, supervise data analysis, and supervise the organization of data for presentation (i.e. publication or conference presentation). His CV is included as part of this application. Dr. Siefert's training included intensive coursework in data analytic approaches, research methods and techniques, the rights of human subjects, and protocols for managing data. In addition, he teaches coursework related to professional Ethics in research settings.

13. **Existing Data (Question 5.2):** This is almost always "No" if you are collecting new data. Unless you are doing medical research on physical specimens or doing a study limited to a chart review of information, the answer to this is no. **5.3** Unless you are using data from another source, pre-existing data collected for another purpose, or doing a chart or records review, you will have to get new data. Thus the answer to this is Yes.

12. **Inclusion/Exclusion criteria**: In section 5.4, you should cut and paste the Inclusion and exclusion criteria from your proposal.

13. **Specific Exclusion (Question 5.5**: Unless your study specifically focuses on race, ethnic issues, or gender in a manner that precludes some from participating and allows others for the purposes of achieving the study goals, you will use a paragraph such as:

No racial, ethnic, or gender groups will be excluded. However, the study does require that the participant be capable of reading English. The reason for this requirement is that participants will need to be capable of reading the consent form (in order to provide informed consent) and capable of completing measures written in English.

14. **Age range**: Minimum for my studies will always be 18 unless you have explicitly discussed and somehow convinced me to use children (very UNLIKELY to happen). I suggest entering the upper age range as 999. If you are using subject pool, feel free to enter an upper age range of 70.

15. Sections 5-1.1 through 5-1.6. For these sections, you should be largely cutting and pasting from your proposal. Here is an example of 5-1.1:

The overall purpose of this study is to examine how explicit personality relates to narrative-based freely recalled memories. The study also aims to examine similarities and differences across narrative-based data analysis.

Here is an example of 5-1.2:

There are three objectives to this study: The first is to examine concurrently how personality features correspond to types of memories recalled. The second is to examine how personality factors correspond with linguistic qualities (i.e., word usage) of narrative based memories. The third is to examine the linguistic qualities of narratives to free report stories (collected earlier in the Affective and Cognitive Social Personality Study) relate to linguistic usage in narrative-based memories. To date, previous studies have not compared linguistic usage cross-method. Further, they have not looked for similarities or differences with external variables (e.g., personality scales) across methods.

The exception is section 5-1.3. Here you want to include a more condensed version of your introduction section. Do NOT include the entire Introduction section. DO include list references and in-text cites at the bottom of this section. Below, please find an example:

Previous research has demonstrated that ratings of recalled memories relate to many aspects of personality and life functioning (e.g., Barrett, 1980; Mayman, 1968; Porcerelli et al., 2001; Shedler, Karliner, & Katz, 2003). One example of a narrative-data rating system for coding memories is the Social Cognition and Object Relations – Global Scale (SCORS-G; Westen, 1995; Hilsenroth, Stein, & Pinsker, 2007). The SCORS-G is an external rater system for coding narrative data, such as memory narratives. Trained raters have been shown to be able to code these scales in a reliable and valid

manner (Stein, Hilsenroth, Slavin-Mulford, & Pinsker, 2011; Stein et al., 2012). Studies have shown that students can be trained to use these scales to rate memories in reliable ways (e.g., Peters et al., 2006; Slavin, et al., 2007).

Though personality traits assessed via self-report measures show some agreement with personality assessed with narrative data from memories, this agreement tends to be limited. Initially this was attributed to method variance, however, recent research suggests that the limited agreement across measures is more likely to be more real than not and to reflect legitimate differences in the construct assessed. Said differently, narrative-based measures of self-esteem show limited agreement with self-reported self-esteem because they are assessing different aspects of the self-esteem construct. Support for this argument has been obtained in a number of studies showing that narrative-based personality ratings and self-report personality ratings often differentially relate to important outcomes, indicating that they are capturing unique data that has predictive utility (e.g., physical symptoms; life satisfaction; Pennebaker, 1993; Pinsker, Stein, & Hilsenroth, 2007 Shedler, et al., 1993; Shedler, Mayman, & Manis, 1994; Stein, Pinsker-Aspen, & Hilsenroth, 2007). It has been suggested by some that narrative based data may capture more "implicit" aspects of personality while self-report measures capture more "explicit" aspects of personality (e.g., McClelland, Koestner, & Weinberger, 1989). Thus, rather than considering one form of measurement correct and the other incorrect, it has been suggested that both may be valid measures of personality that have utility for uniquely and differentially predicting outcomes.

At present, the hypothesis that personality features assessed via early memory narrative differentially and uniquely contributes to the prediction of important outcomes beyond that accounted for by self-report has primarily been assessed in clinical or healthcare settings. In some cases, findings from such settings have been extrapolated to non-clinical settings (e.g., Shedler et al., 1993) based on studies in related fields (e.g., motivation; McClelland, Koestner, & Weinberger, 1989) For theoretical and practical reasons, it is important to examine if findings hold across settings and populations directly. The present study intends to extend prior research in this domain by examining how narrative-based personality and self-reported personality ratings relate to important outcomes (e.g., life satisfaction; experience of physical symptoms) in a non-clinical, college sample. Further, the proposed study will build on previous research by examining how self-reported personality relates to linguistic aspects of memory recall (e.g., higher levels of neuroticism are expected to relate to more frequent use of negative emotion words [e.g., sad; angry; nervous]). Linguistic word usage will be evaluated using the Linguistic and Word Count Software developed by Pennebaker and colleagues (Pennebaker, Booth, & Francis, 2007).

Here is an example of Section 5-1.5

The method for this is as follows: Participants who have completed the study Affective and Cognitive Social Personality (HUM00060174) will be asked if they would like to sign up for this study. If they agree to participate, they will be given a consent form for their data from the previous study to be shared with the research team for this study. Participants will then sign up for participation in this study via the SONA subject pool system at UM-D. They will then chose a code of 8 numbers using the month & day of their birthday and the last 4 digits of their phone number (e.g. 09034782). This code will be associated with their participant ID from the previous study in order to compare data across both studies. Participants will be brought into the lab in small groups (maximum of 4 participants). Participants will be given a consent form, asked to read the form, and an examiner will be there to explain the form to them and answer any questions. If the participant consents to participate, they will be sat at an individual table. There are four separate tables in the room and each table faces a separate wall. Thus, participants will not be facing one another. Each table has a laptop. Participants

will then be asked to complete a series of self-report questionnaires. Self-report measures will tap 1) Personality Traits; 2) Attachment dimensions; 3) Interpersonal Dimensions; 4) Self-Esteem, 5) Life Satisfaction; and 7) Physical Symptoms. In addition measures tapping 8) Psychopathy and 9) possible selves are included as part of student projects or to examine mediating effects of these variables. In addition, participants will be asked to complete a basic demographic form. The self-report portion of the study will require roughly 18-23 minutes. The memory recall portion requires 27-30 minutes. Total time for the study is expected to be 60 minutes.
Participants will then be asked to complete a memory task. The memory task will involve writing down significant memories from their life. Participants will be given a series of instructions. In this task, participants are asked to think of a memory related to a series of prompts. In sum, they will be given a series of 10 specific prompts (e.g., Write down a self-defining memory from your early childhood; Write down a self-defining memory involving a turning point in your life). For each prompt, participants will be asked to describe the events of the memory. To do this, each participant will type the memory into a word document on the laptop on their respective tables. Word documents will not contain any identifying information. Participants will be instructed to refrain from using their names when reporting memories. These word documents will be saved using the participant number. There will be no way to link participant numbers back to participant's identifying information. All computers will remain in the lab. After the memory task is completed, participants will be thanked and debriefed.

All self-report data will be entered into SPSS at the item level. Narrative data will be coded in two different ways. First, the Linguistic and Word Count Program (Pennebaker et al...) will be used. This program assesses the frequency of various word use categories (e.g., nouns; self-referential pronouns). It is well validated and has been used in many studies. 2) Student raters will be trained to code memories using the Social Cognition and Object Relations - Global (Westen, 1991) rating scale.

This methodology is innovative for three reasons: first, there have been few attempts to examine linguistic usage across narrative-methods. Though linguistic usage is assumed to be a person-level (i.e., trait construct), there is precious little data to support this conclusion. As such, the current method, which collects two very different types of narrative data on two occasions, can be analyzed for this innovative purpose. Second, analysis of narrative data for early memories and stories has focused almost exclusively on expert-rater based methods. These methods have never been examined using generalizability theory. This is problematic as rater agreement is treated as the only source of variance. A recent study by Stein, Slavin, Siefert, Sinclair, & Blais (in press) strongly suggests other sources of variance that should be considered in establishing the reliability of these techniques. The present method allows for a generalizability analysis of the memory prompts utilized in this study. This has never been previously done. Finally, as stated previously, early memory" or "significant memory" studies almost always assess narratives with any other technique except expert-rater methods. Major advances in linguistic analysis software allow for rapid coding of text-files opening the door for using these tools as an alternative (and possibly more valid and generalizable) technique for analyzing narrative data. The present study will collect data in a manner that allows for examination of linguistic aspects of narrative data (i.e., memories) using such tools.

Here is an example of Section 5-1.6

All data will be analyzed using SPSS, SPSS syntax scripts for generalizability calculations, and AMOS. After presenting descriptive data for the sample, we will first employ correlation analyses to determine if personality variables relate to memory ratings/linguistic usage. However, these will be supplemented with theory-based regression analyses (because the number of variables in the study is likely to result in spurious findings) that also employ Bonferri corrects for comparisons. We anticipate that neuroticism and extraversion will account for the majority of variance in use of negative and positive affective words respectively. We expect that openness will account for the greatest amount of

variance in total affective word usage (i.e., positive and negative combined). We expect that aggreeableness, attachment anxiety, and interpersonal warmth will all be uniquely associated with use of social word

14. **6.1 Benefits**: Several things to consider, we'll take them one at a time:

Direct benefits of participating. This is when the participation gets you something. Subject pool credit DOES NOT COUNT, nor does payment for participation. Typically, benefits are things like access to services (e.g., treatment). Many of you will have no benefits. That is very common.

Benefits to society: How will the present study shed light on issues in this area? How will it seek to replicate prior research? And/OR How does it extent prior research? Ultimately, how will it contribute to knowledge in this domain? AND why is that of value? Everyone will have some of these.

Later we'll talk about risks.

15. **Will results of research be communicated back to subjects**? Always click yes. But then in the next section (6.2.1) include text that better explains this. For example:

During the consent procedure, participants will be informed in writing that they can request to have the a summary of the findings from the study sent to their email. Participants will have the option of providing their email on the consent form (see appendix XXXX). Thus, feedback regarding the study is optional. Participants are informed that their consent form will be housed and stored separately from their data. Thus there will be no way to connect their data to their consent form. Participants will be informed that they will receive a paragraph summary of the results of the study. Participants will be explicitly informed that they will not receive any results about their specific participation and will not receive and results specific to them. After completing data collection and analyses, study staff will write up the results of the study (in plain English). This write up will be reviewed (and modified as needed) by the faculty adviser (Dr. Caleb Siefert). It will then be emailed to participants who opted to request the information during the consent process.

NOT SURPRSINGLY…you need to include a place where people can put their email on the consent form.

16. 6.3 **Describe any direct risks to the public or community, which could result from this research**. Here you want to first state if there is anything that could do public harm to the field of psychology are a specific group. This tends to be rare, but if you think your study might do this you need to talk to me and we need to explain it in the IRB. If risks are not expected simply state:

No risks to society are expected.

Then, this is a good place to begin to review potential risks to participants. The approach to including this information varies study to study based on the specifics of that study. Typically, one presents the risk, reviews how this will be managed, and, whenever possible, discusses how this studies methods are similar to other studies methods (in part to indicate that the risk is reasonable…if you can't find anyone else who has done something similar you need to be VERY thoughtful about risks!). Risk assessment is

not always easy. When possible, try to qualify risks as mild, moderate, high in terms of both likelihood of occurrence and potential negative impact.

Even mild or unlikely risks should be noted. For example, it should ***always*** be mentioned that participants may find some of the requested information in self-report measures or demographics to be intrusive. For example, one might state:

Participants may experience some mild discomfort completing self-report measures. Similarly, they will place these measures into a packet themselves and seal this packet. Participants will be informed at the start of the study that their responses will be kept confidential. Participants are also able to leave any question blank that they wish. No identifying information will be present on any measures or packets.

If you're having people view emotional material you should mention they might have an aversive response.

If you're using deception, you need to explain that participants will be debriefed and allowed to withdraw their data should they choose following debriefing.

Again, though not necessarily likely, all studies should have a mechanism for managing very aversive responses. Below is an example of what you might put. This example was taken from a study in which participants are viewing film clips that are designed to induce negative emotions (e.g. anger; sadness).

Film clips may engender mild to moderate negative emotions in participants. These procedures have been utilized in a number of prior studies, and generally induced emotions are transient in nature. Further, engagement in the creativity task is expected to reduce the experience of these emotions. Finally, all participants will be shown an amusement clip designed to induce a positive mood prior to leaving the study. Though not expected, any participant who experiences a strong or excessive negative affective responses or report overt experiences of distress (during the study or after the study) will be directed to the faculty adviser, Dr. Caleb Siefert, to discuss this issue. Additionally, study staff will immediately contact Dr. Siefert (via phone) to discuss this matter. Dr. Siefert is a clinical psychologist. Dr. Siefert will meet with the participant to discuss their response (not to provide therapy). If necessary, he will take steps to refer the participant to resources (e.g., the University Counseling Clinic) to assist them with their response. If the student wishes to pursue aid outside of the university, then Dr. Siefert will assist them in reviewing options and obtaining a referral.

17. **Benefit and risk level detail 6.6**: Are there potential direct benefits of this research to subjects. Most often, the answer to direct benefits is "No." Payment and subject pool credit are NOT benefits.

If you are collecting data at a site where participants complete the study and are not given anything (e.g., patients in treatment who participate voluntarily, but for whom treatment is NOT contingent on participation and no incentive is provided) , then the answer is no.

For 6.7 and 6.8, review the risks. Use the Risk Grid to help you. If you are inducing feelings or using stimuli that are on par with what someone might experience on any given day OR if your study is limited to self-report data/surveys alone, then risks are expected to be minimal and aversive responses are expected to be "Rare" (i.e. < 1%) or "Infrequent" (i.e. approximate incidence of 1-10%).

In 6.9, you will need to explain why completing the study is worthwhile given the present risks. You should integrate information from 6.1 *Benefits to society (i.e.* How will the present study shed light on issues in this area? How will it seek to replicate prior research? And/OR How does it extent prior research? Ultimately, how will it contribute to knowledge in this domain? AND why is that of value?) into this section. Ultimately, if risks are relatively unlikely to occur (i.e. infrequent or rare) and of minimal risk (and in some cases moderate risk) then the benefit to science may outweigh the risk of participation.

18. **Special Considerations**: This section has a lot to do with biomedical research, but you still need to stay alert. Every once and while things will be strongly related to us!

19. **Other Special Considerations that will apply**. This section will not exist until you answer other questions. As by now I hope you surely know, for 7-1.1 if you are using subject pool the answer is yes and incentive is course credit. Obviously if you are using another incentive (e.g., services; extra credit; money) note that.

20. **Subject Participation**: You want to estimate a little high here. In other sections I tend to report a range from the minimum necessary to the maximum desired (e.g., 40-100 participants). In this section, I report the maximum desired.

21. **8-2 Subject Recruitment**: If you are using subject pool, report that in 8-2.2. If not, explain where you will get your participants. You will then have to fill out the other sections specific to your study. However, if you are using subject pool, then here are your answers:

8-2.3

8-2.3.1 N/A

8-2-4. The students comprising the introductory psychology student pool generally represent a diverse body of participants. The subject pool is monitored by University of Michigan Dearborn staff. Students self-select for participation.

8-2.5 GUYS THIS DEPENDS ON YOUR STUDY. IF YOU ARE ONLY HAVING THEM COME INTO THE LAB 1 TIME THEN THE ANSWER IS "no."

8-2.6 Sona-systems.com advertisement; University of Michigan Dearborn – Subject Pool

8-2.7 N/A

8-2.8 Sona-systems.com (put this under: "If Web pages will be used…"

For the exaction that says upload recruitment material here…upload your recruitment docs and study advertisement or solicitation docs (#6 from the "Before IRB" section).

22. **Subject populations**: For my studies pretty much always you will click Adults age 18 and older. For research with subject pool you will also click Normal, healthy subjects AND College students.

23. **Informed Consent**: For my work with will almost always be Comprehensive Written. You will have to upload your form as a separate doc.

10.1.2 Here is an example of how you should respond:

Potential participants will have the opportunity to read a summary description of this study as part of signing up for the study through the University of Michigan Dearborn Subject Pool. When students sign up for the study they will be given a date to come into the lab. Upon arrival to the lab. Each participant will have the opportunity to review the written consent form, speak with study staff, and ask questions about the study. Study staff will also provide information about the study. Ultimately, potential participants will have to provide written consent (as indicated by signing the written consent form). If they choose to do so, they will be entered into the study as a participant. No study procedures will begin until written informed consent is obtained.

24. **Confidentiality/Security/Privacy**: The answer to 11.1 is almost always no. The only common exception would is if you plan on collecting data from the same participants at two separate time points.

11.2 Here is an example of a response:

Consent forms will be kept separate from each participant's data. Each participant will be given a study ID number. There will be no way for study staff to connect study numbers to consent forms. There will be no way to connect study numbers to identifying information. Participants will be given forms in a packet. At the end of the study, participants will place all forms into the packet and seal the packet. Packets will not be opened until a minim of 1 month following the collection of the data OR at the conclusion of the study. No identifying information will be entered in the database. As such, all database information will only contain participant study IDs.

11. 3 Data will be kept in a locked office with restricted access in a locked file cabinet and de-identified data (i.e. data with NO identifying information) will be kept on a secure laptop in my lab. I click on the things I can click on, then click other and report the information above.

11.6: The answer is always: Retain for study recordkeeping purposes. Then include the following in response to 11.6.2:

Consistent with the recommendation of the American Psychological Association, all study data will be retained for seven years post the completion of the study. As such, it is anticipated that the hard data will be destroyed in (Month and Year). The faculty adviser for this study, Dr. Caleb Siefert, will assume responsibility for keeping the data secure and confidential.

25. **End of Subject Participation**: For 11-3.1 consider something along the following lines:

Participants can voluntarily withdraw from the study at any point. Any participant who wishes for any reason to withdraw from this study at any time is allowed to do so. If a participant appears upset or distressed, research staff will speak with them and direct them to speak with Dr. Caleb Siefert (Faculty Adviser).

For 11-3.2, always talk to me. This differs for specific studies.

26. **Payments or Incentives**: For 13. 4 consider:

Completion of subject pool units. Participants will receive 1 subject pool unit for participation.

For 13.5 consider:

Subject pool provides undergraduates in psychology with a chance to participate in psychological research. Students is Psych 170 and Psych 171 are required to complete four units. Students have the option of completing an alternative assignment (research article review) which requires roughly the

same amount of time. Thus students can opt not to participate in research and still fulfill this requirement for class.

For 13.6 consider:

Any participant that drops out for any reason at any time will receive full credit for having participated in the study.

27. **Surveys (this really means measures)**: You will have to upload each measure as an individual doc. The measure needs to be EXACTLY as you will give it to the participant.

Here is an example of how to respond to 29.15 if you have material that is disturbing:

The participants have to option to stop at any point. Should participants experience marked distress or report lingering problematic feelings as a result of this study they will be directed to the faculty adviser, Dr. Caleb Siefert. Dr. Siefert is a clinical psychologist who will meet with them to discuss their response. This meeting will not be for therapy, but rather to assess and better understand the participant's reaction. Should this discussion indicate that the participant is in need of additional services or counseling, Dr. Siefert will work with them to obtain a referral. Such participants will initially be referred to the University of Michigan Dearborn counseling center. Should a participant wish to seek services outside the university, Dr. Siefert will work with them to determine an appropriate referral.

For 29.11.1, you can refer them to the section in your proposal. Here's an example of what the section should look like:

5. Experiences in Close Relationship Inventory - Short - Form (ECR-S; Wei, Russel, Mallinckrodt, & Vogel, 2007). The ECR-S is developed as a short-form for the Experiences in Close Relationship Inventory (ECR; Brennan, Clark, & Shaver, 1998). The ECR is the most widely used self-report measure of adult romantic attachment. The ECR-S is growing in use. It is composed of 12 items worded as statements. Respondents rate each statement on a scale of 1 (strongly disagree) to 7 (strongly agree). The ECR-S produces scores for two scales: Attachment Anxiety and Attachment Avoidance. Six of the items load onto the Attachment Anxiety scale and 6 items load on the Attachment avoidance scale. Internal consistency estimates (i.e.coefficient alpha) for both scales have been reported to be within acceptable ranges (i.e. coefficient alpha >0.76) across six independent studies (Wei et al., 2007). Wei et al. (2007) reported strong test-retest agreement over a four week period for both attachment anxiety ($r = 0.82$) and attachment avoidance ($r = 0.86$). Correlations between the ECR long-form scale scores and ECR-S scale scores are strong (i.e. $r > 0.90$; Wei et al., 2007). A copy of the ECR-S is included in appendix 5.

28. **Watching/Listening to Audiovisual Materials**: Yup…you have to upload all of these!

Consider this example for 31.2.1

It is important to note that though such reactions are not anticipated, a protocol has been developed in the case of an adverse response to the study. The stimuli utilized in the present study are consistent with those typically used in highly similar studies. Additionally, the inclusion of an "amusement" video clip at the conclusion of the study has been shown to induce a more positive mood state in participants prior to discharging them from the study. Nonetheless a protocol for the possibility of an adverse responses has been created.

Participants who report distress at any point in time during this study will be allowed to discontinue participation immediately without any penalty. Any subject reporting continued distress during or following the study and/or lingering problematic feelings as a result of this study will be directed to the faculty supervisor for this study, Dr. Caleb Siefert. Dr. Siefert is a clinical psychologist. He will arrange to speak with the participant and may set up a meeting with them if appropriate. This meeting would be to better understand the participants response and to discuss potential options (formal therapy would not be provided). Should the participant be in need of counseling services, Dr. Siefert will work with them to identify treatment options. Students will be referred, as needed, to the student counseling center. Should the student wish to pursue treatment resources outside of the University, Dr. Siefert will work with them to identify potential treatment options.

29. Subjects vulnerable to coercion:

Consider this for 41.1

Students provide a non-clinical sample in which to study emotional responses and creativity. The subject pool also provides students in psychology with a chance to participate in psychological research.

Consider this for 41.2

All study procedures (and recruitment procedures) are consistent with the regulations imposed on researchers making use of the Subject Pool at the University of Michigan - Dearborn. This study has been created in a manner consistent with the Ethics code of the American Psychological Association. Participants will be a given a written consent form detailing their rights as study participants and study staff will answer all questions prior to obtaining informed consent. All participant data will be kept separate from participant consent forms. All study data will utilize participant ID numbers. There will be no way to link participant ID numbers back to participant consent forms. Students have the option of completing subject pool requirements without participating directly in research. They are also able to complete subject pool requirements by completing alternative assignments (i.e. research article reviews).

Example of a SONA Screenshot