

Taking the Red Tape Out of IRB
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Tuesday, April 15, 2014
Noon
SCC 212

Feeling confused about when and how to submit an IRB application? Frustrated that there's one more obstacle in the way of getting research with human subjects done? We get it, and in this presentation we seek to help make your job easier when working with the IRB (as well as convince you of the value of the IRB process in protecting human subjects). We will provide you with information about the IRB's purpose, what types of proposals should be submitted to the IRB, and how to prepare your proposal in line with the IRB's guidelines so as to streamline the process. We will conclude with a discussion of ethics in research and ways in which the IRB can better support student and faculty research. Attendees will gain an understanding of the ethical guidelines of the IRB as well as practical tips for making their interactions with the IRB easier.

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- I. Legal requirements for IRB:
 - A. National Research Act of 1974: framed congressional discussions on establishing ethical standards for research
 - B. 1978 Belmont Report: resulted from congressional discussions and articulated clear guidelines.
 - C. Dept. Health and Human Services (DHHS) IRB regulations laid out in the CFR Title 45, Part 46. These are frequently referred to as "The Common Rule". Lays out basic and necessary standards for protection of research subjects, including informed consent, protection of privacy and confidentiality, the right to withdraw from a study without penalty, minimizing of risks and protection of vulnerable subjects, and justification of risks by potential benefits of the study.

- II. IRB – purpose of the committee
 - A. To vet research proposals involving human subjects that are being conducted by faculty, staff, students, or affiliates of Pomona College
 - B. To set the tone for the types of work we deem ethical to conduct on human subjects

- III. Criteria for proposals that ought to be submitted to the IRB
 - A. Any study or project involving human subjects as participants, and -
 - B. Any study that is not confidential or that involves the collection of potentially sensitive personal information (e.g. mental health questionnaire requires IRB review; anonymous course evaluation does not)

- IV. Differences between exemption, expedited review, full review
 - A. Exempt: Studies eligible for exemption involve one of the following:

- i. Continuation of a research project that previously was approved by Pomona College IRB (changes in procedures are minimal)
- ii. Project that received IRB approval at another institution
- iii. Project is being conducted in educational settings and involve practices that are commonly used in these settings, such as research on special education strategies.
- iv. Studies involving use of educational tests, surveys, interviews, observations of public behavior which are conducted in such a way that data are unidentifiable
- v. Studies involving use of educational tests, surveys, interviews, observations of public behavior in which participants are elected/appointed officials or candidates for public office
- vi. Studies involving collection of existing data, records, or specimens that are publicly available or if the data are collected such that participants are unidentifiable
- vii. Research and demonstration projects conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.
- viii. Taste and food quality evaluation and consumer acceptance studies that either test a) wholesome foods without additives or b) foods containing a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the USDA.B.
Expedited Review:

B. Expedited Review:

- i. Any study where exempt status is questionable should be submitted to the IRB; proposals meeting 'exemption criteria' qualify for expedited review.

V. Full Review:

- i. Proposal involves collection of new data from participants who could be identifiable (unless precautions are taken).
- ii. Data collection may also involve a sensitive population (e.g., children, pregnant women, prisoners, Pomona college people)
- iii. Data collection may involve deception
- iv. Data collection that is highly personal and may evoke painful or disturbing memories, or be triggering;
- v. Data collection that involves collection of physiological data or samples or other procedures with potential safety risks (e.g. EEG, dietary interventions, metabolic studies, collection and analysis of urine, saliva, etc.)

VI. Methods for making alterations to existing IRBs (amendments)

- i. Submit a revised protocol to the Associate Dean for Research (currently Dean Wright).
 - ii. Include a letter detailing the changes you intend to make to the approved protocol
 - iii. If the changes are minor (e.g., changing the location of flyer postings), you would be eligible to submit an exemption rather than a full proposal)

- VII. What does it mean to have IRB approval? You are committing yourself to the following:
 - i. Performing the project by qualified personnel according to the approved protocol;
 - ii. Implementing no changes in the approved protocol or consent form without prior approval of the Human Subjects Protection Committee (except in an emergency to safeguard the well-being of subjects);
 - iii. Obtaining the legally effective informed consent from human subjects or their legally responsible representatives;
 - iv. Promptly reporting significant or untoward adverse effects to the Human Subjects Protection Committee; and
 - v. In your absence, arranging for a co-investigator to assume direct responsibility. This person is either named as co-investigator in the application or the Committee is notified in advance of such arrangements.

- VIII. Big picture things that need to be addressed in IRB proposals (from the practical to the values we are looking for [i.e., ensuring welfare of human participants])
 - i. Background, purpose and scientific significance of the study: why does this study matter? What is the theoretical justification for conducting this work? How will the results of this study advance our knowledge in your field?
 - ii. Number of subjects: How many people you intend to collect data from and why.
 - iii. Inclusion/exclusion criteria: Who will be allowed to participate and why? Who will be excluded from participation and why? We use this information to evaluate the risks of your study – for example, if you are intending to study the effects of receiving small electrical shocks on learning and don't exclude elderly people or people with heart defects, we will be much more concerned about our protocol.
 - iv. Method of subject identification and recruitment: How will you gain access to your participants? Here we pay attention to whether or not we think your methods of recruitment have the potential for coercing participants. For example, recruiting participants at a food bank by telling them you will pay them \$20 for their help might be considered a moderate form of coercion.

- v. Personnel recruiting participants: Who are the people who will be responsible for recruiting participants to enroll in your study? Do those people have the requisite skills to recruit in a way that is sensitive to people's privacy? Are these personnel going to be mindful to avoid coercion?
- vi. Methods and procedures: This is the bread and butter of your proposal. What will participants do during participation in your study? What specific questions will they answer? What procedures will they complete? Have these methods been validated as assessment tools? Are they safe? If the methods are questionable at face value with respect to their safety, it would be helpful if you provide support within your proposal for their safety/efficacy with the population in which you are interested in studying.
- vii. Data collection, storage and ultimate data disposal precautions to ensure confidentiality: What will you do with the data? Who will have access to the data once they are collected? How will you ensure that participants' identifying information will be dissociated from their other data? How will you protect against breaches of confidentiality? And when and how will you destroy the data when you are done with it?
- viii. Potential risks and discomforts: What are the potential risks to the participants themselves? Typical risks include things like temporary upset or thinking about negative experiences.
- ix. Minimizing risks: If your protocol involves risk, you should present a plan (here and in the consent form) for options you will give participants for addressing their discomfort following the study (for example, by providing participants with low-cost community mental health resources).
- x. Potential benefits: In this section we are interested in the immediate direct benefits to the participants (they may gain some insight about something in their lives) and also the broader impact of the findings (this work may help people later down the road).
- xi. Payment for participation: What do you intend to pay participants? Typically we recommend \$10/hour of participation though different rates apply if you are using MTurk.
- xii. Capacity to consent: Do the participants have the capacity to consent? If they are adults without developmental delays who can read English (or the consent forms are translated into other languages), they should be able to consent. Modifications may be necessary for other populations (e.g., oral consent for people who cannot read). If you work with children (people under 18) it is customary to have their parent/guardian provide consent and the youth provide assent.
- xiii. Comprehension of the information provided: Describe the methods you will use to ensure that potential participants understand what you have

said. You can offer them the chance to ask questions and also remind them that they can say no at any time.

- xiv. Debriefing procedure: Describe verbatim what you will tell participants (or provide the written information you will give to them) when they complete the study. If there is any deception involved in the study, please state how you will (or if you will) convey this information to the participants.
- xv. Process of consent: How will you go about obtaining consent? Will you provide potential participants a written document to sign? Will you ask them for oral consent after verbally explaining the study to them? Please be sure to attach your consent (and assent where appropriate) forms to the IRB application.
- xvi. Information Withheld from Subjects: This section refers to any deception that may occur. Please be sure to state what participants will not be told and how you will address this upon study completion (if at all).
- xvii. Demonstrate a Basic Understanding of Research Ethics with Human Subjects: All researchers involved in a research project involving human subjects at Pomona College now need to complete one of two web-based certifications prior to obtaining IRB approval: 1) NIH Training: <http://phrp.nihtraining.com/users/login.php>; 2) CITI Training: <https://www.citiprogram.org/>

- IX. Policies for student projects (in classes, for senior theses and independent projects):
 - i. Our working guidelines are that we do not require students to get IRB approval for projects using human subjects that fall under the auspices of a course. In this context, we assume that the instructor for the course serves as an extension of the IRB and that the instructor will prevent students from conducting research that would be deemed unethical. We also assume that students completing research for a course will not undertake projects that pose significant risk for human subjects or that would be at all questionable (from the protection of human subjects point of view).
 - ii. For seniors theses or larger scale student research projects (e.g., SURP projects), we do expect that students either obtain IRB approval for their own projects (if they are completing independent projects) or that they conduct projects that clearly fall under the auspices of faculty projects that have already received IRB approval.

- X. 5C data collection and policies
 - i. As of earlier this semester, we as a consortium have revised our policies regarding IRBs. It is no longer necessary for researchers to get IRB approval at each campus even if researchers want to collect data at each campus. It is required to get permission from the Student Affairs Offices at each school if researchers want to post flyers or publicly recruit

participants from their schools. If need be, researchers from one institution (e.g., Pomona) can send a copy of their approved IRB protocol and letter to another institution's Student Affairs Office to document that their project has been deemed ethical in this context.

- XI. Policies for handling proposals with cross-institutional collaborators
 - i. If you have collaborators at other institutions, it is typically only necessary to gain IRB approval (with the full protocol) at a single institution, but this may vary by institution. At Pomona, if you are working on a project that has previously been approved by another institution, you can submit the approved proposal for exempt review by the Pomona College IRB.

- XII. Sample IRB proposal: See attached

SAMPLE IRB PROPOSAL FOR YOUR REVIEW

Pomona College
Institutional Review Board
Human Subject Protection Committee
APPLICATION TO INVOLVE HUMAN SUBJECTS IN RESEARCH

Project Title: Emotions in College Students
Principal Investigator(s): Jessica Borelli, P.I.
Campus Contact Information: 909-607-3757 (Office); 909-607- 3644 (Lab)

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Human Subjects Committee. I agree to comply with all applicable federal, State and local laws regarding the protection of human subjects in research including the following:

- Performing the project by qualified personnel according to the approved protocol;
- Implementing no changes in the approved protocol or consent form without prior approval of the Human Subjects Committee (except in an emergency to safeguard the well-being of subjects);
- Obtaining the legally effective informed consent from human subjects or their legally responsible representatives;
- Promptly reporting significant or untoward adverse effects to the Human Subjects Committee; and
- In my absence, arranging for a co-investigator to assume direct responsibility. This person is either named as co-investigator in this application or the Committee is notified in advance of such arrangements.

Principal Investigator's Signature

Date

FUNDING

List current or pending funding sources for the research, including grant number, if applicable.

Limited funding needed; participants will be compensated with research credits applicable to their Psychology 51 course or offered \$10 cash.

SUMMARY INFORMATION

Subject Population:

- Children
- Elderly
- Pregnant Women
- Cognitively or Psychologically Impaired
- Institutional Residents
- Prisoners or Parolees
- Non-English speaking
- Pomona College students/staff

If the research involves any of the following, check the appropriate boxes:

- Interviews
- Surveys/questionnaires
- Behavioral Observation
- Deception
- Waiver of Consent
- Study of Existing Data

Location of Research:

- Pomona College or 5-College campus
- Specify other locations:

PROPOSED PROTOCOL

Include information about the following:

1. Background, Purpose and Scientific Significance of the Study
2. Number of Subjects
3. Inclusion/Exclusion Criteria
4. Method of Subject Identification and Recruitment
5. Methods and Procedures Applied to Human Subjects
6. Data Collection, Storage and Confidentiality
7. Potential Risks and Discomforts
8. Minimizing Risks
9. Potential Benefits
10. Payment for Participation
11. Capacity to Consent
12. Personnel Recruiting Participants
13. Process of Consent (attach copy of Informed Consent Form)
14. Comprehension of the Information Provided
15. Information Withheld from Subjects
16. Debriefing Procedure

Children's Attachment and Emotion Study
Institutional Review Board Proposed Protocol
PI: Jessica Borelli, Ph.D.

1. Background, Purpose, and Scientific Significance of Study:

Research Question One: Language use differences as a function of attachment style

Attachment theory maintains that people employ different relational strategies that are all designed for the same purpose: keeping other people close (Bowlby, 1973). These different relational strategies are better known as attachment styles. Adult attachment styles are thought to vary on two central dimensions – attachment anxiety and attachment avoidance. Those who have insecure attachments are classified with either an anxious attachment style or an avoidant attachment style (Mikulincer & Shaver, 2007). Attachment styles manifest in internal working models, which represent coherent ways in which individuals approach and interpret relationship experiences throughout their lives (Bowlby, 1980). Extensive research has shown that these attachment styles set the foundation for how individuals process and regulate emotion during interpersonal experiences (e.g. Shaver & Mikulincer, 2002), and that different styles are related to distinct patterns of regulation in both friendships (Welch & Houser, 2010) and romantic relationships (Domingue & Mollen, 2009).

Little is known, however, about how individuals manifest differences in emotion regulation through language use. A wide body of research supports the notion that the words people use can reveal subtle but important differences in personality (Pennebaker & King, 1999), psychological states (Pennebaker, Slatcher, & Chung, 2005), emotional states, and cognitive styles (Pennebaker, Mehl, & Niederhoffer, 2003). Pennebaker and others argue that specific word choice provides a window into whether one is focused on the self or others (Rude, Gortner, & Pennebaker, 2004), whether one is lying or telling the truth (Newman, Pennebaker, Berry, & Richards, 2003), and whether one is in a high quality relationship or not (Simmons, Chambless, & Gordon, 2008). For example, language researchers argue that there is a fundamental difference between saying “I’m happy” and “I’m not sad”, and that subtle differences such as these may reveal important information about emotional experience and regulation.

Few studies have examined individual differences in language use with respect to attachment style and language use, though cursory research has been supportive of a connection. Recent research has shown that different attachment patterns are associated with detectable and predictable differences in the words used during attachment interview assessments, and that word-count text analysis is a reliable way to uncover such differences (e.g. Borelli, David, Rifkin-Graboi, Sbarra, Mehl & Mayes, 2012; Borelli, Sbarra, Mehl & David, 2011). For example, specific combinations of pronoun, present tense, and discrepancy word usage are thought to indicate “verbal immediacy,” or the degree to which one is emotionally connected and immersed in the situation being described (Cohen, Mehl, & Pennebaker, 2004). Uncovering a clear link between language use and attachment style, we (2011) found that lower verbal immediacy scores were related to insecure attachment in school-aged children.

Given these previous findings, we propose here that self-reported attachment style will be associated with the language people use when describing the content of their interpersonal, relationship-relevant experiences, and seek to explore whether this relationship holds in the context of non-interpersonally based experiences as well.

Research Question Two: Sensory processing origins of first-time non-suicidal self-injury

One form of maladaptive behavior that is often linked with the psychopathology associated with emotion dysregulation is non-suicidal self-injury (NSSI), which is an increasingly prevalent phenomenon that occurs in 13 to 20% of adolescents (e.g., Lloyd-Richardson, Perrine, Dierker, & Kelley, 2007; Ross &

Heath, 2002). This maladaptive coping behavior is often indicative of deeper internal or social problems, and can act as a gateway to other negative risk behaviors, including drug use, smoking, bulimic behavior, aggression, sexual behavior, and, in some cases, suicide (Brown, Houck, Hadley, & Lescano, 2005; Guertin, Lloyd-Richardson, Spirito, Donaldson, & Boergers, 2001; Laye-Gindhu & Schonert-Reichl, 2005; Webb, 2002). Research over the past few decades has ventured to describe and deconstruct this dangerous behavior (Favazza, 1989, 1998; Klonsky, 2007; Nock 2009). Trauma, dissociation, impulsivity, poor attachment, depression, and anxiety have been linked to NSSI as explanation for the behavior (Nock, 2009; Yates, 2004), yet there remains a paucity of research addressing the initiation of NSSI in adolescents and, specifically, why adolescents turn to self-injury over other coping strategies.

Possible explanations must look deeper into the biological and internal sources of individual differences. Until recently, NSSI research focused primarily on exploring the homogenous traits of NSSI, such as the risk factors or characteristics associated with NSSI. Current functional models posit that adolescents engage in NSSI to regulate internal emotional states or communicate with others (Nock, 2010). Though a consensus appears to be forming in regards to the purposes served by NSSI, debate continues over issues of initiation; in other words, how and why this behavior is initially chosen as a self-regulation strategy over other strategies (Nock, 2009). Some of the more recent explanatory models tend to avoid omnibus explanations by accounting for multiple pathway possibilities and accommodating the heterogeneous nature of this behavior. Though some of these models account for the social, cognitive, emotional, and neurochemical aspects of NSSI, there is lack of focus on why some adolescents choose such a sensory specific—visceral, tactile, or proprioceptive (pressure on joints and muscles)—means of regulating their bodies and emotions or communicating their needs. A next step in further understanding NSSI is exploring the role of the sensory system in regards to how self-injuring adolescents take in external information (processing), how they modulate their responses (modulation), and how these sensory elements are integrated.

Negative factors such as trauma and poor attachment often result in sensory processing deficits starting in childhood (Shore, 2008). The senses act as a gateway for external information to enter the brain, and the Central and Autonomic Nervous systems work together to regulate arousal states (Shore, 2001). An overly reactive or under-reactive sensory processing system, especially when related to trauma, can impact the ability to appropriately modulate arousal. Research by Liss, Timmel, Baxley, & Killinsworth (2005) found that sensory processing sensitivity predicts depression and anxiety in adulthood. Despite these findings, researchers have yet to explore the connection between sensory preferences and NSSI.

Dunn's Model of Sensory Processing demonstrates that differences in neurological thresholds (our tolerance to receive sensory information) and regulatory strategies (our tendency to be active or passive in reacting to stimuli) allow for an array of sensory integration types and variety in individuals responses to stressors (Dunn, 1997, 2007). The need to modulate affect through the skin (tactile or proprioceptive / muscular senses) combined with "low threshold" preferences and active or passive regulation strategies may be an underlying component of what leads adolescents to choose NSSI as a coping strategy. "Sensory experiences provide the core foundation for how we perceive our bodies and the world (Lillas & Turnbull, 2009, p. 57)." A deeper understanding will strengthen connections among the various components of current NSSI models and explanatory factors.

This study aims to bridge sensory integration research with child and early adolescent development and emotion regulation research. By exploring the role of the sensory system in NSSI, as well as acknowledging the transactional and relational nature of all four systems within the NRF, we will be able to look at both the individual and the behavior as a whole when making determinations for prevention and treatment. We propose that adolescents who engage in NSSI have unique sensory processing patterns that influence their self-regulatory preferences. We predict that both the origins of self-harm and underlying sensory functions of self-harm have a role in predicting first-time engagement

in NSSI. Ideally, a relationship between sensory processing and NSSI would contribute to the designing and implementation of evidence-based prevention and intervention strategies, as well as support treatments that focus on adolescents' sensory preferences and self-regulation as opposed to solely focusing on higher order cognitive-behavioral approaches.

Research Plan:

We plan to study 300 undergraduate students, administering the Experiences in Close Relationships - Revised (Fraley, Waller & Brennan, 2000) as well as other self-report questionnaires. Participation in the study should take about 30 minutes. Students will complete questionnaires online using our secure server hosted by Qualtrics.

Participant Protocol:

Demographic Form: This form is a brief 12 question self-report measure of demographic information.

Experiences in Close Relationships Revised: The ECR-R (Fraley, Waller & Brennan, 2000) is a 36-item self-report attachment measure that assesses attachment style. The reliability and validity of this measure are shown elsewhere (Fraley & Shaver, 2004)

Sensory Profile (SP): This 125 item caregiver-completed questionnaire examines how children respond to sensations in everyday life (Dunn, 1999). The SP assesses sensory processing in six subsections (auditory, visual, movement, touch, multisensory experiences, and oral sensory experiences), sensory modulation, and behavioral and emotional responses related to sensory processing ability. The Sensory Profile Supplement will be used to convert SP scores into quadrants for comparison with the A/ASP. Though the SP is intended for children aged 3-10, examples will be added to ensure items are age appropriate. These scores will be compared to the children's A/ASP scores to help obtain an accurate picture of children's sensory preferences.

Functional Assessment of Self-Mutilation. This is a self-report measure of frequency and functions of children's self-injurious behavior (Lloyd, Kelley, & Hope, 1997). Eleven items assess various types of self-injurious behavior (e.g., "cutting/burning/scraping skin," "picking at a wound," "biting or hitting oneself," "inserting objects under skin," "hair pulling") engaged in during the past year, their frequency, and whether or not medical treatment was received. Six additional items inquire about other aspects of self-injury, including whether or not the participants had suicidal intent, how much pain they felt, how long they thought about it before doing it, whether or not they were taking drugs or alcohol at the time, how old they were the first time they harmed themselves, and whether or not they had ever engaged in self-injurious behavior (if not in the last year). Finally, 22 items assess the reasons why participants engaged in self-injurious behavior. Participants rate each reason on a 0-3 scale (0 _ never, 1 _ rarely, 2 _ some, and 3 _ often).

Beck Depression Inventory. The Beck Depression Inventory (BDI - II; Beck, Ward, Mendelsohn, Mock, & Erbaugh, 1961) is a 21-item self-report measure of severity of depression that has high reliability and validity (Beck, Steer, & Carbin, 1988). Items are rated on a 4-point scale, with a score of 0 indicating the absence of a symptom and a score of 3 signifying a persistent or severe expression of the symptom. The BDI yields a total score between 0 and 63 with scores between 20 and 28 indicating moderate levels and between 29 and 63 indicating severe levels of depression (Beck, Steer, & Brown, 1996). See Appendix J for all questionnaires completed by the parent.

Personal and Interpersonal Experiences Reflection. This section includes four separate open-ended questions (e.g. "Please describe in detail a positive interpersonal experience you have had in the past month.") with sub-questions created for the current study and designed to elicit written responses from

participants about how they emotionally and cognitively process experiences in their lives. Two questions ask the participant to reflect on and describe recent *interpersonal* interactions, one positive and one negative, and two questions ask the participant to reflect on and describe recent *personal* interactions (taking place without another person present), one positive and one negative. For each situation, participants are asked to describe the experience in detail, how it made them feel, and what it made them think about. (See Appendix A)

2. Number of Subjects:

We plan to study 300 undergraduate students. It is estimated that data collection will last for up to one year and data analysis will ensue for the following six months.

3. Inclusion/Exclusion Criteria:

Inclusion criteria Inclusion criteria include being a college student who is willing to provide consent to for their own participation in the study (i.e., only students over the age of 18 will be allowed to participate). All ethnic and racial groups will be eligible to participate.

Exclusion criterion include being a non-college student.

4. Method of Subject Identification and Recruitment:

Recruitment will involve three central components. The first will involve making professors of psychology courses with research participation requirements aware of the study. The principal investigator will explain the purpose and requirements of the study to these professors, and if given permission, will contact the class in one of two ways. One way the principal investigator would contact the class is by sending out an email to the class list informing them of the opportunity to participate in the study in exchange for research participation credit for the intro psych course. Alternatively, the principal investigator could make an announcement to the course at the beginning of the lecture announcing the opportunity to participate in the study. The second main component to recruitment will be announcing the study in college newsletters and bulletins. In order to attract participants to the study who are not eligible for course credits, we will announce that those who participate will be eligible for cash compensation.

Finally, it is possible that some people will hear about the study by word of mouth, but in order to participate they will have to meet the inclusion criteria of being a college student.

5. Methods and Procedures Applied to Human Subjects

The student will view a consent form to read before beginning taking the surveys. As the experiment will be completed via an online survey host, students will be notified that their continuation of the study indicates their consent; as such, no written documentation of consent will be collected. Participants who continue past the consent page will have provided their consent through continuation.

Process of Consent:

Students will provide informed consent for their own participation in the study via their continuation past the consent page of the online survey, which will be the first page they see upon logging into the online survey program; as such, no physical consent document will be collected. The rationale, procedures, and potential risks of the procedures in this study will be explained to each participant on survey page explaining consent. Also, each subject will be informed that participation in the study is strictly voluntary, that refusal to participate can happen at any time during the experiment, and that the study constitutes research. Furthermore, they will be told that information obtained is likely to increase understanding of how students in college make sense of their emotional experiences

and how this process might be different for different people. Students will be notified that their continuation of the study indicates their consent, but that they can withdraw their consent by stopping at any point, without consequence.

6. Data collection, Storage, and Confidentiality:

Subject names will not be collected, and as such will never be made available on any records of the study. Strict confidentiality of all information provided to us by the subjects will be upheld. In the event that any hard copy protocols are generated, they will be kept in locked filing cabinets, and only study identification number will identify participants on these forms. Similarly, in all records of the study, subject identification number alone will identify individuals; individuals will never be identified by name. Protocols will be given via the online survey program, Qualtrics. These electronic files are only accessible via login ID and password and only key study personnel will be permitted access to these files. No identifying information or names of subjects will be used in any scientific reports of this study.

The data for this study will constitute a study of college students' internal relational models and how these models might influence the process of processing positive and negative personal and interpersonal experiences, as well as a study of college students' sensory profiles and self-harm behaviors. Data will be collected at one time point for each participant. This protocol involves minimal risk and no adverse events are anticipated. In the unlikely event that serious unanticipated adverse events do occur, they will be reported within 48 hours to the IRB and any appropriate funding and regulatory agencies. The principal investigator will specify whether the serious unanticipated adverse event is thought to be related to the study.

The principal investigator will also summarize all adverse events in the annual request for reapproval application to the IRB. She will also examine the adverse events and project data at least once per year in order to decide whether the event alters the risk/benefit ratio of the study and whether or not alterations should be made to the protocol (at Risks to Subjects) or consent form (at Risks/Benefits.)

7. Potential Risks and Discomforts:

There are no risks of physical injury. The most likely risks of the study's self report measures are to confidentiality. However, all research materials are upheld and accessed only by study personnel. There is the potential that answering questions about negative experiences might be stressful for some participants. However, knowing that this potential exists, we will be vigilant about attending to any concerns that might emerge. If an individual is very bothered, the PI, who is a licensed clinical psychologist, will offer appropriate referrals to mental health professionals at Monsour or in the community. There is a possibility that for a small subset of people, discussing negative interpersonal/personal experiences may be stressful and upsetting.

In addition, there is the possibility that answering questions about difficult topics (e.g., depression, self-injury, attachment style) will be upsetting to participants. It is important to note that these are well-validated and carefully-crafted questionnaires which are routinely employed in research studies investigating mental health. The Beck Depression Inventory, for example, has been used in hundreds of studies published within the last 10 years, for example, and is one of the most widely-used scales ever developed within psychology. The Experiences in Close Relationships scale has also been used in several hundred published studies within the last 10 years. Questionnaires such as the ones employed in this study are standard screening tools used to assess psychiatric symptoms in both children and adults. Further, evidence suggests that asking people questions about upsetting topics (e.g., suicidality and self-injury) does not in fact increase that person's risk for experiencing that in the future (see Gould et al., 2005). However, knowing that we are asking people to respond to questions

about sensitive topics, we will be especially vigilant about attending to any concerns that may arise. In the event that any individual is overly distressed, we will provide appropriate referrals to mental health professionals in the community for evaluation and treatment.

8. Minimizing Risks:

Participants will be informed that they can discontinue their involvement in the study at any point and still receive credit for participation. Should a participant be very upset by the protocol, we will provide appropriate referrals to mental health professionals in the community.

9. Potential Benefits:

There are no direct benefits to students participating in the study. The subject might find an indirect benefit from considering aspects of their relationships and selves that they might not have consciously examined otherwise. Furthermore, because the results from this study will help us to better understand the ways that internal ideas about relationships are related to emotional processing of life experiences and the ways in which certain behaviors may be linked to sensory perceptions, it is possible that this understanding may benefit others in the future.

Subjects will incur minor risk and receive course credit or cash compensation for participating in the study.

10. Compensation for Participation:

Students will receive necessary course credit for research participation in their Introductory Psychology courses or will receive cash compensation (\$10 dollars).

11. Capacity to Consent:

Only students capable of providing consent will be able to participate in the study; consent will be indicated through continuation of the study past the consent page of the online survey program, which will be the first page participants see upon logging into the online survey program. Students will not be allowed to participate in the study until they have provided consent. Please also see number 5 above.

12. Personnel Recruiting Participants:

Name	Role	Involved in Recruiting	Involved in Consenting
Jessica Borelli, Ph.D.	Principal Investigator	Yes	Yes
Patricia Smiley, Ph.D.	Collaborator	No	No
Jessica West, B.A.	Lab Manager	Yes	Yes
Natasha Haradhvala	Research Assistant	Yes	Yes
Kizzann Ramsook	Research Assistant	Yes	Yes
Melanie Fox	Research Assistant	No	Yes
John Coffey	Graduate Research Assistant	No	No

Katie St. John	Graduate Research Assistant	Yes	Yes
Eun Saem Cho	Research Assistant		
Jessie Stern	Research Assistant	Yes	Yes
Kelly Miller	Research Assistant	Yes	Yes
David Kyle Bond	Graduate Research Assistant	Yes	Yes
Brian Clark	Research Assistant	Yes	Yes
Brittnay Ahn	Research Assistant	Yes	Yes
Claire Laubacher	Research Assistant	Yes	Yes
Jennifer Somers	Research Assistant	Yes	Yes
Jes Snavely	Graduate Research Assistant	Yes	Yes
Jessica Stern	Research Assistant	Yes	Yes
Julia Koch	Graduate Research Assistant	Yes	Yes
Katherine Harder	Graduate Research Assistant	Yes	Yes
Lauren Kim	Research Assistant	Yes	Yes
Mina Han	Research Assistant	Yes	Yes
Sam Chung	Research Assistant	Yes	Yes
Nicole Welindt	Research Assistant	Yes	Yes
Aleksandra Gawlik	Research Assistant	Yes	Yes
Leena Zurayk	Research Assistant	Yes	Yes
Lauren Vazquez	Research Assistant	Yes	Yes
Christopher Reeves	Research Assistant	Yes	Yes
Leila Zahedi	Research Assistant	Yes	Yes
Laura Perrone	Research Assistant	Yes	Yes
Sonya Zhu	Research Assistant	Yes	Yes
Anna Blanken	Research Assistant	Yes	Yes
Michelle Reade	Research Assistant	Yes	Yes
Jeremy Marks	Research Assistant	Yes	Yes
Yuni Kay	Research Assistant	Yes	Yes
Laura River	Research Assistant	Yes	Yes

13. Process of Consent:

Students will provide consent for their own participation via continuation of the survey past the consent page, which will be the first page they see upon logging into the online survey program. No paper documentation of consent will be obtained; however, students will be duly informed that continuation past the consent page indicates consent to participate, and that they can withdraw their consent by stopping at any point, without consequence.

14. Comprehension of the Information Provided:

A phone number and an email address will be provided to participants on the consent survey page so that they may contact research assistants should they have questions or concerns about the consent form or survey process, in order to make sure the students have an accurate understanding of the study. All relevant information will be present on the consent webpage and it will be clearly communicated that participants can choose to stop at any time if they no longer want to participate.

15. Information Withheld from Participants:

No information will be withheld from participants. There is no element of deception to this study.

16. Debriefing Procedure:

At the end of the study participants view a page describing that the purpose was to learn more about both the way that students process emotions related to personal and interpersonal situations and how self-harm behaviors relate to sensory processing. Should students have specific questions about particular elements of the study, they will be provided an email address and a phone number with which to contact the researchers. If participants have questions that exceed the knowledge of the experimenter, they will be referred to the principal investigator for further information.

POMONA COLLEGE

TITLE OF STUDY:

Emotion in College Students

PURPOSE: You are being asked to participate in a survey on emotion and behavior in college students. You will fill out multiple questionnaires regarding the way you think about relationships, your mood, your current behaviors, your sensory preferences, and different types of emotional experiences people sometimes have.

RIGHT TO REFUSE OR WITHDRAW:

You may refuse to participate in this study. If you decide to participate, you may change your mind about being in the study and quit after the study has started. You may refuse to take any test. You will still receive credit/compensation if you withdraw before completing the entire study. If you are completing this survey for your introductory psychology class, please note that if you decide not to participate in any research studies this semester you will be given the option of completing an alternate assignment to get course credit.

RISKS/BENEFITS:

It is unlikely that participating in the study will expose you to any significant risks or benefits. However, it is possible that answering questions about relationships will cause minor distress. If you do experience distress and would like to talk to a mental health professional about it, please contact the PI (Jessica.borelli@pomona.edu). It is also possible that as a result of participating in the study, you will gain a clearer understanding of your attitude toward and your behavior in close relationships.

COMPENSATION:

Please note that you will either receive course credit or compensation (\$10) after completing the study. At the end of the survey, you will be given a code and instructions for how to submit this code for credit/compensation.

CONFIDENTIALITY: Your individual privacy will be maintained in all publications or presentations resulting from this study. No identifying information will be collected during the study and all information collected will be used for the sole purpose of data analysis and not shared with anyone outside of the research team. Once collected, the data will be imported and stored on a locked computer with only access granted to the Primary Investigator and her research team.

QUESTIONS:

If you have any questions, please contact Dr. Jessica Borelli at 909-607-3757, or Jessica.Borelli@pomona.edu.

CONSENT:

I understand the above information and have had all of my questions about participation on this research project answered. By selecting the box "I agree" I indicate that I am 18 years of age or older, and voluntarily consent to participate in this research. * *This question is required

- Agree and proceed

- Decline and quit

I. Insert study questionnaires/protocols here

II. Insert CITI/NIH Certifications here