1. Project Identification and Abstract

1.1. * Type of Submission:

- Research Protocol or Study on Human Subjects
- Grant/Contract Only
- Facilitated Review (NCI CIRB)
- USC/CHLA Collaborative Review
- Use of Humanitarian Use Device (Not Research)
- Ceded Review (Utilize approval by an outside IRB)

1.2. * Full Title of Research Protocol
Neurology of Social Emotions - Compassion and Admiration

1.3. * Short Title
Neurology of Social Emotions - Compassion and Admiration

1.4. Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.

In this study, we will investigate how the brain processes compassion and admiration, two complex social emotions that contribute to moral reasoning and social interaction. We will also study how the brain processes physical pain and pleasure, for comparison with admiration and compassion. The moral version of the study will investigate how the brain responds to situations that have a moral content. The study will involve two methods: fMRI, which is a type of brain imaging, and psychophysiology, in which we record bodily processes such as heart rate, palm sweating, and breathing. Subjects will spend up to eight hours total viewing photos and video clips, and listening to recorded stories, first with the experimenter and later in the fMRI scanner. While they watch and listen, we will sometimes record their heart rate and other psychophysiological processes. Some subjects will also experience foot massages and mildly painful heat or cold on their feet, first outside of the fMRI scanner and later during a brain scan. We will also investigate how culture modulates the underlying biological processing of social emotions, by conducting the same set of experiments in China and comparing these results to the results from the U.S. study.

1.5. * Select which IRB you are requesting review from:
USC-University Park Campus (UPC)

2. Study Personnel

2.1. Study Personnel and their roles:

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Organization</th>
<th>Study Role</th>
<th>Certifications</th>
<th>Obtain Consent</th>
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<tbody>
<tr>
<td>View</td>
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<td>PSYCHOLOGY</td>
<td>Principal Investigator</td>
<td>HS</td>
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<td>NEUROSCIENCE</td>
<td>Study Contact Person</td>
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<td>PSYCHOLOGY</td>
<td>Research Assistant or Associate</td>
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<tr>
<td>View</td>
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<td>PSYCHOLOGY</td>
<td>Advisor for Chinese portion</td>
<td>HS (GCP (HIPAA)</td>
<td>no</td>
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</table>
2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?
   ☐ Yes  ☐ No

2.3. If there are any individual collaborators from other institutions, check here: ☐

2.5. Specify the group/organization who has reviewed this study for scientific merit:

4. Funding Information

4.1. * What existing, planned, or pending support will be used for this study? (check all that apply)
   - ☐ CTSI
   - ☐ Department of Defense (DOD) Funds
   - ☐ Departmental/Institutional Funds
   - ☒ Federal Grant/Contract
   - ☐ Foundation Grant/Contract
   - ☐ Industry
   - ☒ Intramural/Internal Grant
   - ☐ Residual Funds
   - ☐ State or Local Grant/Contract
   - ☐ Subcontract from another institution
   - ☐ No Funding
   - ☐ Other

4.2. If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), try to select it from the list using the "Add" button. If the funding source is not displayed in the list, enter the information in question 4.4.

<table>
<thead>
<tr>
<th>Grant #</th>
<th>Principal Investigator</th>
<th>Grant Title</th>
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   There are no items to display

4.2.1. If the grants selected in question 4.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.
   - name  Version  Modified
   There are no items to display

4.4. Add any funding source that is not listed above. Use the "Add" button for each funding source for this study.

<table>
<thead>
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<th>Type of Funding</th>
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5. Type of Study Review
5.1. Select the type of review that you are requesting for this study:

- Full Committee Review
- Expedited Review
- Exempt Review
- Coded Specimens/Data

6. Study Location(s)

6.1. Select the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

- HSC - Health Sciences Associated Locations
- **UPC - University Park Associated Locations**
- CHLA
- **Other Sites/Institutions (Outside the US)**

6.2. Are there other sites besides USC/CHLA involved in the research?

- Yes
- No

6.3. Is USC/CHLA the coordinating site or are there sites where USC/CHLA is conducting the study?

- Yes
- No

6b. UPC Location(s)

_This screen is required if you indicated UPC - University Park Associated Locations (Question 6.1.)_

6b.1. UPC Locations (check all that apply and provide detail where indicated):

- **Campus location (includes ISI and ICT)**
- Off-campus location

If campus location, please specify:
Dana and David Dornsife Cognitive Neuroscience Imaging Center; also, Brain and Creativity Institute offices

6b.2. If off-campus location, please specify:

6c. Other Sites/Institutions

_This screen is required if you indicated that USC/CHLA is the coordinating site or is conducting the study at other sites (Question 6.3)._  

6c.1. List ALL participating sites below:

Site Name Address Engagement
There are no items to display
6c.2. **Other Sites/Institutions (Outside the United States):** List the institution(s) and country(ies) at which the Principal Investigator will conduct the study.

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Address</th>
<th>Country</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>China</td>
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9. **Methods and Procedures - Selected Descriptors/Community Engaged Research**

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. **This study will involve:** (check all that apply)

- Prospective collection of data/specimens
- Use of existing or retrospective data/specimens

9.2. **Study Procedures:** (check all that apply)

- Audio/Video Recordings or Photographs
- Behavioral Observations and/or Behavioral Experimentation
- Behavioral Interventions
- Deception
- Interview/Focus Groups
- Population-based Field Study
- Psychophysiological Testing
- Surveys/Questionnaires/Psychometric Testing
- Creation of a Data or Tissue Repository
- Magnetic Resonance Imaging (MRI)
- Stem Cell Research
- Venipuncture

9.2.1. I attest that I have read, will adhere to, and informed all research staff, including students, of the Dana and David Dornsife Imaging Center Policy concerning human subject research.

9.4. **Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?**

- Yes  
- No

9.5. **Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?**

- Yes  
- No

10. **Characteristics of the Study Subject Population**

10.1. **What is the maximum number of subjects you plan to recruit for this site?** (Integer values only)
10.1.1. If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)
200

10.1.2. If necessary, provide further explanation of accrual goals for all subject populations.
Emotions only:
50 American subjects.
60 Chinese subjects will be recruited in Beijing, China, and 30 in the Los Angeles area for the Chinese version of the study.

All conditions:
10 pilot subjects (to ensure that results are obtainable using this protocol and to test any protocol changes made), 50 subjects using the final version of the protocol

10.2. Describe the inclusion criteria for enrollment.
Any normal adult subject who has passed the initial screening (see screening form attached to 40.1). For the new amendment to the moral version, we will include subjects raised in India, as well as those whose first language is hindi.
When recruiting Indian subjects in the Los Angeles area, we will use the screening form (screening questionnaire for Indian subjects). We will select subjects who were over 18 when they came to the U.S. They should have Hindi as their first language. English is the official language of India, and we will include only those subjects who also speak English.

10.3. Describe the exclusion criteria for enrollment.
Each subject will be required to complete a screening questionnaire to detect the presence of any devices or conditions, e.g., pacemaker, ferrous metal bodily implants, etc., that might present a safety risk. Subjects with any yes response on the screening form will be excluded from the study. This screening form is uploaded in section 40.

Since there is a visual component to this study, subjects must have either have normal or corrected normal vision.

Subjects will also be excluded if they have any history of serious psychiatric or neurological disorders, or if they have a history of abuse, as either could impact emotional perception and expression.

Subjects will be excluded from the portion of the study involving the infliction of physical pain if they have peripheral vascular disease, diabetes, Reynauds phenomenon, cryoglobulinemia, vasculitis, lupus, or any peripheral neuropathies.

Additionally, cultural background may be a relevant criterion for exclusion; see section 10.3.1 for details.

For some portions of this study, left-handers will not be enrolled. This is a standard exclusion criterion for brain research, and will be determined by a modified Oldfield handedness questionnaire (Oldfield, 1971) attached in section 21.1.1

The level of autonomic arousal within an individual is affected by numerous factors, such as body mass index (BMI), diet and water intake, physical fitness, medications, and position in the menstrual cycle (for females). Therefore, we may require that subjects abtain from intense exercise, smoking, alcohol, and caffeine for 12 hours prior to the testing. Additionally, when measuring autonomic arousal, we may exclude subjects whose BMI is higher than 30 (in the range of obesity), who are trained atheletes, or who have known cardiovascular problems. We will ask the subject what medications they are taking, and determine at that time whether that medication would affect their autonomic arousal level. Some common medications that affect autonomic arousal include but are not limited to alpha and beta blockers, acetylcholine antagonists, and some over-the-counter cold medications (e.g. decongestants). As it is difficult to compile
10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.

Age restriction: 18 and above. We are only testing the adult population.

Because we are examining emotional processes which are known to be influenced by cultural factors, cultural and ethnic background will be taken into account in accepting subjects into the study. For the current phase of the study, we will exclude subjects not raised in the United States, as well as those whose first language is not English. We may also exclude American participants of East Asian descent, to avoid potential cultural confounds.

For the Chinese version of the study, we will exclude subjects not raised in Mainland China, as well as those whose first language is not Mandarin Chinese.

When recruiting Chinese subjects in the Los Angeles area, we may also exclude subjects based on the nature of their immigration experience. A screening questionnaire (40.1 screening questionnaire for Chinese subjects in LA) will be used to assess subjects' background. Subjects have to be over 18 when they came to the U.S. The score of items 2-6 in the questionnaire will be averaged. At this stage of the study, we want to get a population close to that in Beijing, so subjects with high average scores will be recruited. Its hard to specify a cutoff now, because it depends on the subject population we are able to get. During data analysis, the average score may be used as a covariate in our regression model, to look for neural activities that change with different level of acculturation.

For the new amendment to the the moral version, a screening questionnaire (screening questionnaire for Indian subjects) will be used to assess subjects' background. Subjects have to be over 18 years of age when they came to the U.S. The score of items 2-5 in the questionnaire will be averaged. Subjects with high average scores will be recruited. Its hard to specify a cutoff now, because it depends on the subject population we are able to get. We will exclude subjects not raised in India, as well as those whose first language is not hindi. English is the official language of India, and we will include only those subjects who also speak English.

11. Research Objectives and Background

11.1. Describe the specific objectives or aims of the study and hypotheses or research questions.

We seek to test the following hypotheses:

Hypothesis 1:
In contrast to the neutral foot pressure condition, the painful and pleasurable foot stimulation conditions will elicit brain activations previously associated with pain or pleasure.

Hypothesis 2:
In contrast to the neutral photo viewing condition, viewing photos meant to inspire admiration or compassion will elicit activations previously associated with moral reasoning and emotion.

Hypothesis 3:
In contrast to comparisons between the neutral photo viewing and foot pressure conditions, comparisons between the pain and compassion conditions and between the admiration and pleasure conditions will reveal significant overlaps in activations. Specifically, we hypothesize that the activations associated with pain will share key features with the activations associated with viewing compassion-inspiring photos/video clips, and that the activations associated with pleasure will share key features with the activations associated with viewing admiration-inspiring photos/video clips.
By comparing results from American subjects and Chinese subjects, we seek to test the hypothesis that there are similar neural substrates underlying admiration and/or compassion in the two cultures.

Hypothesis 4
For the moral version, we hypothesized that in contrast to the neutral video clips viewing condition, viewing video clips depicting moral violation will elicit activations associated with moral reasoning and emotion. In the new amendment, we hypothesize that subjects belonging to American and Indian cultures will differ in their judgment of everyday and more global moral issues.

11.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations.

Emotions are cognitive and physiological processes that utilize aspects of basic homeostatic, pain and pleasure mechanisms. However, while the processes involved in basic, non-social emotions such as sadness, fear and anger have been studied (e.g. Damasio et al., 2000), the physiology of the so-called social emotions that govern our interpersonal relationships and moral sense has not been well established. A better understanding of the physiological underpinnings of these high-level social emotions, particularly of how they are based in low-level pain and pleasure mechanisms, would contribute significantly to our knowledge of human moral and social functioning.

Specifically, recent research has established important shared mechanisms between the neurological correlates of experiencing pain directly and witnessing or imagining another's pain (e.g. Singer et al., 2004; Morrison et al., 2004; Avenanti et al. 2005). In addition, mechanisms of physical pain have been found to underlie experiences of social pain, such as from social exclusion or loss (Eisenberger and Lieberman, 2004; MacDonald and Leary, 2005). At the same time, while there has been a small amount of work on the neurological substrate of physically pleasurable tactile sensations (e.g. Rolls, 2003), the possible neurological link between such sensations and positive social emotions such as admiration has not been examined.

As a first step toward testing these hypotheses, in this study we plan to use fMRI and psychophysiological methods to learn about the neurological and psychophysiological processes involved in admiration and compassion, and their relationships to physical pain and pleasure processing. We hypothesize that social compassion, in essence the vicarious experience of another's social pain, will recruit aspects of basic pain processing. In addition, we hypothesize that the emotion of admiration will share key aspects of processing involved in physical pleasure. In the moral version of the study, we hypothesize that different brain networks will be activated during the evaluation of video clips depicting moral violation as compared to neutral and emotion inducing clips.

In our experiment, participants’ psychophysiological responses to painful, pleasurable, neutral, compassion- and admiration-inducing stimuli and moral reasoning will be tested. Participants will lie in the fMRI scanner while they either view photos or video clips meant to inspire admiration or compassion, or experience either foot massage or a moderately painful stimulus on their foot. The painful stimulus will be delivered either by a safe, thermal pain-inducing machine that has been designed by the manufacturer for the purpose of pain research with no tissue damage (e.g. Becerra et al. 1999, deCharms et al. 2005, Farrell et al. 2005, etc.), or by using the "cold pressor” technique, which involves submerging the participant’s foot in a bucket of ice water for a predetermined amount of time that has been experimentally shown to be safe (e.g. Martikainen et al. 2004, Hagelberg et al. 2002, Drummond 2006). Because we are building from established methods, we foresee no undue risk to our participants.

That there are cultural differences in the expression of social emotions between China and the United States has long been recognized. There is evidence for universality in the pattern of response for given emotions, but emotions are typically experienced with lower frequency, intensity and duration in China (Bond, 1993). Given that cross-cultural differences in social emotions are well established, and that social emotions have a biological origin, related to neurological and body regulatory processes, how does culture modulate the underlying biological substrates of complex social emotions? While the psychological and behavioral aspects of the social emotions, such as pride, shame, guilt, respect, and liking have been described for the two cultures (Mascolo, Fischer and Li, 2002; Cohen, Hsueh, Zhou, Hancock and Floyd, in press), very little is known about the neural substrates underlying these emotions. In order to begin to investigate this, we plan to do an analogous set of experiments in China, and compare the results from US
subjects and Chinese subjects. A better understanding of the differences in neural substrates underlying social emotions between the two cultures would have valuable implications for US-China relationships, including politics, communication and business.

In healthy humans, the level of autonomic arousal changes constantly to maintain homeostasis in the body, in response to both internal and external environmental changes. Emotion is one source of these internal bodily changes, and we hope to tease apart the interplay between the nature of the emotional stimulus being presented, the observed physiological response (measured both with psychophysiology and fMRI), and our other factors of interest, including cultural background.

Most studies have presented subjects with extreme and highly dramatic moral dilemmas and thus preclude the possibility of exploring the neural correlates of moral reasoning in everyday life situations. The present study overcomes this limitation by presenting participants with video clips depicting persons’ engaging in banal acts that may or may not have a moral connotation. We also expect there to be a correlation between participants’ judgment of everyday moral transgressions and their views of global political issues. However, we expect that there will be differences in between American and Indian subjects’ reasoning of moral issues.


deCharms, R. C. et al. (2005) Control over brain activation and pain learned by using real-time functional MRI. PNAS 102(51) 18626-18631


Hagelberg, N. et al. (2002) Dopamine D2 receptor binding in the human brain is associated with the response to painful stimulation and pain modulatory capacity. Pain. 99: 273-279


issue? Cognitive, Affective, & Behavioral Neuroscience. 4(2) 270-278

Rolls, E. et al. (2003) Representations of pleasant and painful touch in the human orbitofrontal and cingulate cortices. Cerebral Cortex. 13(3) 308-317


12. Methods and Procedures - Prospective Studies

12.1. Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity and the total length of subject participation.

The first phase of the study will only involve the emotional tasks. It will consist of one fMRI session per subject, preceded by a two-hour preparation session.

The full study will consist of at least two and no more than four separate fMRI sessions per subject, with the appropriate pre-training sessions. The precise ordering of the tasks and sessions will be determined during the pilot study, but all subjects will participate in the same set of tasks. The tasks, which will be explained in more detail below, are divided into two groups - physical (Physical Pain, Physical Pleasure, Neutral Touch) and emotional (Compassion for Physical Pain, Compassion for Social Pain, Admiration for Skill, Admiration for Virtue, and Emotionally Neutral). Subjects will be instructed by trained personnel in the Brain and Creativity Institute research facilities. All fMRI scanning will be done in the Dana and David Dornsife Cognitive Neuroscience Imaging Center, and in the Cognitive Neuroscience Imaging Center of for the Chinese version.

Participants will be in the scanner for no more than 90 minutes per session.

Physical tasks
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All physical stimuli will be applied to one or both feet. Prior to any session with one or more of the physical components, participants will first be given the opportunity to clean their feet or do whatever else they deem to be necessary preparations for these stimuli. For all three physical tasks, participants will be instructed to relax, pay attention to their foot, and to indicate either when the stimulus becomes painful/pleasurable or how painful/pleasurable the stimulus is. Participants will be told in advance when to expect each physical stimulus.

Physical pleasure
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Prior to the session in which physical pleasure will be administered (by means of a foot massage given by a trained masseuse), the participant will be introduced to the masseuse who will work with each participant to calibrate the foot massage to be maximally pleasurable. While in the scanner, the participant's foot will be massaged for a period of no greater than five minutes at a time. Sessions which contain the physical pleasure stimuli will also contain the physically neutral stimuli (and possibly also the emotional stimuli and/or the physically painful stimuli, depending on results from the pilot subjects).

Physical pain
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We will be using one of two methods of stimulating pain receptors - either the Medoc Pathway, which uses a thermode to apply rapid-onset controllable heat pain, or immersion in a bucket of ice water. Prior to entering the scanner, participants will work with the experimenter to calibrate the painful stimulus to a level which is painful but tolerable, and to make an initial measure of the delay between administration of the pain stimulus and the pain sensation, which (particularly with the bucket of ice water) can vary across individuals.

Heat pain calibration protocol: Starting around room-temperature, the temperature of the thermode is increased in small steps, and the participant is asked to rate the painfulness of the stimulus at regular
intervals. Once the participants pain threshold (the lowest temperature at which the stimulus is considered painful) is determined, the thermode is returned to room temperature and the process repeated several times. The typical threshold used in pain research is a rating of 60-70 on a scale of 1-100 (with 1 being no pain and 100 being the worst pain imaginable). There is a relatively large temperature difference between the point at which a thermal pain stimulus is considered painful, and the point at which it becomes intolerable, such that we will be able to easily stop the pain stimulation during this calibration phase before it becomes intolerable.

Cold pressor calibration protocol: Participants are asked to lower a foot into the bucket of ice water, and remove it once the stimulus becomes painful (or once four minutes have passed, whichever comes first). The experimenter times the duration between the first insertion of the foot and the pain sensation, and uses this information to determine how long the stimulus will need to be applied once in the scanner. The participants foot will be warmed up and dried off between applications.

While in the scanner, the physical pain stimuli will be administered by a trained individual who will be in the room with the participant. If the Medoc Pathway is being used to provide the painful stimulus, the thermode will be applied to the participant's foot for a duration no greater than 60 seconds or the maximum safe duration, whichever is shorter. There will be a recovery interval between each stimulus. If the bucket of ice water is being used to provide the painful stimulus, the participant's foot will be placed in a bucket of ice water for a duration no greater than four minutes and then dried off before the next stimulus. Sessions which contain the physical pain stimuli will also contain the physically neutral stimuli (and possibly also the emotional stimuli and/or the physically pleasurable stimuli, depending on results from the pilot subjects). Participants will either be able to move their foot away from the stimulation or signal to the experimenter to stop the stimulation immediately, should the pain level become intolerable. This will be explained to them before they enter the scanner.

Neutral Touch

Participants will also be introduced to the physically neutral condition prior to entering the scanner. For this condition, the participant's foot will be held in a neutral fashion by an immobile hand or an innocuous inanimate object (e.g. a smooth block of wood at room temperature). The precise nature of the neutral stimulus will be determined in the pilot phase of this project.

All physical tasks

After the scanning portion of the study is complete, subjects will be taken into another room and asked to rate their experience on several dimensions. (see EmotionPhotoRatingQuestionsdoc attached to question 21.1)

Emotional tasks

The photographs/video clips

For the emotional portions of this study, we will be showing participants photographs and/or video clips with or without captions. These images are of real people doing real things, drawn from news and other sources. The photos/video clips were selected to elicit four categories of emotions, with specific types of content for each:

1. compassion for physical pain, in which injured people are shown. The cause of their injuries must not have had any moral implications (e.g. it cannot be the result of abuse).
2. compassion for social/moral pain, in which people in states of grief and despair are shown
3. admiration for skill, in which people performing feats of skill are shown
4. admiration for virtue, in which highly virtuous or otherwise morally admirable acts are shown.
5. moral clips, in which moral violations are shown.

Control photographs/video clips were selected to contain comparable people in interesting but not emotion-provoking situations.

No photographs/video clips include:
- Deceased people
The people portrayed in the photographs/video clips are from a variety of cultural and social backgrounds, of various ages, and of both genders. For the Chinese version, when possible we will use translated versions of the stimuli from the American version. Stimuli that do not fit the Chinese cultural context will be replaced by more suitable stimuli featuring stories about Chinese nationals.

For this study, these photos/video clips may or may not be accompanied by captions or short stories. These captions/stories were written by the experimenters to enhance the emotional impact of the images and are designed to tell the story behind the image. They will have been piloted in a separate study before being shown to participants in the scanner.

Participants will be warned in advance that they may see disturbing photographs/video clips, and that if they do not wish to see such images, they can recuse themselves from the study without consequences.

Pre-scan Training

Participants may be pre-trained on the photographs/video clips. In this training, they will do one or more of the following:
- view the photographs/video clips with or without the captions
- read or hear the story affiliated with each photograph/video clip
- provide feedback as to the nature and intensity of the emotions elicited by the photographs/video clips/stories

The preparation session may be videotaped, as a way to document subjects' reactions to the stories.

Within the scanner

Within the scanner, participants will be shown the photographs/video clips, possibly accompanied by an audio clip, either with or without captions projected onto a video screen. The video and audio clips may be shorter than the versions used in the preparation session. For all stimuli, they will be instructed to look at the image for the whole time it is shown. The specific task they will be asked to do will depend both on the results of the separate pilot study (to determine which task is most effective at inducing the desired emotional experiences) and on whether they had already been trained on the stimuli. They may be asked to look carefully at the person in the picture, to pretend they were there when the picture was taken, to remember how they felt when they first viewed the stimulus/heard the story about the stimulus, etc. They will not be asked to imagine that they are the person in the photograph.

Participants may be asked to provide feedback about their emotional state, either by pressing a button (using an fMRI-safe button box) to indicate that they are feeling an emotion and the strength of the emotion they are feeling, or using an fMRI-compatible pneumatic squeeze ball, which can be squeezed with continuously-varying pressures to indicate strength of emotional response.

The number of photographs/video clips will be determined after the separate pilot study has determined, for example, whether as strong an emotional response can be obtained after multiple viewings of a photograph as with the first viewing.

Given the differences between admiration and compassion, the design may be different for these different subsets of the study (for example, the compassion pictures may be more effective on the first viewing without a story, while the admiration pictures may be most effective if viewed several times after a story), but within the admiration or compassion subset, all stimuli will be presented in the same fashion, with a comparable number/quality of neutral stimuli.

Stimuli will be presented for no longer than a minute each, with blank screens of either static or varying durations between images.

Post-scanning
Once the scanning is complete, subjects will be taken into another room where they will be debriefed. Depending on the outcome of the pilot, and the sort of training the participants had experienced, they may either just talk with the experimenter, or be asked to sit at a computer and provide responses to each photograph/video clip they had just seen. Photographs/video clips will be presented on a computer monitor with the same captions, and participants will provide their responses using a standard computer keyboard. A mock-up of the computer program, containing the questions which will be asked, is attached to section 21.1. (The questions may be changed slightly depending on the outcome of the piloting).

Overall Structure

Depending on the outcome both of the separate pilot study and of the initial pilot phase of this study, the physical stimuli will either be presented in a separate session from the emotional stimuli, or intermixed with the emotional stimuli. If intermixed, the physical pain stimuli will be presented with the compassion stimuli, and the physically pleasurable stimuli will be presented with the admiration stimuli. All combinations will include the appropriate neutral stimuli. Compassion and admiration will likely be presented in separate sessions.

Participants will be told what sort of stimuli to expect prior to the beginning of the session.

Psychophysiological measurements (heart rate, skin conductance, respiration and/or blood pressure) may be measured during the scanning using fMRI-compatible equipment.

12.1.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition.

Each subject will participate in all of the tasks involved in that phase (just emotional for the first phase, emotional and physical for the second phase). The preparation sessions will take 1-2 hours. The scanner sessions will take 1-1.5 hours. If both a preparation and a scanner session are on the same day, subjects will be allowed a break in between.

12.2. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable.

Data will be analyzed for each individual subject as well as the group. In a typical fMRI study such as this one, 10-12 subjects are required for each variant of the test conditions. Thus, the number of subjects was determined by the usual number of subjects used in published studies of this type.

20. Methods and Procedures - Psychophysiological Testing

This screen is required if you indicated the use of Psychophysiological Testing as a procedure (Question 9.2.)

20.1. List all instruments and psychophysiological measures that will be used for this study.

We will be performing additional psychological measurements, both in and outside the MRI scanner. When these measurements are taken during the fMRI scan, we will use equipment designed for the purpose of taking these measures in an MRI context.

Psychophysiology:

While performing many of these tasks, and/or during rest, participants may undergo psychophysiological measurements. These are non-invasive measurements of the functioning of the body. These physiological measurements will include recording the sweat gland activity on the palms by placing two pads on each hand. The physiological measurements will also include recording of heart EKG and heart rate by attaching one pad to the right neck, one pad to the left waist, and one pad just below the Adams apple. We will also record the movements of facial muscles by placing three pads on the cheeks and forehead. We will monitor the blood pressure by placing a cuff on the left arm, and we will measure the skin temperature by placing a small sensor on the left index finger. All these pads stick to the skin like a Band-Aid, and they don't cause any pain. At the end of the experiments, all the pads will be removed. Pulse will be measured with an infrared sensor wrapped around the subject's finger with velcro.
2. Physiological variables will be recorded using psychophysiological recording equipment (MP-150, Biopac Systems, Inc.). The recorded signals will be simultaneously transferred to a Macintosh computer through an MP150WS system (BIOPAC Systems, Inc.), an analog to digit converter system. The recorded data will be stored and subsequently accessed for analyses with an Acknowledge III software. The Acknowledge software allows performance of post-acquisition mathematical transformations. Also, the software provides an extensive array of measurements that can be applied to the collected data.

The SCR data are acquired through the MP150WS system (BIOPAC Systems, Inc.) at a rate of 100 samples per second. First, the electrodes are attached to the thenar and hypothenar areas on the palms of the subject as part of the preparation for the fMRI scan. SCR activity will be monitored all the time the subject is in the scanner. Simultaneously, timing data will be collected on the onset and offset of stimuli, and (if such data is being collected) when the subject indicates s/he is feeling the target emotion. The recording allows SCRs generated in association with a specific stimulus to be precisely identified on the physiological records. For EKG and HR recording, three electrodes will be attached. One will be placed on the lower third of the right neck over the area of the carotid arteries. Another electrode will be placed over the left flank, immediately above the iliac crest of the pelvic bone. The third electrode will be placed immediately above the sternal notch, below the prominence of the thyroid cartilage of the trachea. For respiration, a sensor belt is wrapped around the superior border of the abdomen, at the level of the xiphoid process. Facial EMG is recorded from 3 electrodes placed over muscles on the face (masseter, corrugator, and zygomatic muscles).

3. Quantification of physiological variables: The quantification of SCRs entails 1) elimination of the down drift in the SCR wave using a mathematical transformation function named "Difference". This function measures the difference (in amplitude) of two sample points, which are separated by 10 samples. The difference is then divided by the time interval between the first selected sample and the last selected sample. 2) Measurement of the "area under the curve" in the 30 second time window between giving the hand signal and 30 seconds later. The "area under the curve" measurement is similar to the function of an "integral", except that instead of using zero as a baseline for integration, a straight line is drawn between the endpoints of the selected area to function as the baseline. The area is expressed in terms of amplitude units (mS) per time interval (seconds). The quantification of HR entails measurement of the average BPM in the same time window described for SCRs. These measures are provided on line by the computer software, and one can very quickly determine whether the subject achieved the criteria for the emotion induction experiment.

In subsequent analyses we will conduct additional quantification measures for the purpose of establishing physiological patterns associated with particular emotional states as proposed in Project 1. (1) Heart rate variability: the quantification of heart rate variability using the EKG entails using the EKG signal to obtain a continuous R-R interval tachogram from which simple time domain indices of heart rate (e.g. mean R-R interval) and heart rate variability (e.g. SD of R-R interval) are calculated. Spectral analysis of the continuous R-R interval tachogram is then applied. The power spectrum in the high (0.15-0.40Hz) and low (0.04-0.15Hz) frequency components constitute indices of the relative contribution of vagal and sympathetic activity, respectively, to heart rate variability (Malliani et al., 1991; Pagani et al., 1997). In addition, the combination of respiratory and heart rate measurements allow the quantification of the respiratory sinus arrhythmia, as an index of vagal tone (Grossman et al., 1990; Porges et al., 1999). (2) The quantification of respiration entails measurements of the frequency and amplitude of each breathing cycle with additional characterization of the periodicity using frequency domain analyses (e.g., power spectrum) (Wientjes, 1992).

Additional standard analyses of the psychophysiological data may be performed.

20.1.1. Attach information or diagrams that explain how the measures are being used, if applicable.

There are no items to display.

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing (Question 9.2.)
21.1. List all of the measures/instruments that will be used for this study and attach copies below. Explain the purpose of the measures and indicate if any have been previously validated.

As detailed in question 12.1, participants will be debriefed about the photographs/video clips and the pain/pleasure experience after the MRI portion of the session for each condition, either through discussion with the experimenter, a paper rating sheet, or by means of a computer program.

EmotionPhotoRatingQuestions.doc contains the questions which will be used to follow up on the pleasure, pain, and neutral experiences of the participants after that portion of the study, and the questions contained in PictureResponseDemo.ppt (a mock-up of the computer program) will be used to determine the affective reaction of the participants to the photographic stimuli used in the Compassion/Admiration portion of the study.

Handedness will be determined using the Handedness Determination Questionnaire. (reference in section 10.3)

Moral Version:

Moral Foundations Questionnaire, Moral Judgment Test, Moralizing Self Control and Moral_Disgust Questionnaire contain statements that aim to measure the participant's competency in moral reasoning. All these questionnaires are standardized and have been validated by their respective authors. New additional questionnaires include (1) Identity writing prime which aims to prime participants to characteristics that they identify with such as being a citizen of the US, student of a college etc; (2) Morality of Politics Scale (MOPS) which aims to quantify participant's views on political issues such as illegal immigration, education etc; (3) Moralization of Everyday Life Scale which requires participants to judge the moral appropriateness of everyday life behaviors such as faking an injury to collect on insurance; (4) Moral Transgression Vignettes measures the participant's competency in moral reasoning by presenting them with vignettes that they must rate on a scale of moral appropriateness; (5) Activism questionnaire measures participants' willingness to participate in activities that would support issues of most concern from MOPS scale; and (6) HEXACO personality measure will be sued to measure participants' helpfulness behavior.

English is the official language of India and we will recruit Indian subjects who can also speak English.

21.2. Attach copies of all measures/instruments that will be used for this study.

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22. Special Subject Populations

22.1. Indicate any vulnerable subject populations you intend or expect to enroll in the research: (check all that
22d. Special Subject Populations - Non-English Speaking Subjects

This screen is required if you indicated you will be recruiting non-English speaking subjects (Question 22.1.)

22d.1. Describe how you will communicate with non-English speaking participants. (check all that apply)

☐ The use of interpreters
☐ Translated informed consent documents
☐ Translated short forms
☐ Other

22d.1.1 Please explain:

All materials used in the Chinese version have been translated. This part of the study, including the consent process for the Chinese version, will be conducted in Mandarin Chinese by [name] who is a native Chinese speaker. Language will not interfere with subjects’ understanding of the study and their participation in research.

Indian participants in the new amendment to the moral version, will be English speakers. English is the official language of India and we will recruit those subjects who can speak English as well.

22d.2. If the study will likely include subjects and families for whom Spanish is the primary language, the consent documents must be translated into Spanish. Select the method of translation.

☐ Investigator will provide the IRB with a translation of the approved consent form
☐ Request that the IRB office translate (HSIRB Only)

22d.3. If the research will primarily include subjects who speak a language other than English or Spanish, the informed consent documents should be translated into that language. Indicate the languages and method of translation.

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23. Study Resources
23.1. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient. Please check-off the items that apply to this study.

- Employed interns, residents, fellows, or postdocs with dedicated time to conduct this research.
- Employed faculty and or staff with dedicated time to conduct this research.
- Students with dedicated time as part of their training to conduct this research.
- Volunteers
- Other

23.1.1. Please specify:
The P.I. and assistant will devote at least 25% of their time to this project, which is sufficient to complete this project in an efficient manner.

23.2. Describe the staff and justify their qualifications. Please check-off the items that apply to this study.

- All biomedical investigators are privileged and credentialled to perform the study activities in the study locations.
- All study staff are trained and credentialled to perform the duties assigned to them.
- All study staff have fulfilled the training mandated by their respective departments or institutions.
- Other

23.2.1. Please specify:
The investigators listed may be assisted by graduate, undergraduate, and staff research assistants who are qualified members of our laboratory. All participating members of our staff will be informed about the protocol and their research-related duties and functions via the investigators, and will not have access to subjects without the presence of at least one investigator. All staff members will complete the CITI training course before interacting with subjects/data. We feel that our staff is adequate in number and qualifications for this study.

23.3. Describe the study facilities and justify they are adequate.
The study will be performed in the Dana and David Dornsife Cognitive Neuroscience Imaging Center and the Cognitive Neuroscience Imaging Center of [insert name], which both have state-of-the-art MRI systems, and in Brain and Creativity Institute research-dedicated space.

23.4. Describe how staff and others will receive necessary information and training to assist in the conduct of this study.
All persons assisting with the research are trained personnel for this type of research.

23.5 Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.

(deprecated field, used to be 23.1 - only used for existing studies)
The primary method of subject recruitment will be fliers (attached) that will be posted around the University Park Campus. When a potential participant first contacts the lab, they will be provided with further information about the study (InitialContactLetter.doc, attached to section 40). Direct contact will only be made by authorized study personnel, following the verbal recruitment script (VerbalRecruitmentScript.doc, attached) They will then be sent the same initial information and contact form as participants recruited with the fliers.

In the Chinese version of the study, subjects will be recruited in the same way. Chinese versions of our fliers, initial contact letter and verbal recruitment script are attached, which are basically direct translations of the English version. Revisions may be made to meet the IRB requirements of [insert name].
24. Subject Recruitment and Informed Consent

24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool): (check ALL that apply)

- [ ] E-mail/Electronic Mailing List
- [ ] Brochure
- [ ] Flyers
- [ ] Letters
- [ ] Newspaper/Magazine Advertisements
- [ ] Radio/Television Announcements
- [ ] Subject or Participant Pool
- [ ] Telephone Scripts
- [ ] Verbal (Personal Solicitation)
- [ ] Website / Social Media Outlets
- [ ] Other
- [ ] None of the above

24.1.2. Describe how you will be obtaining contact information:

24.1.3. Describe in detail all recruitment strategies for each participant group (including controls) involved in this study. Explain who will approach the participants, how and when the participants will be approached, and what will be said. (deprecated field, used to be 24.3 - only used for existing studies)

Potential subjects will be recruited through the attached fliers, through e-mail, through Experimetrix and through direct contact. Only authorized study personnel may approach the subjects. Please refer to the attached Verbal Recruitment Script and “Recruitment E-mail” for further information.

24.2. Attach copies of all recruitment tools that will be used by the local site. (Do not attach any advertising or recruitment materials that will not be used at the local site or under control of the local site.)

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**fMRI Recruitment E-mail Chinese - LA.doc**

**fMRI Recruitment E-mail.doc**

**fMRI Verbal Recruitment Script - Chinese - Beijing**

**fMRI Verbal Recruitment Script - Chinese - Beijing - English translation**

**fMRI Verbal Recruitment Script - Chinese - Beijing - with abstaining**

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**fMRI Verbal Recruitment Script - Chinese - LA - English translation**

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**fMRI Verbal Recruitment Script Emotions Only.doc**

**fMRI Verbal Recruitment Script.doc**

**Initial Contact Letter_supplementary survey_Chinese.doc**

**IRBA_Revised Initial Contact Letter for Supplementary Survey - English, dated 04-26-2012.doc**

**IRBA_Revised Recruitment Flier for Morals, dated 01-07-2011.docx**

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**recruitment flierFRI1 - Emotions Only.doc**

**recruitment flierFRI1.doc**

**recruitment flierFRI2 - Chinese**
24.3. Informed Consent and Waivers:

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

- [x] Written/signed consent (participants will sign an informed consent document)
- [ ] An information sheet will be provided and/or verbal consent obtained
- [ ] Waiver of consent (participants will not be asked to sign a consent document or be given an information sheet)
- [ ] Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

24.3.1. If the informed consent process for adults (see above) will differ for certain parts of the study (e.g., specific procedures or populations) please explain below.

24.4. Select the applicable justification for not obtaining written/signed informed consent:

The research is no more than minimal risk of harm to subjects and does not involve any procedures for which written consent is normally required outside the research setting (for example, written consent is not needed for minimal risk surveys or non-invasive health measurements in everyday life).

- The only record linking the participant and the research data would be the signed consent document, and the main risk to participants would be a breach of confidentiality (participants could suffer from social stigma or embarrassment or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, drug use, HIV or mental health problems). NOTE: THIS STILL REQUIRES SUBMISSION OF CONSENT FORMS AND DOCUMENTATION OF THE SUBJECTS' WISHES.

24.7. Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used.
IRB Informed Consent Templates and Forms

Personnel from section 2.1 obtaining consent/permission/assent:

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<th>First Name</th>
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If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.8. Describe the circumstances and location of the process of recruitment and consent: (check ALL that apply)

- [ ] In a private area
- [ ] In a waiting room, open area, group, or public setting
- [ ] Online, over the telephone, by mail, or fax
- [ ] Other

24.9. Describe how you will assess the individual’s comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating. (check ALL that apply)

- [ ] An assessment tool will be used. (attach a copy of the tool below)
  
  This will be verbally assessed. Individuals will be asked to answer the following questions (as applicable): (1) What are you being asked to do? (2) What question is this study trying to answer? (3) What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?

- [ ] Other (specify below)

24.9.2. If Other, please explain:

Every section of the consent form will be carefully reviewed with the participant of the study by one of the study personnel. The risks and benefits will be explained and we will emphasize that the study is STRICTLY voluntary and that they may withdraw at any time without further explanation.

24.10. Describe all measures that will be taken during the recruitment and consent process to ensure that individuals have adequate time to consider participation and to safeguard against potential coercion and undue influence: (check ALL that apply)

- [ ] They will not be forced, threatened or coerced in any way to participate in this research, and no undue
influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. (Note: Coercion is the use or threat of the use of force to gain compliance. Undue influence is when an individual who is in a position of authority (e.g., physician, teacher, employer) exerts inappropriate or excessive manipulation to gain power and compliance over a vulnerable individual (potential research subject). Constraint means force, obligation or pressure.)

They will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.

They will be given an adequate amount of time to consider participation in the study relative to the initiation of study procedures.

The information presented to individuals during recruitment and consent will reflect that provided in the informed consent document/informed consent script.

The recruitment and consent process will not promise them a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.

The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.

They will be given the opportunity to take the informed consent document home in order to discuss participation with their family, friends and/or others before making a definitive decision.

They will receive payment for their participation, but the amount of payment will be commensurate with their participation (not an inducement for participation), and receipt of the payment will not be contingent upon the individuals completion of the study. (Note: The specific method, schedule and amount of payment must be outlined in the payment section of the application.)

Other (explain below)

24.10.1. If Other, please explain:

	We emphasize that the subjects' participation is strictly voluntary and that they may withdraw from the study at any time, no reason necessary. No promise of additional benefits/compensations other than those listed in the consent form will be implied.

24.10.2. Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures. Describe how prospective participants/families will be permitted to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study. If more than one consent form will be used in the study, explain when and how each form will be used to obtain consent from participants. (deprecated field, used to be 30.2 - only used for existing studies)

The consent process will take place at the Dana and David Dornsife Imaging Center, in the Brain and Creativity Institute facilities that will be used for pre-scan training, or at the Cognitive Neuroscience Imaging Center for the Chinese version. A copy of the consent form will be provided to the participant. During the consent process, one of the study personnel will review the consent form with the participant. Upon completion of the review, the study personnel will then ask the participant if they need any clarification, or have any questions.

If the subject consent to show the video for scholarly purposes, a short video clip of their different emotional responses may be shown in a scientific conference. We will clearly explain to subjects that their face and voice will be maintained in the video, as they are crucial parts of emotional responses. Choosing not to consent to this use of the videorecording will not affect participation in the study.

If the participant requires further discussion with others, a copy of the consent form will be provided to the participant to take with them and review with others prior to signing.

For subjects who participate in the supplementary survey, the information sheet will be presented prior to the survey, and participants will need to read it through and agree to it before beginning the questionnaire.
25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe who pays for financial obligations that the subject may incur as a result of participating in the study.

- All costs are paid by the sponsor or funding agency.
- Research costs are paid by the sponsor or funding agency. Other costs are the responsibility of the participants and/or their healthcare plans.
- All costs are the responsibility of the participants and/or their healthcare plans.
- Study drug will be provided but not the costs of preparation or administration, which will be the responsibility of the participants and/or their healthcare plans.
- All costs are covered by the department/division.
- There are no financial obligations related to participation.
- Other

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

For the emotions-only phase of the study, subjects will be paid ____/hour for their participation in the preparation sessions, and ____/hour for their participation in the fMRI sessions. The experiment takes about 4 hours and the estimated total compensation is ____.

For the all-conditions phase of the study, subjects will be paid ____/hour for their participation in the training sessions, and ____/hour for their participation in the fMRI sessions. The experiment takes about 4 hours and the estimated total compensation is ____.

Chinese version of the study will only use the emotion-only protocol. For Chinese version of the study conducted in Beijing, China, subjects will be paid ___________ for their participation in the whole study (standard rate in ___________). For Chinese version of the study conducted in LA, subjects will be paid at the same rate as American subjects in emotion-only phase.

If subjects choose to terminate the study before it is finished, they will still be paid for the finished portions of the sessions.

Parking will be arranged in advance, if the subject is driving to campus.

Additionally, if possible and if the subject desires it, we may provide them with either a digital image or a printed picture of their brain.

25.3. Research-Related Injury and Compensation for Injury: For studies of greater than minimal risk, if participants require care, medical services, or psychological services as a consequence of the research, who will provide this care? If applicable, describe who will pay for research-related injuries.

Medical and/or psychological care/treatment will be offered. In addition:

- Costs for medical care from research-related injuries will be paid by the sponsor or funding agency.
- Costs for medical care from research-related injuries will be the responsibility of the participants and/or their healthcare plans.
- Other

25.3.1. If other is selected, please specify:
In the unlikely event that subjects should need medical or psychological services as a consequence of this research, and depending on the severity of their needs, referrals will be made to counselors and/or physicians located within the USC community (or community for the Chinese version). Participants will be financially liable for research-related injuries.

26. Participant Privacy and Data Confidentiality

26.1. Privacy Protections: Privacy is a participants ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

- Research procedures will be conducted in person in a private setting.
- Data will be captured and reviewed in a private setting.
- Only authorized research study personnel will be present during research related activities.
- The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
- Other (specify below)

26.1.1. Please specify:

The imaging data are stored digitally. Prior to any transfer of information among investigators, or into any summary publication, all identifying information about the subjects will be removed. Each subject's MRI data set is automatically coded numerically as it is acquired by the scanner. The standard data interchange formats we will be using will contain no identifying information beyond the ID number. The coding between subject name and ID will be maintained digitally in the archived records of the secure laboratory. For all scientific uses, the images will be displayed without identifying information. Further, the images will only be viewable using special purpose computer hardware and software, so that unauthorized viewing of the data would be highly unlikely.

The volume of data collected over the course of the research will be very large. On completion of the study, data will be digitally archived onto CD-ROMs, etc. The data obtained in this study will be stored indefinitely at the USC laboratory and at the laboratory of the PI and/or co-investigator should that eventually be elsewhere, safe-guarded with computer access codes and accessible only to research investigators who have previously obtained IRB approval to use this data.

The non-fMRI data will be stored in a similarly confidential manner. The responses of the subjects to the stimuli will be stored only with the same ID number used for the fMRI data. This data will be stored on a secure computer or in a secure office, depending on the format of the data (computerized/handwritten).

26.2. Confidentiality Precautions: Confidentiality is an extension of the concept of privacy; it refers to the participants understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be recorded? (check ALL that apply)

- Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
26.3. How will the research data and/or specimens be protected against inappropriate use or disclosure? (check ALL that apply)

- [x] Locked office
- [ ] Locked storage unit
- [x] Restricted access to authorized study personnel
- [x] Secure computer/laptop
- [ ] Individual ID plus password protection
- [ ] Encryption of digital data
- [ ] Network Restrictions
- [x] Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study
- [x] Restrictions on copying study related materials
- [ ] Destruction of source data immediately after data collection (to preserve anonymity of participants)
- [x] Audio and/or video recordings will be transcribed and then will be destroyed
- [ ] Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified
- [ ] Photos or images will be modified to eliminate the possibility that study participants could be identified
- [ ] Study personnel will sign statements agreeing to protect security and confidentiality of study information
- [ ] Access rights are terminated when authorized study personnel leave the study
- [ ] Not Applicable
- [x] Other (specify below)

26.3.1. Please specify the physical location and describe how data will be secured to protect confidentiality.

Personal information assessed by the questionnaires and responses to the stimuli will be stored in locked offices with access limited to the principal investigator and her direct staff. Copies of this information will be stored in a locked file cabinet at the scanning facility. Access to the identifying information records will be limited to the scientific research personnel, including the senior staff members and their direct employees, such as laboratory technicians, post-doctoral fellows and graduate students directly involved in this research. All staff members have been or will be instructed in subject confidentiality.

26.4. Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?

- [ ] Yes  - [x] No

26.4.1. Specify what data and/or specimens will be released, to whom (the individuals and/or agencies), and why.

N/A
26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

- Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).
- Retained for study record keeping purposes per institutional policy.
- Retained by the investigator for future research use.
- Retained for future research use (create data or tissue repository/bank).
- Restricted use data will be destroyed or returned to the source.
- No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.
- This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.
- Other (specify below)

26.5.1. If Other is selected, please specify:

- The non-identifiable data, including all psychophysiological, MRI and behavioral data, will be stored indefinitely.
- Identifying information will be stored separately for 5 years, as this is the average amount of time that most potential subjects will be associated with the university, and therefore could volunteer for future experiments. When five years have elapsed, the identifying information will be properly destroyed.

26.6. Do you have, or plan to apply for, a DHHS issued Certificate of Confidentiality for this study?
- Yes
- No

27. Risk/Benefit Assessment - Risks

27.1. Risks, Discomforts and Potential Harms: Describe the risks associated with each research intervention. Include consideration of physical, psychological, social, and other factors. (check all that apply)

- Discrimination based on genetic findings.
- Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.
- Some of the questions may make the participant feel uneasy or embarrassed.
- There is a small risk that people who are not connected with this study will learn a participants identity or their personal information.
- The participants are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, they could have problems getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, they could be charged with a crime.
- Biomedical risks, including drug, device, biologics, radiation, surgery or other research procedures (please specify).
- The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide.
- Venipuncture risks including: mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).
- Other (specify below)
27.1.1. Describe the biomedical or other possible risks and discomforts participants could experience during this study:

**Emotional Stimuli**

There are no anticipated risks associated with the emotional stimuli. Participants will be informed in advance that they may see disturbing images (e.g. of injured or distressed people), and that if they do not wish to do so they should recuse themselves from the experiment.

**Physical Pain**

As mentioned in the methodology section, we will be using one of two different techniques to administer the physical pain stimuli. Both techniques are standard in the field of pain research and are considered extremely safe. Safety details for both are below.

**Thermal Pain - Medoc Pathway**

The Pathway is a device designed by Medoc (www.medoc-web.com) specifically for the administration of thermal stimulation and widely used by pain researchers. It uses a contact thermode (up to 30x30mm), and can administer stimuli between -10 and 55 C. (This is below the threshold for tissue damage, and has been used safely by numerous studies, e.g. Yarnitsky and Ochoa 1990, Bhalang et al. 2005, etc.). It is completely programmable, with additional built-in safety limitations on both temperature and duration as follows:

1. Never above 56 C  
2. No more than 0.05 sec at 55 C  
3. No more than 0.4 sec at 52 C  
4. No more than 1 sec at 51 C  
5. No more than 5 sec at 50 C  
6. No more than 10 sec at 49 C  
7. No more than 60 sec at 47 C  
8. No more than 5 minutes at 6 C and below

Temperatures between 6 C and 47 C are safe at longer durations.

Previous studies using the Pathway (and the previous generation of devices from Medoc, as well as other thermal pain techniques such as warm water baths) have found that normal subjects typically find temperatures of 46-50C to be warm enough to cause physical pain, but not too warm to be intolerable. (e.g. Brooks et al. 2002, Hoffman et al. 2004, etc.)

The Pathway is designed to be completely fMRI compatible, so is safe to use with the scanner.

Additional technical information about the Pathway is available at http://www.medoc-web.com/Pathway_Overview.pdf

If the pain becomes intolerable, participants will either be able to move their feet away from the thermode, signal to the experimenter to immediately stop the pain, or press a button to stop the pain. (Once the machine has been obtained, these alternatives will be piloted to determine which is best)

**Thermal Pain - Cold Pressor (Ice Water)**

Another standard technique in pain research is the "cold pressor" technique, which involves immersion in an ice water bath. The typical ice water bath is maintained at 1-2 C (though if this temperature is intolerable to a participant, as determined in the training session, it can be raised to a higher temperature which is still perceived as painful but is tolerable). At these low temperatures, immersion for up to five minutes has been shown to be safe (e.g. Greene et al. 1965, Campbell et al. 2006, and many others). We intend to use a much shorter duration, no more than three minutes but likely under one minute, depending on the durations necessary for the other components of the study as well as participant-specific considerations (how long the...
participant's foot needs to be submerged before the first sensation of pain, and how long it takes before that pain becomes intolerable, both of which can vary across subjects and will be determined in the training session.) If a participant's tolerance is less than our standard immersion duration, we will either decrease our immersion duration (and, if necessary, the duration of the other stimuli) or increase the temperature of the bath to accommodate that participant.

Participants will be able to signal to the experimenter to remove the ice bucket early should the pain become intolerable.

After completion of immersion, the participant's foot will be dried off to avoid any lingering discomfort.

Physical Pleasure - Massage
============================
The massages will be administered by a trained masseuse who will work with participants to determine the most effective and safe way to elicit physical pleasure from that individual. The masseuse will have received explicit safety training for fMRI. Participants will be able to signal to the masseuse to stop at any time, should it become necessary.

Psychophysiology
==============
There are no risks associated with these procedures.

Functional Magnetic Resonance Imaging (fMRI)
=====================================
There are no known significant risks with this procedure at this time since the magnetic fields, at the strengths used, are felt to be without harm. There are conservative federal guidelines for radiofrequency magnetic field exposure and our examinations fall within those guidelines. We feel these are safe levels and less hazardous than a comparable x-ray computed tomography examination (CT scan).

Exceptions include if a person has a cardiac pacemaker or a certain type of metallic clip in their body (i.e., an aneurysm clip in the brain); if a person has worked with metal or had a piece of metal removed from the eye(s); or if a person has shrapnel, bullets, or buckshot in their body.

As metallic objects may experience a strong attraction to the magnet, it is very important that the subject notify the researcher of any metal objects, devices or implants that are in or on his/her body before entering the magnet room. This includes biomedical devices such as pacemakers and aneurysm clips, prostheses, and other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal.

All other metallic objects must also be removed from the subject prior to entering the magnet room or approaching the magnet to prevent them from becoming a projectile or being pulled by the magnet. This includes keys, jewelry, pocketknives, money clips, paper clips, safety pins, hairpins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for the subject to secure all his/her items and valuables.

If the subject is or may be pregnant, we will not perform the examination at this time, as the effects of the scan on a fetus are unknown. Some of the radiofrequency imaging coils and the imaging software being used to perform scans at the Dana and David Dornsife Cognitive Neuroscience Imaging Center are not approved by the FDA.

There is a risk of heating from radiofrequency imaging coils, the cables of radiofrequency imaging coils, and/or the cables from monitoring devices such as those that record physiologic processes by way of an electrocardiogram, pulse oximeter, and/or plethysmograph.

There is a possibility that the subject will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful.

Dizziness and nausea may occur momentarily when the subjects head is moved in or out of the tunnel of the magnet. The sensation should disappear quickly.

Some subjects may experience claustrophobia; they may discontinue the scan at any time.


Green, M. et al. (1985) Circulatory dynamics during the cold pressor test. The American Journal of Cardiology 16(1) 54-60


27.2. Describe the precautions that will be taken to minimize risks/harms. (check all that apply)

- We will use our best efforts to keep the findings in this study as confidential as possible.
- Subjects can choose to skip or stop answering any questions that make them uncomfortable.
- Data will be coded and identity stored separate from data.

- Data will be collected anonymously.
- Biomedical precautions, including precautions relating to drugs, devices, biologics, radiation, surgery or other research procedures (please specify).
- Venipuncture by individuals certified and privileged to perform the procedure.
- Other (specify below)

27.2.1. Other precautions (including biomedical precautions) that will be taken to minimize risks/harms include:

Thermal pain

As described above, durations and temperatures for the thermally painful stimuli will be within established safety limits. Additionally, the Medoc Pathway has built-in safety controls, preventing the device from administering harmful levels of stimulation. The participant and the stimulation will be constantly monitored to ensure safety. Participants will be able to end the painful stimulation at any time.

Massage

As described above, the masseuse administering the pleasurable stimuli will have been trained in the relevant safety issues. Participants will be able to end the massage stimulation at any time.

fMRI

When compared to imaging modalities that employ ionizing radiation such as x-ray and positron emission tomography, magnetic resonance imaging (MRI) is a safe modality. In a recent review, Schenck (2000) estimated that 150,000,000 MRIs were performed worldwide between the inception of widespread clinical testing in the early 1980s and 1999, that 20,000,000 are performed each year, and that more than 50,000 scans are performed each day. That the vast majority of these scans are performed without incident is a comforting fact. (Schenck JF (2000) Safety of strong, static magnetic fields. Journal of Magnetic Resonance Imaging 12:2-19.) The small risk of metal objects being dislodged will be reduced by the screening process previously described. Headphones and ear protectors will be used to reduce any discomfort that might be associated with the scanner noise. Subjects are asked to report any heating/burning sensation or claustrophobic experience immediately. A call button and an intercom are provided such that the subject may have the scan stopped at any time during the study. To help reduce risks associated with claustrophobia, we will be using volunteers who are savvy
about MRI.
At the Dana and David Dornsife Cognitive Neuroscience Imaging Center, safety will be the top
priority of the director (who will be charged with safety as a primary mission), the executive board
and the technical advisory board as well as any other personnel (faculty and staff) involved in the
operation of the MRI facility. Several procedures, including supervision by the Institutional
Research Board, safety training and education, safety screening and informed consent, and
regular safety inspection will be strictly enforced in the facility. All the faculty, staff, graduate
students, and advanced undergraduates who are conducting research in this facility that is, all
users of the MRI research equipment will undergo what has become, more or less, standard
safety training and certification, consisting of:

1. Self review of online safety information
2. A 75 minute safety orientation consisting of viewing a safety DVD followed by a short
   presentation of site specific safety issues
3. A passing score on a safety quiz that covers the online materials, the DVD and the site specific
   presentation
4. Orientation to the safety features of the scanner room(s), typically conducted as part of more
general training regarding use of the scanners
5. A passing score on a practical safety examination in which a working knowledge of the safety
   features and procedures in the scanner room is demonstrated
6. For those who have been certified, there will be an annual safety retraining (one hour), the
   content of which will be determined annually.

27.3. Who will monitor the research for the safety of the participants? (check all that apply)
   - The USC/CHLA Principal Investigator (or designee)
   - A USC/CHLA Data Safety Monitoring Committee/Board
   - A Non-USC/CHLA Data Safety Monitoring Committee/Board
   - The Sponsor/Funding Agency
   - Other (specify below)

27.3.1. Other Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the
participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan (monitoring
provisions) which may include information on: the type of data or events to be captured, who is
responsible for monitoring data related to unanticipated problems and adverse events, time frames
for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of
assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate
when an action is required, and procedures for communicating to the IRB, sponsor, investigator, and
other appropriate officials the outcome of the reviews by the monitoring entity.
The PI will supervise general equipment and imaging safety issues. The principal investigator and other
researchers named in this document will be responsible for ensuring the validity and integrity of the data
obtained and downloaded from the imaging system. These researchers will also take an active role in
ensuring subject safety during imaging sessions. The raw data will be backed up on CD ROMs and
stored in file cabinets with restricted access.

27.3.2. All Reportable Events or unanticipated problems will be submitted to the IRB in compliance with
USC/CHLA policy, Federal/state regulations, and sponsor requirements (as applicable).

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study: (check all that apply)
   - There are no direct benefits to some or all of the research participants
   - Improvement in some or all of participants’ symptoms
   - Improvement in some or all of participants’ survival or longevity
   - Information gained from testing or monitoring procedures
28.1.1. Describe other potential benefits to participants:
The subject will not benefit from participation.

The magnetic resonance imaging (MRI) scan the subject will receive during the course of this study is for research purposes only. It is not a clinical scan intended for diagnostic or therapeutic purposes. The Dornsife Imaging Center is a research center. It is NOT a Clinical MRI facility in a hospital. There are no neuroradiologists at the Dornsife Imaging Center; therefore the staff are unable to make any medical comments about the subject’s scan. Should the subject want to know if his/her scan is normal or abnormal, the staff will not be able to tell him/her. However, all structural scans obtained in normal research subjects are sent to a Neuroradiologist for blind review. In the rare event the neuroradiologist detects an abnormality s/he will be given your name and contact information along with the name and contact information of the physician you provided on the Dornsife Subject Agreement. The Neuroradiologist will contact you and your physician and discuss the findings and suggest further action. You will also be given the data of the structural images on a CD so you can further consult with your physician. You may decline the offer of receiving the images on a CD.

28.2. Describe potential benefits to society, if any. (check all that apply)

- The advancement of knowledge
- A new treatment or therapy for the condition under study
- None
- Other (explain below)

28.2.1. Describe other potential benefits to society:
The results from these experiments may improve our empirical and theoretical understanding of human emotions, human moral reasoning and the human brain.

28.3. What are the alternatives to participation? (check all that apply)

- Not participating
- Continue current medical care for their condition
- Participation in other research studies
- Palliative care
- No treatment or therapy
- Participate in other subject pool activities
- Other (specify below)

28.3.1 Describe other alternatives to participation:
The alternative is not to participate.

28.4. Risks in relation to benefits:

- The potential benefits to the research participants justify exposure of the participants to the risks.
- The potential benefits to humanity justify exposure of the participants to the risks.
- Other (specify below)

28.4.1. Other risk benefit analysis:
Although there are no direct benefits to the subjects, as the risk is extremely low, the risk to benefit ratio is favorable.

28a. Incidental Findings

This screen is required if you indicated the use of Magnetic Resonance Imaging (MRI) as a procedure (Question 9.2.)

28a.1. Please explain how incidental findings are to be managed. You may also upload any necessary documents below.

If the subject gives consent, his/her structure scan will be sent to a neurologist for review. The neurologist will directly contact the subject if any image that suggests an abnormality is detected. The subject can choose not to have his/her scan reviewed.

See attached document for more information.

28a.1.1. Documents pertaining to Incidental Findings:

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<td>Requirements for research at</td>
<td>History 0.01</td>
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35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use or disclose protected health information (PHI) in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)

☐ Yes  ☐ No

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

☐ Yes  ☐ No

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a limited data set. If you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.

name                   Version       Modified
There are no items to display

USC Template Data Use Agreement

39. Conflict of Interest Information

Do any of the participating study investigators or other research personnel (or their immediate family/domestic partner) have a financial interest (equal to or exceeding $10,000 per year) and/or intellectual property interest in the sponsor or products used with this project? Conflicts of interest may include (but are not limited to) any of the following items below: equity (stocks or options, do not include mutual funds); consulting fees; speaking fees; gifts; a position as a Corporate Officer or on the Board of Directors; other employment relationships; trademarks or copyrights; licensing agreements; royalty rights; or patent holdings; or compensation that will be affected by the outcome of the study. If so, describe which party or parties have a conflict of interest and indicate the nature and extent of the conflict of interest. Note: recruitment bonuses of any amount must be disclosed.

☐ Yes  ☐ No

39.2. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed.

name       Version       Modified
There are no items to display

39.3. To the investigator's knowledge does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?

☐ Yes  ☐ No

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.

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<td>ExampleClip-banal</td>
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<td>0.01</td>
</tr>
<tr>
<td>ExampleClip-moral</td>
<td>History</td>
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</tr>
<tr>
<td>fMRI screening form - Chinese</td>
<td>History</td>
<td>0.01</td>
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<tr>
<td>fMRI screening form.pdf</td>
<td>History</td>
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</tr>
<tr>
<td>Initial Contact Letter - Chinese - Beijing</td>
<td>History</td>
<td>0.02</td>
</tr>
<tr>
<td>Initial Contact Letter - Chinese - Beijing - English translation</td>
<td>History</td>
<td>0.01</td>
</tr>
<tr>
<td>Initial Contact Letter - Chinese - LA - English translation</td>
<td>History</td>
<td>0.01</td>
</tr>
</tbody>
</table>
40.2. If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.
We are in the process of obtaining editable versions of the video clips along with appropriate copyright permissions. Because the choice of specific stimuli is contingent upon the technical considerations inherent in this process, at this time we can provide you with links to the unedited versions of video clips and stories of the sort we plan to use:

Compassion for social pain - http://www.emailthis.clickability.com/et/emailThis?clickMap=viewThis&etMailToID=1611788556
Admiration for skill - mms://video.oprah.com/200604/tows/tows_20060425_1.wmv
Admiration for virtue - http://www.cbs2.com/video/?id=22492@kcbs.dayport.com

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the "Finish" button on the top or bottom application navigator bar to return to the workspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the "Send Study Ready Notification" activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.
5. Once all the Co-Investigators have agreed to participate, the Principal Investigator (indicated in item 2.1.) can submit the application by using the "Submit Application to _____", where _____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.

4.4. Funding Source

Please enter the fields below and click 'OK' when done.

4.4.1. * Name of Sponsor:

4.4.2. * Named Principal Investigator:

4.4.3. Institution awarded the grant-award:

4.4.4. Grant-award number provided by the Sponsor:

4.4.5. Title of the Funding Project, if applicable:

4.4.6. * Type of Funding:

4.4.7. Attach a copy of the proposal/contract/grant with the project budget. (salary information need not be displayed or included.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Version</th>
<th>Modified</th>
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There are no items to display

4.4.8. *(HSC ONLY) Please indicate where the funds will be deposited and the amount:*

- [ ] USC: Total: $0.00
- [ ] USC CRO (formerly HRA): Total: $0.00
- [ ] Other, Specify: Total: $0.00

6c.2. Other Site/Institution (Outside the United States)

6c.2.1. * Site Name:

6c.2.1.1. * Please provide a short purpose, justification, or rationale for selecting this site:

We plan to investigate how culture modulates the underlying biological processing of social emotion. We will be collecting data from Chinese subjects to investigate these emotions in the Chinese cultural context.

Beijing Normal University has the same fMRI scanner as we do at USC, which enables us to do comparable studies in both centers. [**Prof. Name**], who is a professor at USC and also has an adjunct professorship in [**Institution**], will help us to set up the collaboration.
6c.2.2.  * Address: 

6c.2.3.  * Country: 
China

6c.2.4.  * Will any of the personnel at this institution carry out research activities such as obtaining consent or conducting study procedures? 
- Yes  
- No

6c.2.5.  If yes, indicate under which category(ies) the institution is engaged (see guidance) and attach a copy of the IRB approval from that site below.

<table>
<thead>
<tr>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e., awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.</td>
</tr>
<tr>
<td>(2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.</td>
</tr>
<tr>
<td>(3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.</td>
</tr>
<tr>
<td>(4) Institutions whose employees or agents interact for research purposes with any human subject of the research. Examples of interacting include engaging in protocol-dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.</td>
</tr>
<tr>
<td>(5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.</td>
</tr>
<tr>
<td>(6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institutions employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to: (a) observing or recording private behavior; (b) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and (c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.</td>
</tr>
</tbody>
</table>

6c.2.6.  Attach a copy of the IRB approval/permission letter from that site here.

6c.2.7.  If no, please attach a letter of agreement for conduct of the study from that site.

6c.2.8.  Does the institution have an IRB or Ethics committee?
6c.2.8.1. If yes, attach a copy of the approval for this study.

6c.2.9. Does the institution have a Federal Wide Assurance?
   • Yes  • No

6c.2.9.1. If yes, please indicate the FWA number.

22d.3. Language and Method of Translation

22d.3.1. * Indicate the language:
   Chinese

22d.3.1.1. If you indicated "Other", specify the language:

22d.3.2. * Method of translation of consent form:
   • Investigator will provide the IRB with a translation of the approved consent form
   • Request that the IRB office provide contact information of qualified translation services (translation agreements made by study team)