PHYSICAL CONTACT WITH STUDY PARTICIPANTS	SOP 4.4.02

1. Purpose

The purpose of this SOP is to provide the procedures for studies involving physical contact with study participants and general guidance for consent and interaction with the participants.

2. General Information

IRB-approved human subjects' research may require investigators to have physical contact with participants. Examples of such physical contact range from providing assistance onto a chair or into an imaging device to attaching an experimental or data collection device to a participant's body. Questions regarding physical contact with participants can be directed to the IRB (https://researchcompliance.caltech.edu/committees/institutional-review-board, irb@caltech.edu) and/or the Equity and Title IX Office (https://equity.caltech.edu/; 626-395-3132; equity@caltech.edu)

3. PI Training Requirements

All investigators should attend a presentation (or review a recording of a presentation) from the Equity and Title IX office on this subject.

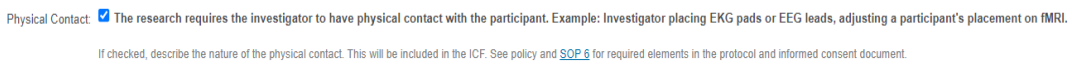
4. Procedure

A. Any study requiring physical contact with a study participant must be presented as a Full Application to the IRB.

B. The physical contact needs to be described in the protocol and disclosed, in detail, in the informed consent document. The description must include the nature of the contact, location or part of the body that will be touched and whether the contact will be firm or light, the duration of the contact, whether there will be any period of temporary immobility or restraint and methods to ensure continued consent, and the right to decline the contact or withdraw from the study at any time.

(1) In the Protocol:

a. Select Physical Contact in the Application Section, Study Participation:



b. Describe the physical contact in the protocol under "Description of Participation" (Application Section, Study Participation) Indicate if the contact is once or ongoing and where on the body the participant may be touched. Describe how you will inform the participant that they are going to be touched. The IRB Protocol Application System (PAS) will provide template language that investigators should update according to the study details.

*‡ Description: Part of this study requires that the researcher have physical contact with you. The contact consists of [helping you/attaching a device/etc.] that requires the researcher to touch your [body part] [briefly/for (time)]. The contact will be [light/firm/periodically firm/light] and you [will/will not] be restrained [if will: for x minutes] during the study. The researcher will inform you of what will happen throughout this interactive time. At any time during the study, you have the right not to be touched if you say you don't want to be touched anymore. If the physical contact is necessary for the study (for example, a device must be attached to your body), you can withdraw from the study at any time.

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For example: "The participant will be touched at different times during the study session. The participant will be touched on the back, arms or legs to help them get positioned in the MRI. We will touch the participant, applying firm pressure, with dull stick on their hand, to determine if the sensation changes their perception. At the end of the study session, we will offer to help the participant sit up and get out of the MRI.

(2) The Informed Consent Form includes the language that is entered into the Physical Contact section of the protocol application.

C. Consent for physical contact should be both informed and affirmative.

D. When a study protocol includes physical contact between an investigator and participant, the IRB recommends that two investigators be present in the room, for the duration of the study. However, for all portions of the study where there is to be physical contact between an investigator and a participant, two attentive investigators must be present. A participant may be left alone in a room, for example, to fill out a survey or during MRI scanning. The IRB will consider exceptions to the two-observer requirement on a case-by-case basis.

In general, for the safety and security of both the participants and the investigators, investigators should avoid one-on-one situations where physical contact is expected, be aware of situations in which actions can be misconstrued by participants, be professional, maintain high standards of personal behavior at all times, maintain appropriate physical boundaries at all times, and touch participants only when necessary and only in ways that are appropriate and non-sexual.

E. Recommended Best Practices from Caltech's Title IX Office:

- Think carefully about situations where physical contact with participants may differ based on gender
- Have two attentive investigators present
- Consider genders of the participants and investigators
- Give participants their choice of which investigator will touch them, if possible
- Give immediate notice about a touch that is about to occur and explain each step of contact during contact
- Refrain from joking about the contact in any way
- Use the "magic words:" "Is this ok?"

F. If there is a concern or you or others associated with the project are notified of a concern regarding the touching or other treatment of the participant during the study session, please notify the Equity and Title IX office immediately (626-395-3132 equity@caltech.edu), for guidance, particularly if the concern potentially relates to sexual misconduct, discrimination, or harassment. If there is the possibility that any harm came to the subject during the experiment, you should immediately notify the IRB. (See IRB Policy, Section VII. Unanticipated Problems and Other Events).

5. Informed Consent (ICF) Language

A. When physical contact is expected, the nature of the contact needs to be disclosed, in detail, in the informed consent document. The description of the physical contact should include the nature of the contact, the location or part of the body that will be touched, whether the contact will be firm or light, the duration of the contact, whether there will be any period of temporary immobility or restraint and methods to ensure continued consent, and the right to decline the contact or withdraw from the study at any time.

B. PAS includes the below template language in the protocol application and informed consent document. You must include this language if your protocol involves physical contact with participants.

Part of this study requires that the researcher have physical contact with you. The contact consists of [helping you/attaching a device/etc.] that requires the researcher to touch your [body part] [briefly/for (time)]. The contact will be [light/firm/periodically firm/light] and you [will/will not] be restrained [if will: for x minutes] during the study. The researcher will inform you of what will happen throughout this interactive time. At any time during the study, you have the right not to be touched if you say you don't want to be touched anymore. If the physical contact is necessary for the study (for example, a device must be attached to your body), you can withdraw from the study at any time.