

**Institutional Review Board**

|  |  |
| --- | --- |
| **Date Received—**Office Use Only | **Protocol Number—**Office Use Only |

**Modification Request Form**

**Note to Researchers:** The Revised Common Rule, implemented January 21, 2019, states that minor modifications that do not increase the likelihood or severity of risks to participants do not have to be submitted to the IRB for approval. Contact the IRB Administrator to discuss your modifications if you aren’t sure whether they require a modification application.

**Instructions:**

1. Verify that your modification requires IRB approval under the Revised Common Rule.
2. Complete all sections of this form.
3. Submit revised documents that contain information affected by the modification(s).
4. Submit the protocol material via email to IRB@SoCalBrainspotting.org
5. Modification(s) cannot be implemented until you receive notification of IRB approval.
6. Keep a copy of this completed form for your records.

**General Information**

 Today’s Date: Principal Investigator Name:

Project Title:

 Protocol Number:       Last Approval Date:

 Protocol Approval Category:  ☐ Exempt ☐ Expedited  ☐ Full Board Review

**Description of Modification**

What will be modified? (check all that apply):

☐ Approved procedures ☐ Informed Consent

 ☐ Number of subjects ☐ Survey/Questionnaire

 ☐ Research team\* ☐ Other

 Briefly describe the modification:

\*If adding members to the research team, the modification summary must include name(s) and role(s) of all new team members; you must also submit evidence that they have current human subjects protections training certification. Changes in PI must be submitted and signed by the original PI on the protocol. Include the reason for the change in the modification summary.

**Assessment of Risk (select one)**

 ☐ This modification ***does not*** increase risk to participants.

 ☐ This modification ***does*** increase risk to participants.

**Statement of Assurance**

**A. Investigator’s Assurance**

As a Principal Investigator, I recognize that these proposed changes will be reviewed by the IRB and that changes cannot be implemented until I receive notification that they have been approved. My name typed below serves as my acceptance of this statement and of the contents of this form.

[Type name]

**B. Faculty Advisor** (IF APPLICABLE)

As faculty advisor, my name typed below serves as my approval of the modifications proposed in this form. *(Student applications must include faculty acknowledgement.)*

[Type name]