



**INSTITUTIONAL REVIEW BOARD (IRB)  
REVIEW REQUEST  
FOR PROJECTS INVOLVING HUMAN SUBJECTS**

Dear Investigator,

Thank you for your inquiry regarding human subjects research. As a reminder **Investigators are responsible for ensuring that the rights and welfare of human subjects** participating in research activities are protected, and that methods used and information provided to gain subject consent are appropriate to the research.

Investigators should review and abide by Natividad IRB Policies-2018 (located online at Natividad Policy Manager)

**All research activities involving the use of human beings as research subjects** (participants) must be reviewed and approved by the Natividad Review Board (IRB). Please note that only the IRB may make the determination whether or not an activity qualifies as research or if research qualifies for exemption under Title 45 CFR 46.101.

**Investigators may not solicit subject participation or begin data collection until they have** received approval by both the Natividad Institutional Review Board and Natividad Administration.

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**IRB Review Application Related Forms** are available by requesting an application via email at [irb@natividad.com](mailto:irb@natividad.com). The form may be completed and returned electronically to [irb@natividad.com](mailto:irb@natividad.com). Once completed, a signed hard copy must be submitted to the IRB Office along with any other materials relevant to the proposal (scripts, consent forms, interview questions, surveys, etc.). The Office of the IRB is located in the Natividad Quality Department. If you have **questions** about the IRB application form or about the review process, contact:

**Institutional Review Board Office  
c/o IRB Administrator  
Natividad Cypress Center-Quality Department  
1441 Constitution Blvd  
Salinas, CA 93906  
831-783-2534  
E-mail: [irb@natividad.com](mailto:irb@natividad.com)**

## **INSTITUTIONAL REVIEW BOARD (IRB)**

The Institutional Review Board generally meets quarterly and on an ad hoc basis as proposals are submitted for review. Applicants must allow a minimum of 2 weeks for the initial administrative review. Another 4-8 weeks for the review of research activities will be required to review a completed application. A notice of the IRB's action will be sent to the researcher upon completion of review. Actions include Approval, Approval Pending, Deferred, Disapproval, Tabled. The request for review will be tabled if the applicant does not submit a completed application.

### **INSTRUCTIONS:**

Your responses to the questions in the application are basic to the Institutional Review Board's determination about the protection of the rights and welfare of human subjects in your research. Your responses should be clear, complete, and concise. Applications that are not clear and/or that have excessive spelling and grammar issues will be returned for correction and resubmission.

All answers to the questions on the IRB Application should be typed out in the appropriate questions on the form in the spaces provided. If you believe that a question does not apply to your research, enter a response such as "N/A" or "does not apply." If an application is returned with unanswered questions, it will be returned without review.

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### **Your initial application *must include*:**

- Researchers' CVs, Conflict of Interest documents and Human Subjects CME attestation
- Completed IRB Review Application with signatures from all investigators including all required documentation
- All relevant Natividad Department Manager Consents (if available)
- All relevant External IRB authorization agreements and/or Institutional Departmental Cooperative Agreements (if available)
- All relevant materials pertaining to your research design including but not limited to:
  - Survey Instruments
  - Interview/Focus Group Questions
  - Materials provided to participants
- All correspondence used to recruit and inform subjects including but not limited to:
  - Verbal, written, and/or email recruiting scripts
  - Informed consent, assent, and/or permission forms you have designed for your research that the subject(s) will sign (the template provides the basic framework and needs to be customized to your research).

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