



LOCAL CONTEXT FORM

A copy of this form must be completed by each site seeking to rely on the Chapman University IRB. The form should be completed by an individual who has knowledge of the relying site’s human research protection program (HRPP), its policies, and state and local laws relevant to human subjects research (e.g., the relying institution’s HRPP or IRB Director). Questions about this form should be directed to the Chapman University IRB Office at irb@chapman.edu

General Information

1. Research Title:

2. Overall Principal Investigator:

3. Relying Institution Principal Investigator:

4. Name of Relying Institution:

5. Select all research activities that will be performed at your institution and/or in which your institution’s employees will be engaged:

- Recruiting participants
- Consenting participants
- Communicating or interacting with participants whether in-person, online, through the phone (e.g., surveys, interviews)
- Conduct physical procedures through which information or biospecimens are gathered, or manipulation of the subject’s environment (e.g., taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)
- Analyzing identifiable data or specimens
- Analyzing de-identified or anonymized data
- Prime recipient of funding
- Other:



6. Name and title of person completing this form:

7. Has the relying institution's FWA (federal wide assurance) been extended to non-federally funded research (i.e., does your institution "check the box" on the FWA to apply the Common Rule to all research)?

Yes No

8. Provide any other names the relying institution is known by:

9. Please identify any affiliations your institution has relevant to this study, such as a university, clinic, or hospital.
Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.

10. If any of the sites identified in Question 9 are within a network or system, do they have a separate FWA?

Yes No

11. If the answer to Question 10 is "yes," please identify the sites with separate FWAs.

12. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subject research proposed at the relying institution?

Yes No



13. If the answer to Question 12 is “yes,” please explain any investigations, audits, or findings that may be relevant.

14. Does the relying institution have a post-approval monitoring program or other regulatory oversight for ongoing research?

Yes No

15. If the answer to Question 14 is “yes,” does the post-approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?

Yes No

16. Have all personnel who will be engaged in human subject research at your institution completed institutionally-required training (including but not limited to human subjects protections training and Good Clinical Practice training, as applicable)?

Yes No

17. Are all personnel who will be engaged in human subject research at your institution credentialed and/or appropriately qualified and meet your institution’s standards for eligibility to conduct the research described in the approved protocol?

Yes No



18. Did your institution determine there are any individual or institutional financial conflicts of interest (COIs) related to this research?

- Yes No

If yes, summarize the conflict and the management plan.

Local Context Information

1. Are there any state laws that the reviewing IRB will need to consider when reviewing this study?

- Yes No

2. If the answer to Question 1 is “yes,” please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).

3. Are there any community or cultural differences for the local population that require consideration?

- Yes No



4. If the answer to Question 3 is “yes,” please describe the relevant information.

5. Is 18 the age of majority for the state in which your site is located?

Yes No

6. If the answer to Question 5 is “no,” please identify the age of majority.

Relying Institution Policies

1. Does your institution have a posted policy for the following? NOTE: Please only select those for which there is a posted institutional policy; generally accepted practice and guidance are not policy.

Age of assent policy

If selected, please provide a link (URL) to the policy, or paste the policy below.



Consent process for those with impaired decision-making capacity

If selected, please provide a link (URL) to the policy, or paste the policy below

Use of short forms for non-English speaking individuals

If selected, please provide a link (URL) to the policy, or paste the policy below

Translation of consent forms for non-English speaking individuals

If selected, please provide a link (URL) to the policy, or paste the policy below



2. Please provide any institutionally-required consent form language for compensation in the event of research-related injury:

3. Please provide any other consent form language required by institutional policy or state law:

Relying Institution IRB Designee Name and Title:

Signature:

Date Signed: