**LOCAL CONTEXT FORM**

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

**General Information**

1. Research title:

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1. Chapman Principal Investigator:

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1. Relying institution Principal Investigator:

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1. Name of Relying institution:

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1. Select all research activities that will be performed by the relying institution’s personnel:

[ ]  Participant recruitment

[ ]   Consenting participants

[ ]   Interacting with study participants or manipulating the participant’s environment

[ ]   Analysis of identifiable data or specimens

[ ]  Analysis of de-identified data or anonymized data

[ ]   Prime recipient of funding

[ ]   Other: *Click or tap here to enter text.*

1. Name and title of the relying institution’s point of contact for questions and execution of a reliance agreement:

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1. Has the relying institution’s federal wide assurance (FWA) been extended to non-federally funded research? In other words, does the institution “check the box” on the FWA to apply the Common Rule to all research?

[ ]  Yes [ ]  No

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

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1. Please identify any affiliations the relying 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 agreement and to identify relationships between institutions.

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

[ ]  Yes [ ]  No

1. If the answer to Question 10 is “yes,” please identify the sites with separate FWAs that are involved in this study.

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1. Have there been any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) at the relying institution during the past three years that would be relevant to the conduct of the proposed human subjects research?

[ ]  Yes [ ]  No

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

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

[ ]  Yes [ ]  No

* 1. 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

1. Have all personnel at the relying institution who will be engaged in this research completed institutionally required training (including but not limited to human subject protection training and Good Clinical Practice training, as applicable)?

 [ ]  Yes [ ]  No

1. Will all personnel at the relying institution who will be engaged in this research be credentialed or appropriately qualified and meet your institution’s standards for eligibility to conduct the research described in the approved protocol, prior to working on the research?

[ ]  Yes [ ]  No

1. Do any personnel at the relying institution have a real or perceived conflict of interest related to the research?

[ ]  Yes [ ]  No

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 If yes, summarize the conflict and the management plan.

**Local Context Information**

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

[ ]  Yes [ ]  No

* 1. 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).

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1. If the relying institution is collecting data as part of the study, are there any community or cultural differences for the local population that require consideration?

[ ]  Yes [ ]  No [ ]  N/A, not collecting data

* 1. If the answer to Question 2 is “yes,” please describe the relevant information.

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1. If the relying institution is collecting data as part of the study, is 18 the age of majority for the state in which your site is located?

[ ]  Yes [ ]  No [ ]  N/A, not collecting data

* 1. If the answer to Question 3 is “no,” please indicate the age of majority.

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**Relying Institution Policies Related To This Study**

1. Does your institution have a posted policy for topics relevant to this study? NOTE: Please only select those for which there is a posted institutional policy; generally accepted practice and guidance are not considered policy.

**Age of assent policy**

[ ]  Yes [ ]  No [ ]  N/A, not relevant to this study

If “Yes”, please provide a link (URL) to the policy, or paste the policy below

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**Consent process for those with impaired decision-making capacity**

[ ]  Yes [ ]  No [ ]  N/A, not relevant to this study

If “Yes”, please provide a link (URL) to the policy, or paste the policy below

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**Use of short forms for non-English speaking individuals**

[ ]  Yes [ ]  No [ ]  N/A, not relevant to this study

If s”Yes”, please provide a link (URL) to the policy, or paste the policy below

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**Translation of consent forms for non-English speaking individuals**

[ ]  Yes [ ]  No [ ]  N/A, not relevant to this study

If “Yes”, please provide a link (URL) to the policy, or paste the policy below

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

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

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**Signature:**

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*Relying Institution IRB Designee Signature and Title Date*