

**Brown University**

**Local Context Form**

**When Brown University is serving as the IRB of Record (IoR) this completed form must be signed by an** [**Authorized Signatory**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#authorized) **at the Relying Site and submitted with the Collaborative Research Application.**

**Protocol Title:** Click or tap here to enter text.

**STUDY ID:** Click or tap here to enter text.

**Brown University PI:** Click or tap here to enter text.

**Relying Institution:**  Click or tap here to enter text.

**Relying Institution PI:** Click or tap here to enter text.

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| **PART I. RELYING SITE INFORMATION** | | | | | | |
|  | FWA #: Click or tap here to enter text. | | | | |
|  | IRB #: Click or tap here to enter text. | | | | |
|  | Yes  No | | | Is the Relying Site [AAHRPP](https://www.aahrpp.org/) Accredited? | |
|  | Yes  No | | | Is the Relying Site a [HIPAA](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html#:~:text=The%20HIPAA%20Privacy%20Rule%20establishes,certain%20health%20care%20transactions%20electronically.)-covered entity?  *(If no, skip to Part II)* | |
|  |  | Yes  No | Does the Relying Site require the use of their own HIPAA authorization forms? | |
|  |  | Yes  No | Does the Relying Site require HIPAA authorization forms be separate documents from informed consent documents? | |

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| **PART II. LOCAL INFORMATION** | | |
|  | What is the [age of majority](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#ageofmajority) in the Relying Site’s state? Click or tap here to enter text. | |
|  | Yes  No | Are there circumstances in your state that affect the age at which a person can consent to participation in research (e.g. medical treatment, emancipation, marriage, military service, minor parents)? If yes, describe:  Click or tap here to enter text. |
|  | Yes  No | Are there any state, local laws, and / or corresponding institutional policies regarding [legally authorized representatives](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#legally)? If yes, describe:  Click or tap here to enter text. |
|  | Yes  No | Are there any state, local laws, and / or institutional policies that require RECORD KEEPING for longer than federal law requires (i.e., [HHS](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), [FDA](https://www.ecfr.gov/cgi-bin/text-idx?SID=b3d901788c2a41fdce5d243d3b5e4c8c&mc=true&tpl=/ecfrbrowse/Title21/21cfr56_main_02.tpl), HIPAA)? |

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| **PART III. PROJECT SPECIFIC INFORMATION** | | | |
|  | Yes  No  *(If no, skip to 2.)* | | Is the research being conducted outside the State of Rhode Island? |
|  |  | Yes  No | Are there any international, state, local laws, or requirements that the IoR will need to consider when reviewing this study? If yes, describe:  Click or tap here to enter text. |
|  | Yes  No | | Are there any institutional policies or requirements that would affect the conduct or approval of the research (e.g. local ancillary reviews, recruitment procedures)? If yes, describe:  Click or tap here to enter text. |
|  | Yes  No | | Are there any community or cultural differences for the local population of participants that require consideration? If yes, describe:  Click or tap here to enter text. |
|  | Yes  No | | Is site-specific language required for the informed consent document(e.g. contact information, compensation language)? If yes, describe:  Click or tap here to enter text. |

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| **PART IV. SIGNATORY INFORMATION** | |
| Name of Authorized Signatory: Click or tap here to enter text. | |
| Title: Click or tap here to enter text. | |
| Email: Click or tap here to enter text. | Phone: Click or tap here to enter text. |
| Signature: | Date: Click or tap to enter a date. |