**Institutional Profile**

**Site Name: University of Colorado Boulder**

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About the Institutional Profile

This information is intended to be used by an institution either relying on or serving as the Reviewing IRB, for an investigator at the University of Colorado Boulder.

Please note, this information is not intended to provide all the Institution’s study-specific local considerations. This is general information, and it may be withdrawn, revised or subject to change at any time.

**Section 1: General HRPP Information**

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| Institution | University of Colorado Boulder |
| Federalwide Assurance (FWA) # | 00003492 |
| FWA Expiration Date | 11/16/2025 |
| Does your institution have an internal IRB? | Yes |
| IRB Registry Number(s) | Panel#1 00000191Panel #2 00000774 |
| Is the IRB AAHRPP accredited? | No |
| Describe any board specialties of your IRB. | Social/Behavioral (Panel 1); Biomedical (Panel 2) |
| Is your institution a covered entity? | No |

**Section 2: Site-Specific Local Context**

This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization. Additional, study specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements). However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study specific HRP surveys (including consent form language and format).

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| To what state laws is your institution subject? | Colorado |
| List other names by which your institution is known. | NA |
| Age of majority in your state? | 18 |
| What circumstances affect age of consent in your state?For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment | Minor can consent to own mental health treatment and for birth control |
| Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule? | No |
| Do you require specific language in your consent form to describe what requires mandatory reporting to authorities? | No specific language required |
| Does your site require a site-specific logo appear on consent forms and/or recruitment documents? | No |
| HIPPA requirements | CU Boulder is not a HIPPA covered entity |
| Please enter your specific consent form language regarding payment for research-related injury | If you need medical care because of taking part in this research study, seek medical attention immediately (if it is a medical emergency, first call 911). Generally, this care will be billed to you, your insurance, or other third party. The University of Colorado Boulder has no program to pay for medical care for research-related injury. |
| Please enter your specific consent form language regarding costs to participants to participate. | No specific language required |

**Section 3: Study-Specific Reliance Plan: The information below has been harmonized with the SMART IRB Agreement Implementation Checklist.**

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| CONFLICTS OF INTEREST | Relying Institution(s) will perform conflict of interest analyses under their policies |
| IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE) | Reviewing IRB will provide notifications directly |
| IRB-INITIATED EXTERNAL REPORTING | Reviewing IRB will draft and submit reports to external recipients |
| FINANCIAL AGREEMENTS - For review costs | Reviewing IRB/Institution will not charge. Relying Institution(s) for costs of review: The Relying Institution(s) will not be responsible for financial support of the costs of review of the research. The Reviewing IRB may charge the sponsor or other third parties for those costs. |
| QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM("QA/QI") | QA/QI program access required. Each participating Institution engaged in or conducting human subjects research must have or have access to a human subjects research QA/QI program or service (or analternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research personnel's compliance with human subjects protections and other relevant requirements. |
| INDEMNIFICATION | Indemnification agreements not required. |