IRB REVIEWER CHECKLIST

*(For use by ORI staff and IRB members for New Applications)*

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| **APPLICATION INFORMATION** | |
| **Researcher:** | **Faculty Advisor (if applicable):** |
| Title of Application: | |

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| **ORI ADMINISTRATIVE CHECKLIST** | | | **COMMENTS** |
| Required signatures received | Yes | No |  |
| Project roster received and training completed | Yes | No |  |
| Consent Document(s) received | Yes | No | Consent  Oral consent script  Assent  Information sheet |
| Special Populations Identified | Yes | No | Pregnant women/neonates  Prisoners  Children  Impaired decision-making capacity  Other ‘vulnerable’ population: |
| Recruitment Material(s) received | Yes | No |  |
| Measures/instruments received | Yes | No |  |
| Funding identified | Yes | No | Government  Non-profit  Department  Industry  Unfunded  Other:  *If funding is from DOD, DOJ, DOE, ED or EPA, the review will have additional requirements.* |
| Supplemental Materials included | Yes | No | Debriefing form  Access / permission letters for external sites  Other: |
| Additional reviews may be required | Yes | No | PRO  IBC  IACUC  SCRO  Other: |

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| **ORI ADMINISTRATIVE COMMENTS AND NOTES FOR THE IRB** |
| Comments for IRB and/or IRB reviewer: |
| Comments for researcher to be included in revision request: |

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| **IRB REVIEWER CHECKLIST** | | | | | |
| Criteria for IRB Review and Approval: Please review the federal criteria for IRB approval and indicate whether the research meets each criterion by checking the appropriate box. List any concern you would like communicated to the researcher in the corresponding comment box or in the open space below. Please write comments directly to the researcher.  (Criteria for IRB approval of research in accordance with [45 CRF 46.111](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), [21 CFR 56.111](https://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-sec56-111.pdf) and UCR Policy) | | | | | |
| **General** | | | | | **COMMENTS** |
| 1 | The IRB reviewer has the expertise needed to review this research | Yes | No |  | *If no, contact ORI staff will arrange a consultation with an ad hoc reviewer - ASAP.* |
| 2 | The IRB reviewer has a conflict of interest with this application | Yes | No |  | *If yes, contact ORI staff for reassignment - ASAP.* |
| 3 | The statement of purpose/hypothesis/research question is adequate | Yes | No |  |  |
| **Risk/Benefit Assessment – Risks include possible** [**physical, psychological, economic, social and legal harms**](#Risks)**.** | | | | | |
| 4 | Risks to subjects are minimized by:   * using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk * whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes | Yes    Yes | No    No | N/A |  |
| 5 | Risks to participants are reasonable in relation to both:   * anticipated benefits, if any, to participants; **and** * the importance of the knowledge that may reasonably be expected to result | Yes | No |  |  |
| **Participant Selection** | | | | | |
| 6 | Selection of participants is equitable in relation to the purposes of the research and the setting in which the research will be conducted | Yes | No |  |  |
| 7 | Selection of participants (i.e., inclusion/exclusion criteria) is appropriate based on the research and the setting in which the research will be conducted. | Yes | No |  |  |
| 8 | The recruitment process minimizes the potential for undue influence or coercion | Yes | No |  |  |
| 9 | [Compensation](#Compensation" \o "Compensation refers to money or item given to the research participatns that acknowledges the time and effort they have provided in participating in the research. ) - neither the amount of payment or the proposed method and timing of disbursement is coercive or presents potential for undue influence | Yes | No | N/A |  |
| 10 | Recruitment materials are appropriate | Yes | No | N/A |  |
| **Informed Consent/Assent** | | | | | |
| 11 | Informed consent is sought from each prospective participant or the participant’s legally authorized representative and appropriately documented in accordance with, and to the extent required by [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) and [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), and [21 CFR 50.25](https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol1/pdf/CFR-2012-title21-vol1-sec50-25.pdf) and [21 CFR 50.27](https://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-sec50-27.pdf) as applicable | Yes | No | N/A |  |
| 12 | Waiver of informed consent is requested (i.e., no consent process) and meets the requirements for waiving consent according to [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)   * Research involves no more than minimal risk * Waiver or alteration will NOT adversely affect the rights and welfare of participants * Research could not practicably be carried out without the waiver or alteration * If the research involves using identifiable private information or identifiable biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format. * Whenever appropriate, participants will be provided with additional pertinent information after participation | Yes | No | N/A |  |
| 13 | Waiver of documented (signed) consent is requested and meets the requirements for waiving documentation according to [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)   * The only record linking the participant and the research would be the consent document; * The principal risk would be potential harm resulting from a breach of confidentiality; **and** * Additionally, each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern;   **OR**   * The research is minimal risk **and** * Involves no procedures that usually require written consent.   **OR**   * The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm; * The research presents no more than minimal risk of harm to participants; **and** * There is an appropriate alternative mechanism for documenting that informed consent was obtained. | Yes | No | N/A |  |
| Child Assent *(Mark N/A if no children involved)* | | | | | |
| 14 | Informed assent is sought from each prospective child and appropriately documented in accordance with and to the extent required by [45 CFR 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) and [21 CFR 50.55](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.55), as applicable. | Yes | No | N/A |  |
| 15 | Waiver of child assent is requested and meets the requirements for waiving assent according to [45 CFR 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)   * The capability of some or all of the children is so limited that they cannot reasonably be consulted, OR * The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research | Yes | No | N/A |  |
| 16 | Waiver of parental assent is requested and meets the requirements for waiving documentation according to [45 CFR 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)   * The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) | Yes | No | N/A |  |
| **Subject/Participant Protections** | | | | | |
| 17 | The research plan makes adequate provisions:   * for monitoring the data collected to ensure the **safety** of participants * to protect the [**privacy**](#Privacy) of participants * to maintain the [**confidentiality**](#Confidentiality) of data | Yes | No |  |  |
| 18 | The research **does** involve participants likely to be vulnerable to coercion or undue influence, such as students, children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.  **If YES,** the research plan **does** include additional safeguards to protect their rights and welfare. | Yes    Yes | No    No |  |  |

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| **[IRB REVIEWER COMMENTS](#IRBmemberguide" \o "Write directly to the researcher(s) on behalf of the IRB; Use full sentences and not point form; Be specific by referencing the section of concern; Refer to specific guidelines that researchers may find useful in addressing; Use a friendly, collegial tone) (not included above):** |
| Additional comments: |

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| **DETERMINATIONS** | | | | |
| **Risk Assessment** | [Minimal Risk](#MinimalRisk" \o "Minimal risk is the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations/tests)  More than minimal risk | **Review Level** | [Expedited Category](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiE1bLQ24nNAhVB5mMKHeH-ANYQFggcMAA&url=http%3A%2F%2Fwww.research.uci.edu%2Fcompliance%2Fhuman-research-protections%2Fdocs%2Fcategories-of-expedited-human-subjects-research.pdf&usg=AFQjCNE_1fLcJw4ywb6jZM5U62_fQuZNcw&sig2=rtd_JDiAMk248zN0qOzKTw):  [Exempt Category](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwiE1bLQ24nNAhVB5mMKHeH-ANYQFggqMAI&url=http%3A%2F%2Fwww.research.uci.edu%2Fcompliance%2Fhuman-research-protections%2Fdocs%2Fcategories-of-exempt-human-subjects-research.pdf&usg=AFQjCNEUyCtr62MhM11et20ybdKTVpS5DA&sig2=L0B7sZYVnrjiSLTwYRtFvw):  Full Board Review | |
| **Review Period** | One year  No review period (minimal risk applications only)  Other: | If requesting full board review, please provide rationale: | | |
| If requesting review period (e.g., One year or Other) for minimal risk application, please provide rationale: | | |
| **Recommendation** | Approve as submitted  Minor changes required (ORI/IRB member will review responses/documents) – (**default**)  Deferred for substantive changes (Revised documents will be returned to the reviewer for approval)  Deferred for Full Board Review | | | |
| **IRB Reviewer checklist and determinations completed by (name of reviewer):** | | | | **Date:** |