

Research activities in which the only involvement of human subjects will be in one or more of the categories specified under 45 CFR 46.104 (d) are exempt from the requirements of the basic Health and Human Services Policy for the Protection of Human Research Subjects (Subpart A). Because of this, and in an effort to streamline, the UCI HRP has implemented several efficiencies related to exempt research. You can read more about this, including information on the recently expanded exempt self-determination process on the Office of Research HRP Listserv here: <https://news.research.uci.edu/?s=exempt>

In an effort to continue to promote efficiencies, Effective November 1, 2019, the UCI HRP will no longer require the submission of minor modifications to exempt research. For those studies in which a lead researcher (and faculty sponsor (FS), if applicable) has submitted to and received UCI IRB confirmation of exemption, minor changes may be made without notifying the UCI IRB.

Examples of minor changes: Do NOT submit a modification to the UCI IRB when:

1. Making editorial or administrative revisions to consent documents or other study documents
2. Adding non-sensitive questions to a survey or interview or revising current questions
3. Adding a new recruitment material that follows [IRB guidelines](#)
4. Increasing or decreasing the number of participants - *unless adding a new population as noted below***
5. Making study team/personnel changes - *except a change in Lead Researcher (LR)*

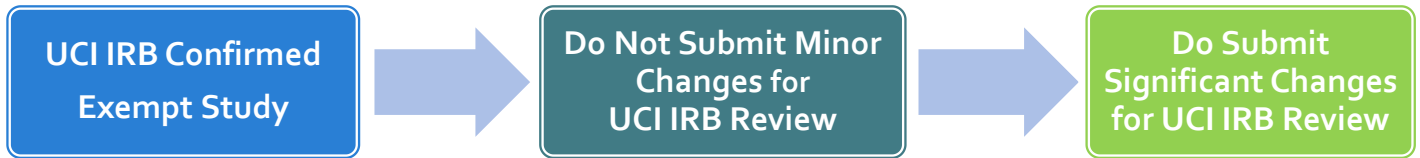
There are exceptions when a modification application must be prospectively submitted to the UCI IRB for review and approval. These align with the exceptions in the [Exempt Self-Determination Tool](#). Please note the following significant changes that would require UCI IRB review:

Examples of significant changes: DO submit a modification to the UCI IRB:

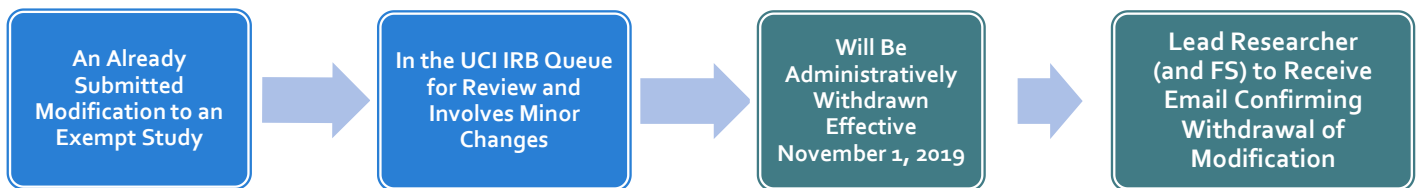
1. ****When adding a new population as follows:**
 - a. A targeted recruitment of children
 - b. A targeted recruitment of adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
 - c. A targeted recruitment of prisoners
 - d. A targeted recruitment of American Indian/Alaska Native tribes
 - e. A targeted recruitment of undocumented people
2. Adding non-UCI personnel engaged in research: a) intervening or interacting with the participants and/or b) having access to participant identifiable private information for research purposes.
3. Adding the use of the [UCI Social Science Human Subject Lab \(SONA\)](#).
4. Adding an international research site
5. Adding questions about sensitive aspects of the participants' behavior such as illegal conduct, drug use, sexual behavior or use of alcohol – to a survey or interview
6. For a change in study LR
7. To disclose a new financial interest
8. When adding Department of Justice (DOJ) funding
9. For any change that makes the study no longer eligible for Certification of Exemption (*study will require expedited or full committee review*)

Next Steps:

Effective November 1, 2019, the submission of minor modifications to exempt research will no longer be required. Lead Researchers (and FS) must submit significant modifications to exempt research that meet the above criteria. Lead Researchers (and FS) will be responsible to ensure that all members of the study team [have the appropriate \(and current\) educational trainings](#), as well as track their various study modifications as part of [suggested record keeping responsibilities](#).



Any modifications already in queue will be administratively withdrawn by HRP staff. An email will be sent to the Lead Researcher to confirm.



If you have any questions, [please contact HRP Staff](#).

Additional Resources:

- You can read more about exempt research at 45 CFR 46.104 here: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1cof5c6937cd9d751316ofc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=H TML#se45.1.46_1104
- You can read more about expedited and full committee review here: <https://research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html>
- Recruitment methods: <https://research.uci.edu/compliance/human-research-protections/researchers/subject-selection-recruitment-and-compensation.html#Recruitment>
- Training and education verification: <https://apps.research.uci.edu/tutorialcheck/>
- HRP education and training requirements: <https://research.uci.edu/compliance/human-research-protections/researchers/training-and-education.html>
- Research Personnel Log: <https://research.uci.edu/forms/docs/irb-forms/rp-perrsonnel-log.xlsx>
- Lead Researcher Recordkeeping Responsibilities: <https://research.uci.edu/compliance/human-research-protections/researchers/lead-researcher-recordkeeping-responsibilities.html>
- To subscribe to HRP [News & Announcements](#), send a blank email to: or-irb-hrp-join@department-lists.uci.edu