Exempt Review of Human Subjects Research Tip Sheet

Consideration of Exempt Status:
1. The research activities MUST fall entirely within one or more of six categories for exemption;
2. Research should pose minimal risk to subjects;
3. The research CANNOT involve prisoners unless it is aimed at involving a broader subject population that only incidentally includes prisoners.

Important Notes:
● Pls DO NOT have the authority to make an independent determination that research involving human subjects is exempt; this is the responsibility of UCSC via Office of Research Compliance Administration and/or the IRB.
● Studies cannot be initiated prior to receiving an exempt determination letter from ORCA/the IRB.
● Each project requires a separate review and exempt determination.
● Studies not meeting the criteria for exemption can be sent for expedited or full board review.
● Studies involving deception do not qualify for exemption, except Category 3 when subject agrees to being either unaware of or misled regarding nature or purposes of the research upfront.
● All engaged researchers except tenure track ("professor" track) faculty are required to take human subjects training.
● Federally-funded studies and other exclusions can not be exempt under category 3x.

Application Form:
● Use latest version of application form found here.
● Eligibility to submit: Only individuals with certain payroll titles are automatically eligible to serve as Principal Investigator on human subjects research protocols. These are primarily faculty. Some staff, though not automatically eligible, can request an “Exception to Policy” by submitting a ticket to the Office of Sponsored Projects (OSP) on their website: https://officeofresearch.ucsc.edu/osp/forms1.html
● Either a scanned full-page signature or email affirmation is required from both PI and co-investigator (there is only one PI and one co-investigator). (No pasted-in jpg’s).
● Funding section should either state “None” or grants/gifts/private funds must be listed.
● Everyone engaged in human subjects research must be listed as an investigator (“engaged” includes recruiting, consenting, conducting procedures with subjects or using, studying, or analyzing identifiable private information or specimens).
● If research falls under Category 2iii or Category 3iC, researchers must also complete the Limited IRB Review Addendum

Research Description:
● Use language directly from the exempt category where possible and applicable
● If survey/interview/test questions are open-ended, include a sample of 3-5 of the questions to support your assertion that disclosure of the data would not put subjects at risk of emotional upset or other harms.
● Anonymous/confidential: The IRB distinguishes between "anonymous" – meaning that data does not have any identifiers, including indirect (like pseudonyms with a master list) – and "confidential"– meaning that the researcher has these identifiers but protects them against unauthorized disclosure.
● If transcribing/translating: Please clarify who will be transcribing/translating—if not a professional service, personnel would need to be treated as investigators.
● Media release: When sharing photographs, videos, and/or audio recordings of subjects publicly, researchers are expected to obtain a signed media release form according to UCSC University Relations. The details of this form are not overseen by the IRB, but your application should state that you will be obtaining this release. Please see the University's preferred form at https://www.ucsc.edu/identity/web/files/photo-release.html.
● EU research: As of May 25, 2018, the EU Enacted the General Data Protection Regulation. Please state whether your study includes subjects from the EU. More info at: https://ucnet.universityofcalifornia.edu/news/2018/05/notice-on-general-data-protection-regulation.html.