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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when research involves waiver or alteration of the consent process. This checklist (or equivalent) may be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist (or equivalent) to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to CHECKLIST: Non-Committee Review (HRP-402 or documents the equivalent in the Review Comments of the electronic system. * For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:  1. The convened IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained. 2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Administration retains this checklist in the protocol file. | | |
| **IRB Number:** | |  |
| **Investigator:** | |  |
|  | **1. Applicable Considerations (Check one)** | |
|  | The request is for a complete waiver of informed consent for research **not involving** a public benefit or service program ***(If yes, complete Section 2)*** | |
|  | The request is for a complete waiver of informed consent for research **involving** a public benefit or service program ***(If yes, complete Section 3)*** | |
|  | The request is for an alteration of informed consent for research **not involving** a public benefit or service program ***(If yes, complete Sections 2 and 4)*** | |
|  | The request is for an alteration of informed consent for research **involving** a public benefit or service program ***(If yes, complete Sections 3 and 4)*** | |
|  | The request is for a waiver of consent for emergency research and meets the criteria set out in HRP-419 ***(If yes, STOP – Complete HRP-419)*** | |
| 2. General Waiver of the Consent Process[[1]](#footnote-1) (Check if “Yes”. All must be checked) | | |
|  | The research involves no more than Minimal Risk to the subjects.  *Provide protocol specific findings justifying this determination:* | |
|  | The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.  *Provide protocol specific findings justifying this determination:* | |
|  | One must be checked:  The research is being reviewed under the Pre-2018 Rule;  The research uses only de-identified or anonymous private information or biospecimens; or  The research cannot practicably be carried out without using identifiable private information or identifiable biospecimens because *:* | |
|  | The research could **NOT** practicably be carried out without the waiver or alteration  *Provide protocol specific findings justifying this determination:* | |
|  | Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participation.  *Provide protocol specific findings justifying this determination:* | |
|  | The research does **NOT** meet the State of California's definition of a medical experiment[[2]](#footnote-2). | |
|  | The research does **NOT** involve non-viable neonates. | |

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|  | 3. Waiver of Consent Process for research involving public benefit and service programs[[3]](#footnote-3) (Check if “Yes”. All must be checked) |
|  | One of the following is true: **(Choose One)**  The research is not FDA-regulated  The research presents no greater than minimal risk including for FDA-regulated studies |
|  | The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.  *Provide protocol specific findings justifying this determination:* |
|  | The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. One must be checked)**  Public benefit or service programs.  Procedures for obtaining benefits or services under those programs.  Possible changes in or alternatives to those programs or procedures.  Possible changes in methods or levels of payment for benefits or services under those programs.  *Provide protocol specific findings justifying this determination:* |
|  | The research could **NOT** practicably be carried out without the waiver or alteration.  *Provide protocol specific findings justifying this determination:* |
|  | The research does **NOT** meet the State of California's definition of a medical experiment[[4]](#footnote-4). |
|  | The research does **NOT** involve non-viable neonates. |
|  | 4. General Alteration of the Consent Process[[5]](#footnote-5)  (Check if “Yes”. All must be checked) |
|  | Consent is sought under circumstances that provide the subject or LAR sufficient opportunity to discuss and consider whether or not to participate. |
|  | Consent is sought under circumstances that minimize the possibility of coercion or undue influence. |
|  | The information is given to the subject or LAR in a language that is understandable to them. |
|  | The information provided is information that a reasonable person would want to have in order to make an informed decision about whether to participate. |
|  | The informed consent begins with a concise and focused presentation of key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research and is organized and presented in a way that facilitates comprehension |
|  | The informed consent includes sufficient detail and does not merely provide isolated facts. |
|  | The informed consent does not include exculpatory language through which the subject or LAR waives or appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |

1. 45 CFR §46.116(f)(3) [↑](#footnote-ref-1)
2. California Health and Safety Code Section 24170:

   (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or

   (b) The investigational use of a drug or device; or

   (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject. [↑](#footnote-ref-2)
3. 45 CFR §46.116(e) [↑](#footnote-ref-3)
4. California Health and Safety Code Section 24170:

   (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or

   (b) The investigational use of a drug or device; or

   (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject. [↑](#footnote-ref-4)
5. 45 CFR §46.116(f)(2) & (3) [↑](#footnote-ref-5)