# Checklist: General Waiver or Alteration of Consent [[45 CFR 46.116(f)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)]

For each item below, please provide a justification as to how this study meets **all** of criteria list below.

|  |  |  |
| --- | --- | --- |
| Must answer ‘**Yes**’ to all criteria | Criteria | Investigator Response |
|  | The research involves no more than minimal risk of harm to the subjects; | *Type text here* |
|  | The research could **not** practicably be carried out without the waiver or alteration; | *Type text here* |
|  | If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; | *Type text here* |
|  | The waiver or alteration will **not** adversely affect the rights and welfare of the subjects; and | *Type text here* |
|  | Whenever appropriate, the subjects or legally authorized representatives will be provided with pertinent information after participation [45 CFR 46.116(f)]. | *Type text here* |