

Requesting a Waiver of Consent or Parental Permission

Instructions and Template Language

For all studies receiving mid-level review (expedited) or convened full board review, informed consent or parental permission is required. If a researcher does not want to seek consent or parental permission for the project, the researcher must request a waiver of consent or parental permission for consideration. This must be submitted within the IRB application and a scientific justification must be made.

The regulatory required information that must be submitted to the IRB when requesting a waiver of consent or parental permission includes justifying that:

- The research involves no more than minimal risk to participants.
- The waiver of consent or parental permission will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver of consent or parental permission (meaning if you have to get consent or parental permission, the research could not occur).
- If the research involves using identifiable or re-identifiable private information or biospecimens, the research could not be carried out without using the information or biospecimens in an identifiable/re-identifiable format.
- Discuss that where appropriate, participants will be provided additional pertinent information after participation. This usually applies to research involving deception in which full disclosure of purpose or procedures would compromise the research.

For each participant group and mode of data collection that the researcher is requesting a waiver of consent for, address the criteria noted above.

You can use and complete the template fill-in-the-blank language below and paste it into your IRB application:

- The research involves no more than minimal risk to participants because **<insert justification>**.
- That the waiver of consent or parental permission will not adversely affect the rights and welfare of the participants because **<insert justification>**.
- The research could not practicably be carried out without the waiver of consent or parental permission because **<insert justification>**.
- The research involves using identifiable or re-identifiable **<select one: private information or biospecimens>** and the research could not be carried out without using and keeping the **<select one: private information or biospecimens>** in an identifiable/re-identifiable format because **<insert justification>**.
- Participants **<select one: will be or will not be>** provided additional information after participation. The additional information participants will receive is **<insert information>** because of **<insert justification>**.