

## Application for Waiver of Consent

**Reference:**

- [National Statement on Ethical Conduct in Human Research](#) (National Statement)

Chapter 2.2 of the National Statement describes the general requirements for waiver of research participant consent as:

***Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information.(Paragraph 2.3.9)***

Chapter 2.3 expands on waiver of consent and includes criteria that the HREC must consider before granting a waiver of consent. Prior to granting a waiver of consent, the HREC must be satisfied that the research protocol adequately addresses these criteria. (Paragraph 2.3.10)

**To assist the HREC in its consideration of a request to waive consent, please address each of the criteria below. The information addressing the criteria can be included in the cover letter or be provided as a separate attachment.**

<b>a)</b>	Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7) to participants
<b>b)</b>	The benefits from the research justify any risks of harm associated with not seeking consent
<b>c)</b>	It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
<b>d)</b>	There is no known or likely reason for thinking that participants would not have consented if they had been asked
<b>e)</b>	There is sufficient protection of their privacy
<b>f)</b>	There is an adequate plan to protect the confidentiality of data
<b>g)</b>	In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
<b>h)</b>	The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
<b>i)</b>	The waiver is not prohibited by State, federal, or international law

**If the research aims to expose illegal activity please also address the following by responding under each point:**

<b>a)</b>	The value of exposing the illegal activity justifies the adverse effects on the people exposed (see paragraph 4.6.1)
<b>b)</b>	There is sufficient protection of their privacy
<b>c)</b>	There is sufficient protection of the confidentiality of data
<b>d)</b>	The waiver is not otherwise prohibited by State, federal, or international law