

## Consent Process: Requesting a full or partial waiver of consent

IRBIS Office of Human Research Ethics  
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**>> 3. Full or partial waiver of consent**

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The default is for subjects to give informed consent. A waiver might be requested for research involving only existing data or human biological specimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

1. Are you requesting any of the following:

- a waiver of informed consent in its entirety
- a waiver or alteration of some of the elements of informed consent
- a waiver of HIPAA authorization (If you are accessing patient records for this research, you must also request a waiver of HIPAA authorization)

To justify a waiver of the requirement for informed consent, you must affirm, by checking each of the following items, that it applies to this study. Provide a brief explanation.

The research involves no greater than minimal risk to subjects or to their privacy  
 Explain

The waiver will not adversely affect the rights and welfare of subjects (Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)  
 Explain

The research would be impracticable to conduct without the waiver  
 Explain how the requirement to obtain consent would make the research impracticable, e.g., most of the subjects are lost to follow-up or are deceased.

When appropriate, there are plans to provide subjects with pertinent information after their participation is over. (e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)  
 Explain (or indicate if not applicable)

The risk to privacy is reasonable in relation to the importance of the knowledge to be gained  
 Explain

2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

Please review the [FAQ](#) section for Tips and Techniques on using the HTML Editor.

\* Required.  
 To navigate the Application, press continue or any link in the Item List to your left.

Save and Continue Clear Responses

At Part D.3, you may alternatively or additionally request and justify a waiver of some or all elements of consent. If your request applies to some but not all of your subject groups, explain at D.3.2