Carroll College

**Waiver of Written Consent**

Informed consent is a process rather than merely a document. Any individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating.

The standard consent process is for all subjects to **sign** a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.

* If you will obtain consent in any manner, use the Consent Form Template (on MyCarroll).
* If you are obtaining consent, but requesting a waiver of the requirement for a **signed** consent document, complete and submit **Section I**.
* If you are requesting a waiver of any or all of the **elements** of consent, complete and submit **Section II**.

You may need to complete more than one section.

**Section I.** **Justification for a Waiver of *Written* (i.e. signed) Consent.**

*The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a **signed** consent form may be waived by the IRB if either of the following is true:

|  |  |
| --- | --- |
| a. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey). **Explain.**1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study involves sensitive data that could be damaging if disclosed).  **Explain.**

If you checked “yes” to either, will consent be oral? Please explain **how** oral consent will be obtained (e.g. will you provide a fact sheet, use an online consent form, include information as part of the survey itself?).       | [ ]  yes [ ]  no[ ]  yes [ ]  no |

**If you have justified a waiver of written (signed) consent (Section I), you should complete Section II only if your consent process will not include all the other elements of consent.**

**Section II.** **Justification for a Full or Partial Waiver of Consent.**

*The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biologicalspecimens (see also Part 4 of the “Application for IRB Review of Human Subjects Research”). 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.

 [ ]  Requesting **waiver of some elements** (specify):

 [ ]  Requesting **waiver of consent entirely**

→ ***If you check either of the boxes above, answer items a - f. To justify a full waiver of the***

 ***requirement for informed consent, you must be able to answer “yes” (or “not applicable” for***

 ***question c) to items a - f. Insert brief explanations that support your answers.***

|  |  |
| --- | --- |
| a. Will the research involve no greater than minimal risk to subjects or to their privacy? **Explain.**        |  [ ]  yes [ ]  no |

|  |  |
| --- | --- |
| b. Is it true that 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.**        |  [ ]  yes [ ]  no |

|  |  |
| --- | --- |
| c. When applicable to your study, do you have 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.**         |  [ ]  yes [ ]  not applicable |

|  |  |
| --- | --- |
| d. Would the research be impracticable without the waiver? *(If you checked “yes,” explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* **Explain.**   |  [ ]  yes [ ]  no |

|  |  |
| --- | --- |
| e. Is the risk to privacy reasonable in relation to benefits to be gained or the importance of the knowledge to be gained? **Explain.**  |  [ ]  yes [ ]  no |

→ ***If you are accessing patient records for this research, you must also be able to answer “yes”***

 ***to item f to justify a waiver of HIPAA authorization from the subjects.***

|  |  |
| --- | --- |
| f. Would the research be impracticable if you could not record (or use) Protected Health Information (PHI)? *(If you checked “yes,” explain how* ***not*** *recording or using PHI would make the research impracticable).* **Explain.**        |  [ ]  yes [ ]  no |