**University of North Dakota Application for Waiver or Alteration of Informed Consent Requirements**

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| **Principal Investigator:** | |  |
| **Project Title:** |  | |
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Written documentation of informed consent that embodies all the required elements of informed consent, as described in [45 CFR 46.116](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#section-46.116), is required for all research subjects. With sufficient justification, the IRB may approve a consent process that does not include, or which alters, some or all of the elements of informed consent provided that it finds and documents specific requirements.

**A. If requesting a waiver or alteration of the requirements to obtain informed consent, justify such in accordance with each of the following five criteria established under 45 CFR 46.116(d) (1-5).** (This option not allowed for FDA regulated research). This waiver is necessary for deception research and instances when all of the required elements of consent are not included on the consent form. This waiver may also be used if requesting to waive parental consent for research involving children/adolescents. ***This form is not used to request to waive the signature requirement.***

1. The research involves no more than minimal risk\* to the subjects;

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2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

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3. The research could not practicably\*\* be carried out without the waiver or alteration;

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4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation; **AND**

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5. 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.

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| (Principal Investigator Signature) | Date: |
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| (Institutional Review Board Primary Reviewer Signature) | Date: |

*\*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*\*\*Practicable refers to instances in which the additional cost would make the research prohibitively expensive, or where the identification and contact of thousands of potential subjects would not be feasible for the anticipated results of the study. Practicable would not mean an inconvenience or increase in time or expense to the investigator or the research.*