SUNY Downstate IRB & Privacy Board

FORM 8-19: Waiver of Informed Consent Requirements

(Version 12.15.2021)

Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.

Note: Free Adobe Reader available at: www.adobe.com

Section 1: Basic Information

A. Project Title:

B. Principal Investigator:

C. Type of request (check up to 3 applicable boxes). investigations.

- ☑ **Waiver of the <u>entire process</u> of Informed Consent.** Complete section 2.
- ☐ **Waiver of some of the <u>required elements</u> of Informed Consent.** Complete Section 2a & 3.
- ☐ **Waiver of <u>documentation (signatures)</u> of Informed Consent.** Complete section 4.

D. Study Populations:

If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this waiver pertains.

Note: A separate Waiver form MUST be submitted when the responses in this form are different for another population or group.

☑ Check box if this request applies to all study participants. Otherwise, uncheck this box and describe the study population(s) for which this waiver applies (e.g., healthy control, patients screened from medical records, specific study arm, population or group, etc.)

E. If applicable, describe the information to be collected under this waiver:

F. If applicable, provide the date range of records to be reviewed under this waiver:

Section 2: Complete to waive the entire process of consent and/or elements of consent:

Please check either box A or box B below:

☐ **(A)** The criteria below are met. **Complete Section 5, 6, & 7.**

- The research involves no more than minimal risk to the research participants;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves the use of identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- Whenever appropriate, the research participants (or their legally authorized representative/ surrogate/parent/legal guardian) will be provided with additional pertinent information after participation (e.g., debriefing research participants involved in deception research).

When (A) is checked, describe how the research participants will be provided with additional pertinent information after participation (explain process to debrief participants involved in deception research and/or attempt contacting participants if life threating results are found, etc) or check N/A if not applicable. ☐ N/A

☐ **(B)** The research cannot practicably be carried out without the waiver or alteration and the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
Complete Section 6.

Section 3: Complete this section to waive the required element(s) of consent:

Please describe the element(s) for which this waiver applies.
For a list of required elements, see 45 CFR 46.116 (b-c).
Note: This does not apply to FDA regulated clinical investigations.
Complete Section 2a, 5, 6, 7.

Provide justification for waiving the required element(s):

Section 4: Complete when requesting waiver of documentation (signatures) of informed consent

A. Provide a justification for making this request:

B. Please check either box 1, 2, or 3 to describe the criteria that justifies the request for a waiver of documentation of informed consent:

☐ (1) That the research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, survey, collection of quality improvement data, etc.).
Complete Section 5.

☐ (2) The only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the research participant wants documentation linking him/her with the research and his/her wishes will govern.

If box (2) is checked, describe how the study team will link a research participant to the research if the research participant requests such documentation:

☐ (3) The research participant (or legally authorized representative/surrogate/parent/legal guardian) are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. **Complete Section 5.**
Caution: Option #3 cannot be used for federally funded research initially approved before 1.21.2019, nor can it be used for research regulated by the FDA or DOJ.

If box (3) is checked, describe the distinct cultural group or community in which signing forms is not the norm:

If box (3) is checked, describe how the study team will document informed consent took place (e.g., making a note on the informed consent document or placing a note in the research record, etc.):

Section 5: Confirmation of Minimal Risk [required to support Section 2A, 3, 4B(1), or 4B(3)]:

A. Indicate all study procedures used in the research to confirm the study involves no more than minimal risk to the participants or their privacy (check all that apply):

- ☐ Blood collection from participants
- ☐ Focus group, survey, or interview research
- ☐ Record, data, document, or non-invasive specimen collection for research purposes
- ☐ Remnants of specimens collected for routine clinical care or analysis that would otherwise be discarded (i.e., left over clinical specimens to be discarded into waste)
- ☐ Collection of video, voice, digital, or image recording data made for research purposes
- ☐ Collection of data through non-invasive means routinely done in clinical practice
- ☐ Mobile applications that track data in accordance with data security requirements
- ☐ Other(describe):

Section 6: Confirmation that research is not practicable without the waiver [required to support Section 2A, 2B, or 3):

A. Explain why the research cannot practicably be carried out without the waiver:

B. If applicable, explain why the research could not practicably be conducted without the information collected under the waiver:

Section 7: Confirmation that waiver will not adversely affect rights and welfare of participants [required to support Section 2A or 3]:

A. Explain why this waiver/alteration will not adversly affect the rights and welfare of participants:

- ☐ The research involves minimal risk to the participants
- ☐ Data will be de-identified and destroyed upon completion of project
- ☐ Data securely maintained with link to the source for validation purpose or future research
- ☐ Other (describe):