Section F. Informed Consent Waiver Form

The traditional informed consent process may be waived under particular conditions. Please review the conditions at this link http://answers.hhs.gov/ohrp/questions/7268 if you believe your project qualified for waiver of informed consent.

WAIVER REQUEST: Either Item 1a or Item 1b must be true in order to be considered for a waiver. The remaining items will determine the necessity of such a waiver. Please utilize the checklist on the following page to determine whether your study poses minimal risk.

Waiver Item 1a. **Is the following statement true?** ◯ **Yes** ◯ **No**

"This research involves no more than minimal risk to the subjects and involves no procedures for which written request is normally required outside of the research context."

Please justify your response in the space below and respond to the checklist on the next page.

Waiver Item 1b. **Is the following statement true?** ◯ **Yes** ◯ **No**

"The only record linking the subject and the research would be the consent document. The principal risk to the subject would be potential harm resulting from a breach of confidentiality."

Please justify your response in the space below.

Waiver Item 2. Please describe why this research could not practicably be carried out without this waiver.

Waiver Item 3. Please describe whether subjects will be provided with additional pertinent information after participation in the research. If this is not possible or appropriate, please explain.

Waiver Item 4. Please explain how this waiver or alteration, if granted, will not adversely affect the rights or welfare of the subject.

Waiver of Informed Consent
Checklist for "Minimal Risk" Eligibility

"Minimal risk" is defined as a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests.

The activities included in the list below are eligible to be considered as "minimal risk." Being on the list does not automatically qualify an item as minimal risk and does not mean that an automatic waiver is granted. It is up to the researcher to justify the need for a waiver of informed consent and up to the IRB to evaluate this justification.

☐ 1. Clinical studies of drugs and medical devices where condition (a) or (b) is met:
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required
   b. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more often than 2x per week; or
   b. From other adults and children1 considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amounts drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2x per week.

☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means.
   a. Examples include (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
   a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7. Research on individual or group characteristics or behavior including but not limited to:
   a. Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior
   b. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ 8. Continuing of research previously approved by the convened IRB as follows:
   a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long-term follow-up of subjects; or
   b. Where no subjects have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis

☐ 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."