CHICAGO DEPARTMENT OF PUBLIC HEALTH

SUBMISSION FORM FOR RESEARCH INVOLVING HUMAN SUBJECTS

IRB use only: #

Instructions: This form must be filled out completely. Incomplete forms will be returned. A copy of the research proposal and instruments are required. Submit the form in Word format and the proposed research project as PDF document to: Chicago Department of Public Health (CDPH) Institutional Review Board (IRB) staff (see below).

Date:

Principal Investigator of Project: _____
Last Name First Name

Principal Investigator Title: _____

Mailing Address: _____
Address City State Zip Code

Email Address: _____

Telephone Number: _____ (ext.) _____ Other Phone#: _____

Co-Investigator: _____
Name Title

CDPH Sponsor: _____

Project Title: _____

Funding Agency or Research Sponsor: ☐ Unfunded ☐ CDPH Funded ☐ Other specify below:

1) **Project Parameters:**
   - Estimated start date: _____
   - Estimated completion date: _____
   - Total number of patients to be recruited into project: _____
   - Total number of CDPH patients to be recruited into project: _____
2) **Project Description**: (Briefly describe objectives, design, and CDPH specific operational plan for proposed research. Attach study protocol)

3) **This project will be conducted at the following site(s):** (Please specify which site, on the line provided)
   CDPH clinic(s): _____
   CDPH field site(s): _____
   In the field (non-CDPH clinical or CDPH field site): _____
   Cermak Health Services/Cook County Jail (requires Hektoen IRB approval): _____
   Other (specify): _____

A) Exemptions, Waiver or Alteration of Informed Consent and Expedited Review

Check box if you are requesting one of the following: (if not exemption, wavier or alteration, please go to next section). Please refer to exempt research (§46.104) in the revised Common Rule

(I) Exemption from Review: Check the box below to indicate which category of exempt research this research consists of:

☐ Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). At least one of the categories must be met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ Category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).[1]

[1] For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

☐ Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(iv) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

☐ Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

☐ Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

If your research does not fit into the exempt categories above, it may be eligible for expedited review (see next page)

(II) Waiver or Alteration of Informed Consent: If you are requesting a waiver or alteration of informed consent, please provide details if the justifications below are met.

May be available if: (i) the research involves no more than minimal risk to the subjects; (ii) the research could not practicably be carried out without the requested waiver or alteration; (iii) 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; (iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(III) Expedited Review: for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

May be available to review (i) a study involving one or more of eight categories of research listed by the Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) for expedited review unless the reviewer determines there is more than minimal risk, (ii) minor changes in previously approved research during the period for which approval is authorized, or research for which limited IRB review is a condition of exemption.

The eight research categories listed below and can be found on the Office of Human Research Protection's website linked here:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) 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. (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 frequently than 2 times per week; or
    b. from other adults and children [2], 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 amount 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 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
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, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review 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 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.

This protocol qualifies for expedited review under category _____

(list the category number)

When writing your protocol, please refer to the “how to write a protocol” guide
If applicable to your protocol, please be sure to include the following elements:

1. Describe how risks to subjects are minimized (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Describe how risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from your study.

3. Describe how selection of subjects is equitable.

4. If informed consent be sought from each prospective subject or the subject's legally authorized representative.

5. describe how informed consent will be documented or waived.

6. Describe how the research plan makes adequate provision for monitoring the data collected to ensure the safety, confidentiality, and privacy of subjects. Describe the data collection process as well as data management and storage.

7. Describe adequate provisions that will be used to protect the privacy of subjects and to maintain the confidentiality of data. If confidential data (using personally identifying information) is collected but will be subsequently de-identified, describe how it will be de-identified and how it will be protected before and after de-identificaiton. Describe data storage- how long will you keep the data (including consent forms) and where will it be stored?

8. If some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, describe additional safeguards included in the study to protect the rights and welfare of these subjects.

B) Additional Protections Categories[2]

(Check all that apply) This research involves:

- ☐ Pregnant woman/women, human fetuses, and/or neonates (May, where applicable, be exempted from review using applicable exemptions below). Please refer to subpart B of the revised common rule (linked above).
- ☐ Biomedical and behavioral research involving prisoners as subjects (May not be exempted from review using applicable exemptions below)
- ☐ Children involved as subjects (The exemptions at paragraphs (3), (4) and (5) of the listed exemptions may be applied to research involving children as subjects if the conditions of the exemption are met. The exemptions at (2)(i) and (ii) of the listed exemptions only may apply to research involving children as subjects involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The exemption listed at (2)(iii) of the listed exemptions may not be applied to research involving children as subjects.

(I) Describe any incentives or benefits investigators or anyone else associated with the proposal are to receive for enrolling subjects and/or completing the study. Describe any conflicts of interest.

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[2] Note to IRB Members: Please refer to additional requirements within the common rule at 45 C.F.R. 46 Subparts B, C and D.

(II) Attach a copy of your Informed Consent Form (if applicable). Consent forms must be submitted in all languages applicable to the study subjects. Attach all data collection instruments.

(III) Attach copies of current IRB approval(s) from collaborating institutions; list these institutions:

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_____

_____

(IV) Required Training for Investigators conducting Human Subject Research:

I attest that I and all co-investigators have read the Chicago Department of Public Health IRB document "Required Training for Investigators Conducting Human Subject Research" and have completed the training courses or equivalent certification.

*Please submit your training certificates with application to IRB Staff Assistant.

Principle Investigator (Print Name) / Signature	Date

Institutional Endorsements

Your endorsement is requested to assure the Institutional Review Board that your office is aware of the existence and status of this research activity, and fully approve:

CDPH Sponsor (Print Name) / Title & Program / Signature	Date
Division Director (Print Name) / Signature	Date

Submit to:

James Esparza, IRB Staff Assistant
Chicago Department of Public Health
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Chicago, Illinois 60604
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(312) 747-9718