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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 Na	me	First Name		
Principal Investigator Title:					
Mailing Address:					
	Address		City	State	Zip Code
Email Address:					
Telephone Number:		(ext.)	Other Pho	one#:	
Co-Investigator:		· –			
	Name			Title)
CDPH Sponsor:					
School:					
Project Title:					
Funding Agency or Research Sponsor	r: 🛛 Unfu	inded [OPH Funded	• Othe	er specify below:

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:

Project Description: (Briefly describe objectives, design, and CDPH specific operational plan for proposed research. Attach study protocol)

This project will be conducted at the following site(s): (Please specify which site, on the line provided)

- $\Box \quad \text{CDPH clinic(s):}$
- $\Box \quad \text{CDPH field site}(s):$
- □ In the field (non-CDPH clinical or CDPH field site):
- Cermak Health Services/Cook County Jail (requires Hektoen IRB approval):
- Other (specify):

Describe (positive and/or negative) impact of proposed study activity on CDPH personnel, resources, and operations.

Describe any incentives or benefits investigators or anyone else associated with the proposal are to receive for enrolling subjects and/or completing the study.





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Check box if you are requesting one of the following:

1) Exemption from Review

Survey procedures, interview procedures, and the study of existing data, documents, or specimens may be eligible if the information is recorded in a manner that participants cannot be identified, directly or through identifiers linked to the participants. If eligible, the exemption is at the discretion of the IRB (Exemption from Review form needs to be completed.).

2) Waiver of Informed Consent

Available only if: (1) no more than minimal risk is involved; AND (2) the rights and welfare of participants would not be adversely affected; AND (3) the research could not practicably be carried out without the waiver.

3) Expedited Review

Available only if minimal risk is involved and waiver is not requested. In cases where the research involves no more than minimal risk or when there are minor changes to previously approved projects, an expedited review process may be granted. Minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Attach a copy of your Informed Consent Form (if applicable). Requirements for consent forms are reviewed in the Informed Consent Checklist (available on request). Consent forms must be submitted in all languages applicable to the study subjects.
- Attach copies of current IRB approval from collaborating institutions; list these institutions:

 Describe how identity of particip 	oants an	d confidentiality of reco	rds are to be safeguarded.				
 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 National Institute of Health (<u>http://phrp.nihtraining.com/users/login.php</u>) training course or equivalent certification. 							
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)	/	Signature	Date				
Division Director (Print Name)	/	Signature	Date				

Submit to: Joslyn James, Staff Assistant Chicago Department of Public Health 333 South State Street, Suite 200 Chicago, Illinois 60604 Email: Joslyn.James@cityofchicago.org (312) 747-8524