# UNITYPOINT HEALTH - DES MOINES
# *Institutional Review Board*

# APPLICATION TO CONDUCT RESEARCH QUALIFYING FOR EXPEDITED REVIEW:

**EXPEDITED REVIEW –**
The IRB may use the expedited review procedure to review the following research activities that:
(1) present no more than minimal risk to human subjects, and
(2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Please answer each question by typing in the text box. If you need additional forms, please access the IRB website at www.unitypoint.org/irb for the most recent version of the form.

## I. ADMINISTRATIVE INFORMATION

**a. Study Title:**

**b. Date of the Request:**

**c. Principal Investigator (PI) with Credentials:**

**d. Sub-Investigators (Sub-I) with Credentials, one line per person:**

***e.*** **List all personnel and their affiliation directly involved in the study, one line per person, with credentials** *(to add more lines: right click in a cell, Insert, Insert columns below)*

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**f. Contact Person if different than PI:**

**g. Full address approval letter should be sent to:**

**h. E-mail:**

**i. Phone:**

**All personnel listed above have taken CITI Human Subjects Protection Training**
*(Training and documentation for all listed personnel must be completed before research is reviewed and approved by the IRB. This will be verified by the IRB Office)*

☐Yes ☐No

## II. STUDY-FUNDING SOURCES

**Specify the funding source for your study:**

☐Investigator Initiated – typically studies conducted by students, residents

☐Federal Grant, specify agency and SPA grant/award #:

☐Industry Initiated - specify companies:

☐Cooperative groups - specify:

☐Foundation grant - specify:

☐Other - specify:

## III. CONFLICT OF INTEREST *(Note: a current COI form must be on file with the IRB Office prior to any study being processed for review):*

Has there been a change in circumstances since the investigator(s) or research personnel last submitted the most current "Conflict of Interest Disclosure Form" to the IRB office? ☐Yes* ☐No

**If yes, submit new COI document*

## IV. STUDY SUMMARY

### a. Purpose of Study:

Briefly describe in layman's terms what the investigator hopes to learn from this study and why it is important, in 3 to 5 sentences.

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### b. Estimate the number of medical charts you expect to review for this study.

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### c. Location where this study will be conducted:

IMMC ☐ ILH☐ MWH ☐ Blank☐

UP Clinic☐ UP at Home☐ TIC☐ MOHA

Other:

**d. Describe the source of the data that you will be studying, e.g., EPIC, AllScripts, etc. (be specific)**

**e. How will you keep the PHI you are collecting safe? How, when and where will this information be reviewed and how will you ensure only the study team has access to this information?**

**f. What is the proposed length of the study? (anticipated study closure date)**

**g. Participant Population: Identify the inclusion criteria for the medical records you will study. Provide age range of the persons whose charts you will be reviewing.**

**h. If you intend to exclude a particular age group, ethnic group or gender, provide a rationale for doing so, e.g., the disease does not occur in children.**

**i. If children are involved in your research, confirm the following:**

The research presents no greater than minimal risk to children and adequate provisions will be made for soliciting the assent of the children and the permission of

their parents or guardians (Note: Waivers of Assent and Consent are considered adequate provisions)

☐Yes ☐No* ☐N/A

**If no, your study may not be eligible for expedited review and may be required to be reviewed by the IRB Chair or the convened IRB. The IRB staff will provide additional information in such a case.*

**j. Indicate if you will specifically target the medical records/charts of any vulnerable populations, and explain rationale for doing so:**

☐children (0-17 yrs)

☐cognitively impaired

☐minorities

☐elderly

☐physically impaired

☐prisoners

☐pregnant women

☐non-English speaking

## V. Confidentiality Protections:

**a.** List the type of health information you will obtain from the medical record (e.g., diagnosis, lab reports, progress notes):

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**b.** List the HIPAA identifiers needed in order to obtain the information (e.g., name, MRN, SSN, date of birth, date of surgery, date of admission, date of death)

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**c.** Describe how data will be maintained (e.g., paper, electronic spreadsheet, desktop computer, laptop or other portable device) and the process for keeping this information secure.

**d.** If data will be de-identified after it is collected, describe who will be responsible for the de-identification, and confirm that none of the HIPAA identifiers will be linked to data.

**e.** If data will be coded, describe the coding system you will use so that the identity of the subjects cannot be readily ascertained from the code (e.g., the code should not contain initials, SSN, date of birth or dates of treatment). Indicate who will maintain the key to the code and describe how the key will be protected.

## VI. Obligations of Principal Investigator (PI)

**By checking each box below, the PI agrees to the following items:**

☐Adhere to principles of sound scientific research designed to yield valid results

☐Conduct the study according to the protocol approved by the IRB

☐Ensure adequate resources are available to conduct the study

☐Be appropriately qualified to conduct the research and be trained in Human Research protection through CITI or Good Clinical Practice (GCP) training

☐Ensure all research personnel are adequately trained and supervised

☐Ensure the rights and welfare of participants are protected including privacy and confidentiality of data

☐Ensure when de-identified materials are obtained for research purposes, no attempt will be made to re-identify

☐Disclose to the appropriate entities any potential conflict of interest

☐Promptly report to the IRB Office any issues of non-compliance, including breach of confidentiality, protocol deviations, etc. via the Non-Compliance form, found on the IRB website at www.unitypoint.org.irb.

☐Submit to the IRB any changes in the research protocol for approval prior to the implementation of such change via a Request for Amendment, found on the IRB website at www.unitypoint.org/irb.

☐Report to the IRB when all study-related activities have ceased and the study can be closed, via a Final Closure form, found on the IRB website at www.unitypoint.org/irb.

**Additional Required Documents to Submit to IRB with the study application:**

- Study application – signed and dated by Principal Investigator
- Request for Waiver of Informed Consent/Authorization/Documentation form– signed and dated by Principal Investigator
- Study Protocol
- Data Collection Form
- Documentation of CITI Human Subject's Protection Training
- Conflict of Interest form
- Any other printed materials used in the study

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Signature of Principal Investigator Date

***Please submit the completed documents to the IRB Office at irbsubmissions@unitypoint.org. If you have any questions, please send an email to this address or call 515-241-8598. Please allow 7-10 business days for initial review of any new study.***