Efficacy Evaluation of Using Finger Stick Peripheral Blood for Point of Care Pregnancy Testing

NCT06747598

Study Protocol and Statistical Analysis Plan

2025-07-28

Human Biological Material Research
SECTION I

1. Title of Protocol:
Efficacy evaluation of using finger stick peripheral blood for point of care pregnancy testing

Add a subject-friendly short title.
Serum POC Pregnancy Study

2. Responsible Personnel:
A. Principal Investigator (PI):
Nguyen, Thanh Thanh - Emergency Medicine - 402-559-7884 - thang.nguyen@unmc.edu - alt #: 402-559-7884 - degree: RN - address: UT 3242 UNMC Midtown (Zip 1150) - phone: 9-7884

B. Secondary Investigator (SI):
Hergenrader, Alex Jan - Obstetrics/Gynecology - 402-559-6160 - a.hergenrader@unmc.edu - alt #: 402-559-4500 - degree: MD - address: UT2 4235 UNMC Midtown (Zip 3255) - phone: 9-6160

Meyer, Isuzu - Obstetrics/Gynecology - 402-559-6150 - imeyer@unmc.edu - alt #: 402-836-9549 - degree: MD, MSPH - address: UT 4500 UNMC MIDTOWN (Zip 3255) - phone: 9-6150

Rimsza, Rebecca R - Obstetrics/Gynecology - 402-559-6150 - rrimsza@unmc.edu - alt #: 520-981-0933 - degree: MD - address: UT2 5248C UNMC Midtown (Zip 3255) - phone: 9-6150

Ukadike, John Emeka - Emergency Medicine - 402-559-6802 - jukadike@unmc.edu - alt #: 402-559-6802 - degree: DO - address: UT 3202 UNMC Midtown (Zip 1150) - phone: 9-6802

Ukah, Obiaara - Emergency Medicine - 402-559-6802 - oukah@unmc.edu - alt #: 402-559-6802 - degree: MD, PhD - address: UT 3202 (Zip 1150) - phone: 9-5413

C. Participating Personnel:

Giombetti, Natisha M - Emergency Services - - nagiombetti@nebraskamed.com - degree: BSN - address: Hixson Lied Center (Zip 68105)

D. Lead Coordinator:

Zimmerman, Brooklin k - Emergency Medicine - 402-559-5237 - brooklin.zimmerman@unmc.edu - alt #: 402-836-9405 - degree: MSN, BA, RN - address: UT 3231 UNMC Midtown (Zip 1150) - phone: 9-5237

E. Coordinator(s):

Are you adding a clinical trial management group?
No

F. Data/Administrative Personnel:

G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
Cooperative Group:
Center for Clinical and Translational Research (CCTR)
Federal (e.g., NIH) Grant - Provide source:
Other Grant:
♦ Departmental funding
Commercial - Provide company name:
Department of Defense
Other - Provide source (e.g. personal funding):

4. Deadline for IRB Approval
Yes - Explain and provide date:
♦ No

5. Contract
Is there a contract or agreement associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
No

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
Study activities will be conducted in the Nebraska Medicine OB/GYN clinic

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
Yes

List the sites.
UNMC/Nebraska Medicine

D. Does this study involve any international sites where the PI will either; 1) conduct 2) supervise or 3) receive / ship HBM or data to / from UNMC?
No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:

- **All information in this application is complete and accurate.**
- **I will conduct the research as described in the application and the protocol.**

- **I will not initiate any change without IRB approval except when it is necessary to reduce or eliminate a risk to the subject.**
- **I will ensure that all research personnel are qualified and properly trained.**
- **I will fulfill my responsibilities as PI, described in** https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/126-pi-qualifications-and-responsibilities
- **I will follow all applicable HRPP and institutional polices, and all applicable laws, statutes and regulations.**

Nguyen, Thanh Thanh - 2025-07-28 12:12:22.590

9. Principal Investigator Financial Interest Disclosure
A. As the PI, I declare:
I have no financial interest in this research.
♦ I have a financial interest in this research.

B. As the PI, I understand
♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:
♦ No Responsible Personnel have a financial interest in this research.
The Responsible Personnel listed below have informed me that they have a financial interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.
Nguyen, Thanh Thanh - 2025-07-28 12:12:22.590

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
The purpose of this study is to evaluate the efficacy of using peripheral finger stick blood for point of care (POC) pregnancy testing. POC pregnancy tests are designed for use with a urine specimen. However, the literature has demonstrated blood as a viable alternative specimen for use with POC pregnancy testing with a sensitivity of 95.8%. Based on our literature review, these studies used blood specimen that were pre-collected into a serum collection vial. We postulate the use of peripheral blood via a finger stick has multiple benefits such as 1) reducing the time needed for a pregnancy result, 2) allow for pregnancy testing in non-traditional scenarios such as wilderness medicine or mass casualty/gathering scenarios, and 3) minimizing the amount of blood required as compared to a traditional 3 ml serum collection vial. We propose enrolling 30 confirmed pregnant patients who present for their routine care visit at the Nebraska Medicine OB/GYN clinic. Eligibility includes: 1) 19 years or older and 2) confirmed pregnant status as indicated by a recorded positive POC, serum, or imaging test. Consented participants will be asked to provide a peripheral blood specimen via the finger stick mention using a lancet. Approximately 100 microliters (1-2 drops) of blood will be collected directly into a POC pregnancy test cartridge, then diluted with 1-2 drops of sterile saline to facilitate specimen absorption onto the lateral flow strip. Enrolled participants will also allow the investigators to perform a review of their EMR to confirm their pregnancy status by recording a positive urine and serum pregnancy result, along with recording the most recent beta-hCG result. No additional follow up required.

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
- Objective 1) Evaluate the efficacy of using peripheral blood for POC pregnancy testing in known pregnant patients

3. Background and Rationale
Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.
Point of care (POC) pregnancy tests are designed for use with a urine specimen. However, the timely collection of a urine specimen is solely dependent on the patient's need to urinate which can delay the initiation of subsequent care activities. Furthermore, when considering

the limitations of urine POC testing in wilderness scenarios, collecting a urine specimen from an injured person may not be a viable option. The literature has demonstrated blood as a viable alternative specimen for use with POC pregnancy testing with a sensitivity of 95.8%. Based on our literature review, these studies used blood specimen that were pre-collected into a serum collection vial. We postulate the use of peripheral blood via a finger stick has multiple benefits such as 1) eliminating the need to wait for urine, 2) expedite the serum collection process as compared to a venipucture, 3) allow for testing in non-traditional scenarios such as wilderness medicine or mass casualty/gathering scenarios, and 4) minimizing the amount of blood required as compared to a traditional 3-5 ml serum collection vial. Data from this pilot study will provide valuable insight on the potential use of this testing method to inform future studies and treatment protocols for the above mentioned scenarios.

SAMPLE TYPES

4. What is the total number of samples to be collected?
1 peripheral finger stick (approximately 1-2 drops) per participant, 30 total specimens collected

5. What is the statistical or other justification for the total number of samples?
30 subjects is an adequate sample size for pilot evaluation to evaluate for treatment effect.

6. Prospective HBM
Will HBM be prospectively (i.e., does not already exist at the time of this IRB Application) collected?
Yes

A. Will any of the prospective HBM be obtained from a tissue bank or research study approved by the UNMC IRB/ Joint Pediatric IRB or external source?
No

B. Will excess (i.e., left-over after completion of a routine diagnostic or clinical procedure which would normally be discarded) HBM be collected?
No

C. Will Extra (e.g. an extra tube of blood taken when clinical labs are drawn or an extra sample of tissue taken at the time of a clinical biopsy) HBM be collected?
No

D. Will HBM be collected through a procedure/intervention (e.g., biopsy, blood draw,

urine specimen, cheek swab, saliva collection) just for purposes of the research study/tissue bank?
Yes

1. List what types of HBM (e.g., blood, urine, tissue, DNA) will be obtained AND explain how (e.g. standard venipuncture) the material will be obtained.
Peripheral serum finger stick using a 1-time use lancet

2. How many samples will be obtained from each subject?
1 specimen collected from each participant

3. What is the amount (e.g. 10 mLs of blood) of <u>each</u> sample that will be obtained?
Approximately 2 drops (about 100 microliters)

4. What is the frequency of the sample collection (e.g., one time only, twice/week)?
1 time at time of enrollment.

7. Existing HBM
Will <u>existing</u> HBM (i.e., in a tissue bank or stored in a freezer at the time of this IRB application) be collected?
No

CHARACTERISTICS OF THE SUBJECT POPULATION

8. Accrual
A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g. UNMC, Nebraska Medicine, CHMC, UNO)?
Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?
35

2. What is the statistical or other justification for the total number of subjects described above?
A study sample size of 30 is sufficient to evaluate feasibility of concept. We are requesting approval for a sample size of 35 subjects but will stop enrollment after 30 participants have completed the full enrollment procedures to account for possible screening failures or withdraws.

3. How long do you estimate it will take to accrue the required number of subjects?
Approximately 6 months

9. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?
Yes

Provide justification.
Only pregnant females will be enrolled in this study

10. Age Range of Subjects
A. Will adults be enrolled?
Yes

1. What is the age range of the adult subjects?
19 years or older

2. What is the rationale for selecting this age range?
Age of consent in NE

B. Will children (18 years of age or younger) be included in this research?
No

1. What is the justification for excluding children from participating in this research?
Research is irrelevant to children (e.g. disease or condition rarely encountered in children).
Knowledge being sought in the research is already available for children or will be obtained from another ongoing study.
♦ A separate study in children is warranted and preferable.
Insufficient data are available in adults to judge the potential risk in children.
Other. Explain.

11. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

12. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
Critically ill patients
Students of the investigator
Employees of the investigator
Educationally disadvantaged individuals
Socially or economically disadvantaged individuals
Individuals with a stigmatizing illness or condition
Individuals from a marginalized social or ethnic group
Other.
♦ No vulnerable subjects will be specifically recruited

13. Inclusion Criteria
What are the specific inclusion criteria?
19 years or older
Confirmed pregnancy status via urine, serum, or imaging testing
Patient of Nebraska Medicine OB/GYN clinic

14. Exclusion Criteria
What are the specific exclusion criteria?
If does not meet inclusion criteria
Males

15. Pregnancy and Contraception Requirements
A. Are women of child bearing potential (WOCBP) included in this research?
Yes

B. Are pregnant women included in this research?
Yes

C. Are breast feeding women included in this research?
Yes

1) Provide justification for the inclusion or exclusion of breast feeding women.
Study interventions has no risk to breast feeding individuals

METHODS AND PROCEDURES

16. Methods and Procedures Applied to Human Subjects

A. Describe the laboratory tests that will be done on the HBM.

The participants will have their peripheral blood (1-2 drops) collected using a one-time use lancet (Brand: CardinalHealth). Their peripheral blood will be inserted into a POC pregnancy test cartridge (Brand: QuPID Plus) then diluted with 1-2 drops of sterile saline. The results is interpreted within 5-10 mins.

B. Who will perform the testing?

The study investigators

C. Where will the testing be performed?

At the Nebraska Medicine OB/GYN clinic

D. Does the study involve the use of surveys, questionnaires or focus groups?

No

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).

Description analysis will be used to evaluate the study results

F. Does this research involve genetic testing including Genome Wide Association Studies (GWAS), Whole Genome Sequencing (WGS) or Whole Exome Sequencing (WES) ?

No

G. Does this study involve the creation of a tissue bank for future unspecified research? This includes un-used (excess) blood, urine, or tissue, obtained for clinical indication or for research, or additional human biological material collected specifically for future research.

No

DRUGS, BIOLOGIC DRUGS AND DEVICES

17. Devices

1. Does this research involve a medical device(s) (including an in vitro device [IVD] (assay), and medical software)?

Yes

A. Check all that apply:

FDA approved (or cleared) device
FDA unapproved device
♦ In Vitro Device (IVD)

Option chosen: In Vitro Device (IVD)
1. Is the IVD 1) in the laboratory research phase of development, 2) not represented as an effective in vitro diagnostic product and 3) labeled with: "For Research Use Only. Not for use in diagnostic procedures."
No

Option chosen: In Vitro Device (IVD)
a. Is the IVD being shipped or delivered for product testing prior to full commercial marketing and labeled with "For Investigational Use Only. The performance characteristics of this product have not been established."
No

Option chosen: In Vitro Device (IVD)
2. Is the IVD being used in a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?
Yes

Option chosen: In Vitro Device (IVD)
a. Does the IVD have an IDE?
No

Option chosen: In Vitro Device (IVD)
3. Is the IVD (a) invasive, or does it (b) require an invasive sampling procedure that presents significant risk; or does it (c) by design or intention introduce energy into a subject?
No

CONFIDENTIALITY AND PRIVACY

18. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
Box@unmc.edu (secure UNMC or UNO designated cloud-based storage site)
♦ Microsoft Office 365 application (including SharePoint, OneDrive for Business, Teams or Streams) (UNMC, UNO or NU system instance) (secure UNMC or UNO designated cloud-based storage site)

Other secure UNMC or UNO designated cloud-based storage site - describe:
OnCor Clinical Trial Management System (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
CCORDA database (biostatistics) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
RITO-hosted databases (for example, REDCap, CV-QOR, Onchem Trials, XNAT) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
Nebraska Medicine PACS (for image files) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
Other secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO - describe:
On an NSRI or designated high security .gov storage site
On a VA-approved storage vehicle for a VA-approved study
On a remote secure server and/or database maintained by the sponsor accessible through the internet
On a secure server and/or database hosted and maintained by another institution accessible through the internet
On a device or mobile application provided by the sponsor to upload data to a coordinating center or central database
On a device or mobile application being developed by a sponsor or by a UNMC, CHMC or UNO investigator
On a device or mobile application that connects to the internet through UNMC or NM network (wired or wireless)
On an encrypted, password protected portable computer, or flash drive
Other - describe:
In hard copy (other than signed Consent Forms)

B. Will health information about the subject be obtained/provided for use in this research?
Yes

1. What is the specific information?
The participant's pregnancy test results via urine, serum, or imaging results will be collected as a control variable. This data will be deidentified to the participant.

2. How will the information be obtained?
♦ Medical record
Provided by a third party honest broker not involved with the research nor listed in section I of this application.
Other Explain

Option chosen: Medical record
a. Who will obtain the information from the medical record?
Study PIs

Option chosen: Medical record
b. How do they have ethical access to the medical record?
Dr. Melissa Mathes is a physician practicing at the Nebraska Medicine OB/GYN and has ethical access to the clinic's patient EMR. Enrolled participants will have approved a one time access of their EMR.

C. Will the HBM be coded with a unique identifier?
Yes

a. Where will the key (that links the unique subject identification code to the subject's name or other identifier) be stored?
The HBM is used once for the POC test and then discarded. The results of the POC test and most recent hCG will be recorded using a chronological study number based on order of enrollment. A key will not be recored. The study number will not be linked back to the specific participant.

b. Does the code number include the subject's initials or other subject identifier as part of the code?
No

c. Do any of the research personnel listed in section I of this application have access to the key linking the code number to the subject identifiers?
No

D. Will specific identifiers (e.g., ANY DATES, medical record numbers, email addresses etc) be recorded and linked with the HBM?
Yes

1. List the identifiers (ie., dates, medical record numbers) being provided with the HBM, recorded or indirectly associated by use of a coding system.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
Postal address information: street address, city, county, precinct, ZIP code
Telephone numbers
Fax numbers

Electronic mail addresses
Social Security numbers
♦ Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice print
Full face photographic images [and any comparable images]
No identifiers

2. What is the justification for recording the specific subject identifiers listed above? Check all that apply.
Schedule appointments
Collect continuous clinical information from the medical records
Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
Compensation
♦ Other. Explain. On consent form

3. How long will the subject identifiers be maintained in association with the research data?
Consent forms will be securely stored in the Emergency Medicine research office for 7 years then securely disposed

4. Will research data that contain subject identifiers be disclosed to:
a. Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

b. Investigators outside of UNMC, NM, UNO or CHMC?
No

c. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization or entity (e.g., NCI cooperative groups)?
No

E. How will the research data be archived or destroyed when the data is no longer required?
Consents forms will be securely stored for 7 years and then destroyed.
The deidentified control result, POC, and beta-hCG test results will be stored on an UNMC secure server

F. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

G. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future research that is not related to this study?
No

RISK/BENEFIT ASSESSMENT

19. Potential Risks
What are the potential risks associated with research?
- Potential pain to the collection site
- Potential for continued bleeding
- Potential for collection site infection
- Potential for loss of confidentiality

20. Risk Classification
What is the overall risk classification of the research?
♦ Minimal risk
Greater than minimal risk

21. Minimization of Risk
A. Describe how the risks of the research will be minimized.
The specimen collection will be performed by a trained medical professional (study PI/SI).
The specimen collection site will be cleansed and sterilized following standard peripheral blood collection procedures.

All study records will securely stored within the locked research office of the dept of EM or on UNMC secure servers. Only the study PIs will have access to the study records.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis.
Data and safety plan analysis will be performed by study PI at the conclusion of study enrollment.

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
Study audit will be performed by study PI at the conclusion of study enrollment.

D. Describe the specific subject withdrawal criteria.
Subjects can withdraw from the study at any time via written or verbal request. If study withdraw occurs after their control, experimental, and beta-hCG results have been recorded, because it is deidentified, it can still be used in the study analysis.

E. Describe the stopping rules for the research (ie, the specific criteria for halting or early termination of the study.
No early termination rule

F. Describe plans and resources available to promptly address any subject injury.
Any study related injuries will be reported to the participants' treating provider. If additional treatment is required, participants will be transported to the Nebraska Medicine ER.

22. Potential Benefits to the Subject
A. Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?
No

23. Potential Benefits to Society
Describe the potential benefits to society that may reasonably be expected to result from this research.
Data from this study may inform future plans for a larger scale research study to further validate the use of peripheral serum for POC pregnancy testing.

FINANCIAL OBLIGATIONS AND COMPENSATION

25. Financial Obligations of the Subject

A. Who will pay for research procedures, evaluations and tests? Check all that apply.
Sponsor
Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
♦ Department/Section funds
Other. Explain

B. Will any of these procedures, evaluations and tests will be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
No

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
No

26. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
No

PRIOR REVIEW

27. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
No

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and not granted approval?
No

SUBJECT IDENTIFICATION & RECRUITMENT

28. Method of Subject Identification and Recruitment
A. Will prospective subjects learn about the research and then contact the investigator about participation (for example, in response to a print, electronic, radio or television advertisement; referral by a clinician or other specifically for this research)?
No

B. Will the investigator make the initial contact with the potential subject to tell him/her about the research (for example, by contacting existing or past previous patients or research participants; or by contacting prospective subjects thru school records, or thru support groups or other Interest Groups; or thru use of the Hospital Opt-In Database)?
Yes

1. How will prospective subjects be identified?
Prospective subjects will be first identified by their primary care team during their clinic visit. The primary care team to inquire about the subjects' interest in discussing the research opportunity. Once approved by the primary care team, a research personnel will approach to discuss the research opportunity.

2. Will potential subjects be screened for eligibility prior to informed consent?
No

3. How will potential subjects be approached and invited to participate?
Prospective subjects will be first identified by their primary care team during their clinic visit. The primary care team to inquire about the subjects' interest in discussing the research opportunity. Once approved by the primary care team, a research personnel will approach to discuss the research opportunity.

a. Describe the process of initial contact
Prospective subjects will be first identified by their primary care team during their clinic visit. The primary care team to inquire about the subjects' interest in discussing the research opportunity. Once approved by the primary care team, a research personnel will approach to discuss the research opportunity.

b. Who will make the initial contact?
The patient's primary OB/GYN provider

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
OB/GYN faculty are practicing providers at the NM OB/GYN clinic and has ethical access to their patient infomration.

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?

Yes

i. Provide the NCT#.
NCT06747598

ii. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

29. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

30. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
No

32. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
Prospective subjects will be first approached by their primary care team during their clinic visit to inquire about their interest in discussing the research opportunity. Once approved by the primary care team, a research personnel will approach to discuss the research opportunity.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
Consent will be obtained in a quiet and private examination room allowing for an open discussion and Q&A with the study investigator. The participant will be allowed to read the consent form at their own pace or consult family/friends if warranted.

C. Who will be involved in the process of consent and what are their responsibilities?
The research PI, SI, or coordinator(s) will be involved in the consenting process. After receiving approval to apporach the participant, they will explain the study background, purpose, interventions, risk/benefits, and alternative to the participants. They will also ensure full understanding by the participant before consenting.

D. Is there any limitation on the amount of time allotted to the process of consent?
No

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
The consenting process will be conducted in a quiet and private room that is conducive to open discussion and question/answer. Participants will be allowed review all research material at their own pace. Participants will also be allowed to consult family or friends as needed.

F. Will non-English speaking subjects be enrolled in this research?
No

Provide justification for exclusion of non-English speaking subjects
There are no direct benefits to study participants at this stage of the research study. A separate larger study will be conducted including non-English speakers if the study concept demonstrates efficacy.

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
Study personnel will ask participants understood all presented study materials along with asking participants to recite the study purpose, procedures, and their alternative options to being in the study.

34. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

REFERENCES

36. Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.
- Fromm, C., Likourezos, A., Haines, L., Khan, A., Williams, J., & Berezow, J. 2012. Substituting whole blood for urine in a bedside pregnancy test. The Journal of Emergency Medicine. 43(3). 478-482
- Gottlieb, M., Wnek, K., Moskoff, J., Christian, E., & Bailitz, J. 2016. Comparison of result times between urine and whole blood point-of-care- pregnancy testing. Western Journal of Emergency Medicine. 17(4). 449-453.
- Knights, F., Munir, S., Ahmed, H., & Hargreaves, S. 2022. Initial health assessments for

newly arrived migrants, refugees, and asylum seekers. BMJ. 377. 1-8

SECTION III

SUBMISSION DEADLINE

A. FULL BOARD REVIEW:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (i.e., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. EXPEDITED REVIEW:
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

SUBMISSION CHECKLIST

Check all that apply.
Subject recruitment material
Performance site approval for all non-UNMC, TNMC, UNO and CH&MC sites
Grant Application
IRB Review Fee Form for all commercially sponsored research projects.
UNMC Disclosure of Potential Conflict of Interest Form for the Principal Investigator if a financial interest has been declared in Section I.11.
UNMC Disclosure of Potential Conflict of Interest Form for any responsible personnel with a financial interest declared in Section I.11.
Other
♦ No attachments

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)

Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
Investigational Device Review Committee (IDRC) Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
Sponsored Programs Administration (SPA)/UNeHealth grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
Other Review
♦ **None of the above organizational requirements apply to this study**

SECTION IV

COVID-19

Human Subjects Research Safety Plan
For studies involving face-to-face encounters, the research team under the responsibility of the principal investigator will agree to comply with the following safety measures:

1. **Masking of the researcher(s) during a face-to-face encounter**
2. **Cleansing of any surface and/or equipment utilized before and after a subject encounter**
3. **The Biosafety Officer (jenna.mckenzie@unmc.edu) will be notified if obtaining saliva, nasal, sputum or stools samples to ensure safe collection, handling, and processing plan is in place**
4. **Suggest addressing the current health of the subject before commencing face-to-face research via questions below:**
    - **Have you or anyone in your household tested positive or had a fever, chills, cough, shortness of breath, diarrhea, nausea, vomiting, recent loss of taste or smell, tiredness or fatigue, or muscle aches? If yes, the monitor will not be allowed on campus.**
    - **Have you recently traveled to an area with a widespread outbreak or had close contact with a person known to have COVID-19, MERs-CoV or Ebola?**
    - **Have you traveled outside of the country within the past month? If so, where did you travel and when did you return?**
    - **Have you had a recent SARS-COV-2 antibody test or nasal swab and if so when and what were the results?**

♦ I acknowledge this requirement.

ADDENDUM B
Research Involving Pregnant Women, Fetuses and Neonates of Uncertain Viability or Non-Viable

Title of Protocol
Efficacy evaluation of using finger stick peripheral blood for point of care pregnancy testing

Principal Investigator
Nguyen, Thanh Thanh - Emergency Medicine - 402-559-7884 - thang.nguyen@unmc.edu

1. Preclinical Studies and Studies on Non-Pregnant Women [45 CFR 46.204(A)]
A. Will Pregnant women/fetuses be included in the research?
Yes

B. Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted?
No

C. Do these studies provide data for assessing potential risks to pregnant women and fetuses?
No

2. Risks and Benefits to the Pregnant Woman or Fetus which are Associated with the Research [45 CFR 46.204(B)]
A. Is there *any prospect* of direct benefit for the woman or the fetus?
No

1) Describe any risks to the fetus.
No risk to fetus

2) Describe how the research could lead to the development of important biomedical knowledge.
The use of peripheral finger stick serum in POC pregnancy testing can have mutiple benefits to patient care such as 1) eliminating the need to wait for urine when using a POC testing and 2) expediting the pregnacy test result allowing for the appropriate treatment to be render (emergency depts, wilderness medicine, mass casualty/gathering events).

3) Could the research be conducted without involvement of pregnant women?
No

Provide the rationale.
The confirmed pregnancy status is required to conduct this study evaluating the efficacy of using serum on POC pregnancy test.

3. Minimization of Risks to the Pregnant Woman and Fetus [45 CFR 46.204(C)]
A. Describe how the risks to the pregnant woman and fetus are minimized to the greatest extent possible consistent with the objectives of the research.
The peripheral serum specimen is administered by a healthcare professional with experience performing the procedure. All standard practices regarding peripheral finger stick collection with be observed.

4. Pregnancy Termination and Determination of Viability [45 CFR 46.204(H-J)]
A. Will the research involve termination of a pregnancy?
No

5. Consent of the Pregnant Woman and Father [46.204(B), 205(B), 205(C)]
Information Only

	BENEFITS				
RISK TO FETUS		**NONE**	**TO MOTHER ONLY**	**TO MOTHER & FETUS**	**TO FETUS ONLY**
	MINIMAL	**Consent of mother**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***
	GREATER THAN MINIMAL	**Not allowable**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***

***Except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity or the pregnancy resulted from rape or incest.**

6. Research Involving Neonates of Uncertain Viability [45 CFR 46.205]

A. Will the research involve neonates of uncertain viability?
No

7. Research Involvng Nonviable Neonates [45 CFR 46.205(c)]
A. Will the research involve nonviable neonates?
No