UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

RESPONSE: Cover Sheet, Conditional Approval

This document contains no hidden branching or guidance.

For HSD Office Use Only

- ☐ Master Copy
- ☐ IRB Working Copy
- ☐ Researcher Copy
- ☒ **YES**: Conditions of IRB approval have been met (verification)
- ☐ **NO**: Conditions of IRB approval are not met. These materials must be reviewed by the IRB.

Date Received:

RECEIVED
Human Subjects Division
JUL 28 2015
UW

In response to:	
DORA MOD #:	2

Printed name of verifier: Leah M. Miller

Date of verification: AUG 10 2015

Role/position of verifier:

☒ HSD staff person ☐ IRB member (not HSD staff) ☐ Other (specify):

Notes: —

PURPOSE and INSTRUCTIONS

Purpose: *Use this form to respond to an IRB review letter when your application has received* ***Conditional Approval***

Instructions:

1. *Complete this form.*
2. ***Open the IRB review letter in an electronic format, and then write your answers to IRB questions directly under each question. Please change the date to the date of your response, make it clear that the new letter is from the PI to the IRB (or HSD), and clearly mark your responses with italics, widely separated paragraphs or a contrasting font of some kind.***
3. ***Print out the IRB review letter with your answers.***
4. ***Attach those pages to this form.***
6. *If you are submitting changes to the consent and/or recruitment materials at the IRB's request, please include copies in "tracked changes."*
7. *When preparing double-sided copies, each item (e.g. application, consent form, study instruments, etc.) should begin on the front of a new piece of paper.*
8. *Collate all attachments so that you have three complete "application packets."*
9. *Use clips, not staples, on at least one packet, so that the IRB staff may easily distribute your materials to additional IRB reviewers, as needed.*
10. *Submit the original and two copies.*
11. ***Do not include a revised application form or any part of an application form** unless requested.*

If the instructions above are not followed as stated, the Human Subjects Division will not review your form.

1. Research Study Information

IRB Application Number:	IRB Committee:	IRB Review Date:
49248	D	Apr 17, 2015

IRB Application Title:

Project DETECT: Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence

Lead Researcher Name:	Box #:
Joanne Stekler	359931

IRB Contact Name (if other than Lead Researcher):	Phone #:	Email:
Sarah McDougal	744-8887	sjmcd13@uw.edu

END PART ONE

2. List of Attachments

- ☐ Assent form(s)
- ☐ Confidentiality Agreement (*1 copy ONLY*)

- [x] Consent form(s) (*Include 1 'clean' copy and 1 'tracked changes' copy per packet*)
- [ ] Consent materials translated into a language other than English
- [ ] Consent materials: addendum consent, information sheets, oral consent scripts
- [ ] Data collection instruments/forms
- [ ] Data safety and monitoring charter and/or report(s)
- [ ] Data Safety Monitoring Plan (DSMP)
- [ ] Data Use Agreement(s)
- [ ] Embryonic Stem Cell Research Oversight committee (ESCRO) approvals/letters/report
- [ ] Environmental Health and Safety (EHS) approvals/letters/report
- [x] Federal Certificate of Confidentiality
- [ ] GIM 10 Review Letter/Conflict of Interest Management Plan Letter
- [ ] Grant application and title page of grant application (*1 copy ONLY*)
- [ ] Implant and Investigational Device Committee (IIDC) approvals/letters/report
- [ ] Individual Investigator Agreements
- [ ] Institutional Biosafety Committee (IBC) approvals/letters/report
- [ ] Investigator brochure (*1 copy ONLY*)
- [ ] IRB Authorization Agreements
- [ ] Letters of cooperation
- [ ] Literature or abstracts supporting the purpose of your research
- [ ] Material Transfer Agreement(s) (MTA)
- [ ] Oral scripts
- [ ] Other funding documentation, only if you have funding that is not a grant application/proposal
- [ ] Other IRB approval letters/notifications
- [ ] Other IRB approvals
- [ ] Other, specify:
- [ ] Protocol (*1 copy ONLY*)
- [ ] Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- [ ] Radioactive Drug Research Committee (RDRC) approvals/letters/report
- [ ] Recruitment-electronic materials: scripts for emails, and/or copies of web pages
- [ ] Recruitment-oral materials: scripts, radio ads
- [ ] Recruitment-written materials: flyers, brochures, newspaper ads, and/or letters
- [ ] Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
- [ ] SUPPLEMENT: Department of Defense (DOD) Involvement
- [ ] SUPPLEMENT: Department of Justice
- [ ] SUPPLEMENT: Devices
- [ ] SUPPLEMENT: Drugs, Biologics, Botanicals
- [ ] SUPPLEMENT: Genetic Research
- [ ] SUPPLEMENT: GWAS dbGaP
- [ ] SUPPLEMENT: Protected and/or Vulnerable Populations
- [ ] SUPPLEMENT: Waiver Request, Consent Requirements
- [ ] SUPPLEMENT: Waiver Request, HIPAA Authorization

END PART TWO

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

May 4, 2015

Researcher Name:		Joanne Stekler, MD, MPH c/c Sarah McDougal, MPH
Department/Division:		Medicine/Allergy and Infectious Diseases
Box Number:		359931
Re:	Application number:	49248
	Application title:	Project DETECT: Evaluation of New HIV Testing Technologies in Clinical Settings With HIV Incidence
	IRB Review date:	05/01/2015
	Application type:	NEW APPLICATION
	Approval type:	Conditional Approval

Dear Dr. Stekler,

A Subcommittee of Human Subjects IRB Committee D reviewed the conditional approval response for the above-referenced application.

Your application has received CONDITIONAL APPROVAL. This means that you may hire and train study staff, and develop or refine questionnaires, surveys, tests, and/or other similar study materials, but **you may NOT start your research at this time.** The IRB has minor conditions or requests for clarification described on the following pages of this letter, which must be met before you may begin your research.

Please submit your response to this letter on the ***Conditional Approval Response Form***: http://www.washington.edu/research/hsd/docs/321. The form includes submission instructions.

***Three* hard copies** of your *Conditional Approval Response Form* must be received by the Human Subjects Division Office sixty days (60) from the date of this letter. **The IRB will close your new application if your response is not received within sixty (60) days.** Once we have received your *Conditional Approval Response Form* it may be reviewed by a Subcommittee.

Should you have questions concerning this letter, please contact Leah Miller, PhD, Human Subjects Review Administrator, at 206-543-2977 or lemiller@uw.edu or Dolly Morse, Human Subjects Review Coordinator, at 206-616-8042 or dollym@uw.edu. Thank you.

Sincerely,

Dolly Morse, MA
Review Coordinator, IRB Committee D

IRB Conditions of Approval:

1. The application is now conditionally approved with the only condition being the requirement to obtain the Certificate of Confidentiality. Once you have obtained the Certificate of Confidentiality, please submit a copy with your response to this conditional approval.

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

RESPONSE: Cover Sheet, Conditional Approval

This document contains no hidden branching or guidance.

For HSD Office Use Only

- ☐ Master Copy
- ☐ IRB Working Copy
- ☐ Researcher Copy

- ☒ **YES**: Conditions of IRB approval have been met (verification) * See notes
- ☐ **NO**: Conditions of IRB approval are not met. These materials must be reviewed by the IRB.

Date Received:
RECEIVED
Human Subjects Division
APR 28 2015
UW

Printed name of verifier: Dolly Morse

Date of verification: MAY 04 2015

In response to:

DORA MOD #:

Role/position of verifier:

☒ HSD staff person ☐ IRB member (not HSD staff) ☐ Other (specify):

Notes: *verified conditions of approval but still need CoC (condition #6) so application will remain conditionally approved until CoC obtained. See attached letter.

PURPOSE and INSTRUCTIONS

Purpose: *Use this form to respond to an IRB review letter when your application has received* ***Conditional Approval***.

Instructions:

1. *Complete this form.*
2. ***Open the IRB review letter in an electronic format, and then write your answers to IRB questions directly under each question. Please change the date to the date of your response, make it clear that the new letter is from the PI to the IRB (or HSD), and clearly mark your responses with italics, widely separated paragraphs or a contrasting font of some kind.***
3. ***Print out the IRB review letter with your answers.***
4. ***Attach those pages to this form.***
6. *If you are submitting changes to the consent and/or recruitment materials at the IRB's request, please include copies in "tracked changes."*
7. *When preparing double-sided copies, each item (e.g. application, consent form, study instruments, etc.) should begin on the front of a new piece of paper.*
8. *Collate all attachments so that you have three complete "application packets."*
9. *Use clips, not staples, on at least one packet, so that the IRB staff may easily distribute your materials to additional IRB reviewers, as needed.*
10. *Submit the original and two copies.*
11. ***Do not include a revised application form or any part of an application form** unless requested.*

If the instructions above are not followed as stated, the Human Subjects Division will not review your form.

1. Research Study Information

IRB Application Number:	IRB Committee:	IRB Review Date:
49248	D	Apr 17, 2015

IRB Application Title: Project DETECT: Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence

Lead Researcher Name:	Box #:
Joanne Stekler	359931

IRB Contact Name (if other than Lead Researcher):	Phone #:	Email:
Sarah McDougal	744-8887	sjmcd13@uw.edu

END PART ONE

2. List of Attachments

- ☐ Assent form(s)
- ☐ Confidentiality Agreement (*1 copy ONLY*)

- [x] Consent form(s) (*Include 1 'clean' copy and 1 'tracked changes' copy per packet*)
- [ ] Consent materials translated into a language other than English
- [ ] Consent materials: addendum consent, information sheets, oral consent scripts
- [ ] Data collection instruments/forms
- [ ] Data safety and monitoring charter and/or report(s)
- [ ] Data Safety Monitoring Plan (DSMP)
- [ ] Data Use Agreement(s)
- [ ] Embryonic Stem Cell Research Oversight committee (ESCRO) approvals/letters/report
- [ ] Environmental Health and Safety (EHS) approvals/letters/report
- [ ] Federal Certificate of Confidentiality
- [ ] GIM 10 Review Letter/Conflict of Interest Management Plan Letter
- [ ] Grant application and title page of grant application (*1 copy ONLY*)
- [ ] Implant and Investigational Device Committee (IIDC) approvals/letters/report
- [ ] Individual Investigator Agreements
- [ ] Institutional Biosafety Committee (IBC) approvals/letters/report
- [ ] Investigator brochure (*1 copy ONLY*)
- [ ] IRB Authorization Agreements
- [ ] Letters of cooperation
- [ ] Literature or abstracts supporting the purpose of your research
- [ ] Material Transfer Agreement(s) (MTA)
- [x] Oral scripts
- [ ] Other funding documentation, only if you have funding that is not a grant application/proposal
- [ ] Other IRB approval letters/notifications
- [ ] Other IRB approvals
- [ ] Other, specify:
- [x] Protocol (*1 copy ONLY*)
- [ ] Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- [ ] Radioactive Drug Research Committee (RDRC) approvals/letters/report
- [ ] Recruitment-electronic materials: scripts for emails, and/or copies of web pages
- [ ] Recruitment-oral materials: scripts, radio ads
- [ ] Recruitment-written materials: flyers, brochures, newspaper ads, and/or letters
- [ ] Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
- [ ] SUPPLEMENT: Department of Defense (DOD) Involvement
- [ ] SUPPLEMENT: Department of Justice
- [ ] SUPPLEMENT: Devices
- [ ] SUPPLEMENT: Drugs, Biologics, Botanicals
- [ ] SUPPLEMENT: Genetic Research
- [ ] SUPPLEMENT: GWAS dbGaP
- [ ] SUPPLEMENT: Protected and/or Vulnerable Populations
- [ ] SUPPLEMENT: Waiver Request, Consent Requirements
- [ ] SUPPLEMENT: Waiver Request, HIPAA Authorization

END PART TWO

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

April 21, 2015

Researcher Name:		Joanne Stekler, MD, MPH c/c Sarah McDougal, MPH
Department/Division:		Medicine/Allergy and Infectious Diseases
Box Number:		359931
Re:	Application number:	49248
	Application title:	Project DETECT: Evaluation of New HIV Testing Technologies in Clinical Settings With HIV Incidence
	IRB Review date:	04/17/2015
	Application type:	NEW APPLICATION
	Approval type:	Conditional Approval

Dear Dr. Stekler,

Human Subjects IRB D reviewed the above-referenced application.

Your application has received CONDITIONAL APPROVAL. This means that you may hire and train study staff, and develop or refine questionnaires, surveys, tests, and/or other similar study materials, but **you may NOT start your research at this time.** The IRB has minor conditions or requests for clarification described on the following pages of this letter, which must be met before you may begin your research.

Please submit your response to this letter on the ***Conditional Approval Response Form***: http://www.washington.edu/research/hsd/docs/321. The form includes submission instructions.

***Three* hard copies** of your *Conditional Approval Response Form* must be received by the Human Subjects Division Office sixty days (60) from the date of this letter. **The IRB will close your new application if your response is not received within sixty (60) days.** Once we have received your *Conditional Approval Response Form* it may be reviewed by a Subcommittee.

Should you have questions concerning this letter, please contact Leah Miller, PhD, Human Subjects Review Administrator, at 206-543-2977 or lemiller@uw.edu. Thank you for your prompt response.

Sincerely,

Jeff Purcell, Pharm.D.
Chair, IRB Committee D

JP/lmm

Page 2: IRB Conditions of Approval

1. The Committee determined that it is not appropriate to include minor subjects (ages 14-17) in this research since there is no increased benefit for including these subjects and there is concern regarding these subjects experiencing increased risk in the form of anxiety due to discordant test results. Therefore, the Committee does not approve the inclusion of minors in this study. Please confirm your understanding of this item.

2. Please revise the Waiting Room Approach Script Outline to include a confirmation that the potential study participant is 18 years old or older.

3. Please provide revised versions of the information sheets and consent forms which contain the updated language for the RISKS, STRESS, OR DISCOMFORT section, as provided in item #7 of your deferral response.

4. Thank you for confirming that the activities described in this application do not meet the FDA's definition of research and therefore the study is not subject to the FDA regulations (deferral letter item #11). Since this study is not FDA regulated, please remove the following statement from the PROTECTION OF RESEARCH INFORMATION section in all information sheets and consent forms:

   > The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

5. Please note that the card that will be provided for Part 2 - Group 2 participants to receive study results must be submitted to our office for review prior to use with subjects.

6. The IRB noted that the study team is in the process of obtaining a Certificate of Confidentiality for this study. As a reminder, subjects cannot be recruited or consented until the UW IRB has received and acknowledged the Certificate of Confidentiality granted by the federal agency. Please confirm your understanding of this item.