Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT)

Attachment 12: DETECT IRB Approval

dentification of Dehaviors; and Chinical Fredictors
of Early NIV Infection
(Frotect DWFECT)

Attachment 12: DETECT IRB 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.

L. I v. famou	For HSD Office Use Only		Date Received:			
aster Copy	YES: Conditions of IRB approval		RECEIVED Human Subjects Division			
B Working Copy	ter Copy have been met (verification) Working Copy				2 to operation Commission of C	
esearcher Copy		NO: Conditions of IRB approval are not met. These materials must be reviewed by the IRB.			JUL 28 2015	
d name Leah M. Miller		Date of verification: AUG	1 0 2015	In response to:	γ	
position of verifier.			A CARLES	DORA MOD #:	a	
SD staff person	not HSD staff)	Other (specify):				
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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)
- П	Embryonic Stem Cell Research Oversight committee (ESCRO) approvals/letters/report
	Environmental Health and Safety (EHS) approvals/letters/report
	Federal Certificate of Confidentiality
T	GIM 10 Review Letter/Conflict of Interest Management Plan Letter
i i i	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: Approval type: NEW APPLICATION 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 <u>Conditional Approval Response Form</u>: 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:

 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.

Dr. Stekler Application #: 44948 Coordinator, at 208-818-8082 or deliamidianically

UNIVERSITY of WASHINGTON

HUMAN SUBJECTS DIVISION

Box 359470 Seattle, WA 98195-9470 Phone: 206-543-0098 Fax: 208-543-9218

RESPONSE: Cover Sheet, Conditional Approval

	For H	SD Office Use Only			Received:
Master Copy	YES: Condition have been m	ons of IRB approval et (verification)	a sastec	HECEIVED Human Subjects Division	
RB Working Copy	NO: Condition	have been met (verification) * See noteS			2 8 2015
Researcher Copy			y the IRB.	land control to the same of	
ted name erifier:	Dolly Morse	Date of verification: MAY	0 4 2015	In response to:	JW
position of verifier.			C * S* C * C * C * C * C * C * C * C * C	DORA MOD #:	
ISD staff person [IRB member (not HSD staff)	Other (specify):	e of Lizzand Section 7.		
Purpose: Use this form Instructions; 1. Complete this fit 2. Open the IRB change the da responses wit 3. Print out the If	to respond to an IRB review letter when form. review letter in an electronic format, the to the date of your response, make hitalics, widely separated paragraph RB review letter with your answers.	anyour application has received and then write your answers to clear that the new letter	ed <u>Conditional Appr</u> rs to IRB questions r is from the PI to th	oval. directly under each	question. Pleas
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. 0	Data Use Agreement(s)
	Embryonic Stem Cell Research Oversight committee (ESCRO) approvals/letters/report
	Environmental Health and Safety (EHS) approvals/letters/report
	The state of the s
	GIM 10 Review Letter/Conflict of Interest Management Plan Letter
	Grant application and title page of grant application (1 copy ONLY)
1 1	A CAMPAN TO A PARK AND THE AND
	Individual Investigator Agreements
	Institutional Biosafety Committee (IBC) approvals/letters/report
T T	Investigator brochure (1 copy ONLY)
Ä	IRB Authorization Agreements
	Letters of cooperation
	Literature or abstracts supporting the purpose of your research
i ii	Material Transfer Agreement(s) (MTA)
	Oral scripts
i ii	Other funding documentation, only if you have funding that is not a grant application/proposal
i i	Other IRB approval letters/notifications
T T	Other IRB approvals
П	Other, specify:
	Protocol (1 copy ONLY)
	Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- H	Radioactive Drug Research Committee (RDRC) approvals/letters/report
片	Recruitment-electronic materials: scripts for emails, and/or copies of web pages Recruitment-oral materials: scripts, radio ads
. 片	Recruitment-written materials: flyers, brochures, newspaper ads, and/or letters
	Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
님	SUPPLEMENT: Department of Defense (DOD) Involvement
H	
	SUPPLEMENT: Department of Justice SUPPLEMENT: Devices
- H	
<u>H</u>	SUPPLEMENT: Drugs, Biologics, Botanicals
H	SUPPLEMENT: Genetic Research
- H	SUPPLEMENT: GWAS dbGaP
и. Ц.	SUPPLEMENT: Protected and/or Vulnerable Populations
- H	SUPPLEMENT: Waiver Request, Consent Requirements
لا ا	SUPPLEMENT: Waiver Request, HIPAA Authorization
END PART TWO	district on the state of the st

Document #321 - Version #3.6 - Date 04/24/2015

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.

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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/Imm

Page 2: IRB Conditions of Approval

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

- 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.

Dr. Stekler Application #: 49248