# 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	Date Received:
Master Copy	YES: Conditions of IRB approval have been met (verification)	RECEIVED Human Subjects Division
] IRB Working Copy	NO: Conditions of IRB approval are not r	
Researcher Copy	These materials must be reviewed by the	
rinted name Leah M. Miller	Date of verification: AUG 1 0	2015 In response to:
ole/position of verifier:		DORA MOD #:
HSD staff person 🔲 IRB memb	er (not HSD staff)	
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	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
ili	Environmental Health and Safety (EHS) approvals/letters/report
$\overline{\boxtimes}$	Federal Certificate of Confidentiality
T.	GIM 10 Review Letter/Conflict of Interest Management Plan Letter
П	Grant application and title page of grant application (1 copy ONLY)
$\bar{\Pi}$	Implant and Investigational Device Committee (IIDC) approvals/letters/report
Ē	Individual Investigator Agreements
Ē	Institutional Biosafety Committee (IBC) approvals/letters/report
Ē	Investigator brochure (1 copy ONLY)
Π	IRB Authorization Agreements
П	Letters of cooperation
Π	Literature or abstracts supporting the purpose of your research
H	Material Transfer Agreement(s) (MTA)
H	Oral scripts
П	Other funding documentation, only if you have funding that is not a grant application/proposal
F	Other IRB approval letters/notifications
Ä	Other IRB approvals
П	Other, specify:
	Protocol (1 copy ONLY)
, . 片	Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- H	Radioactive Drug Research Committee (RDRC) approvals/letters/report
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님	Recruitment-electronic materials: scripts for emails, and/or copies of web pages
	Recruitment-oral materials: scripts, radio ads
님	Recruitment-written materials: flyers, brochures, newspaper ads, and/or letters
片	Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
느님	SUPPLEMENT: Department of Defense (DOD) Involvement
片	SUPPLEMENT: Department of Justice
<u>H</u> .	SUPPLEMENT: Devices
- H	SUPPLEMENT: Drugs, Biologics, Botanicals
	SUPPLEMENT: Genetic Research
	SUPPLEMENT: GWAS dbGaP
<u>H</u> .	SUPPLEMENT: Protected and/or Vulnerable Populations
님	SUPPLEMENT: Waiver Request, Consent Requirements
	SUPPLEMENT: Waiver Request, HIPAA Authorization
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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 <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 <a href="mailto:lemmiller@uw.edu">lemiller@uw.edu</a> 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.

Box 359470

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

# **RESPONSE:** Cover Sheet, **Conditional Approval**

		For HSD Office Use Only		Date Received:
_ n to working copy		YES: Conditions of IRB approval have been met (verification) ** See note S  NO: Conditions of IRB approval are not met. These materials must be reviewed by the IRB.		HECEIVED Human Subjects Division
				Supplects Division
				APR 28 2015
inted name verifier:	Dolly Mors	e Date of verification: MAY	0 4 2015	In response to:
ple/position of veri	fier:			DORA MOD #:
HSD staff perso	n 🔲 IRB member (not HSD s	staff)   Other (specify):		
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	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)
$\boxtimes$	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:
$\boxtimes$	Protocol (1 copy ONLY)
음·-	Radiation Safety Applications or Radiation Safety Approval Letters (RS)
: F	Radioactive Drug Research Committee (RDRC) approvals/letters/report
4/4/4/18 <b>:</b>	Recruitment-electronic materials: scripts for emails, and/or copies of web pages
#### <b>F</b>	Recruitment-oral materials: scripts, radio ads
Haran Ar	Recruitment-written materials: flyers, brochures, newspaper ads, and/or letters
Harrier H	Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
H H	SUPPLEMENT: Department of Defense (DOD) Involvement
T	SUPPLEMENT: Department of Justice
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i i	SUPPLEMENT: Drugs, Biologics, Botanicals
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ā ā	SUPPLEMENT: Protected and/or Vulnerable Populations
	SUPPLEMENT: Waiver Request, Consent Requirements
i i i	SUPPLEMENT: Waiver Request, HIPAA Authorization
END PART TWO	

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

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#### 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.
- 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.

Dr. Stekler Application #: 49248