

October 7, 2014

FROM: Schulman Associates IRB, Inc. ("Schulman")
TO: C. Alan Lyles, M.P.H., Sc.D
SUBJECT: IRB Exemption Determination
PROJECT: Tracking Health Care Reform and its Impact on Patients with Primary Immunodeficiency Disease

The following protocol items were reviewed:

- Request for Exempt Determination

Schuman has reviewed the request for IRB exempt determination. Based on the information provided, it has been determined that the research meets the following criteria and is therefore exempt from IRB review and approval:

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. [45 CFR 46.101(b)(2)]

Any planned changes that would impact the criteria in which the exemption determination was made, requires submission by the investigator to the IRB to ensure that the research remains exempt from IRB review and approval.

Schulman Associates IRB, Inc. is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

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November 30, 2015

FROM: Schulman IRB, Inc. ("Schulman")
TO: C. Alan Lyles, M.P.H., Sc.D
SUBJECT: IRB Exemption Determination
PROJECT: Tracking Health Care Reform and its Impact on Patients with Primary Immunodeficiency Disease

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PLEASE REFERENCE IRB # 201505679 ON ALL CORRESPONDENCE FOR THIS STUDY

November 18, 2016

FROM: Schulman IRB, Inc. ("Schulman")
TO: Christopher Scalchunes, MPA
SUBJECT: IRB Exemption Determination
PROJECT: Tracking Health Care Reform and its Impact on Patients with Primary Immunodeficiency Disease (2016)

The following items were reviewed:

- **Request for Exempt Determination**

Schulman has reviewed the request for IRB exempt determination. Based on the information provided, it has been determined that the research meets the following criteria and is therefore exempt from IRB review and approval:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. [45 CFR 46.101(b)(2)]

Any planned changes that would impact the criteria in which the exemption determination was made, requires submission by the investigator to the IRB to ensure that the research remains exempt from IRB review and approval.

This project is not subject to requirements for continuing review.

Schulman IRB, Inc. is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

PLEASE REFERENCE IRB # 201607318 ON ALL CORRESPONDENCE FOR THIS STUDY