

Attachment A4 IRB Approval Letter

Process Evaluation of the NIH Roadmap Epigenomics Program

National Institute on Drug Abuse

Contract No. HHSN271201000496P (GSA:GS-10F-0381L)

May 2011



April 7, 2011

Susan J. Griffey PhD
Social & Scientific Systems, Inc
8757 Georgia Avenue 12th Floor
Silver Spring, MD 20910

**Re: Protocol #: Principal Investigator Survey for the Process Evaluation of the NIH Roadmap
Epigenomics Program including Principal Investigator survey instrument
IRB Tracking #: SSS1-11-110**

Dear Dr. Griffey,

As your IRB of record for the above referenced study, the Copernicus Group IRB board has reviewed your submission information. Enclosed is your approval notice. Be sure to carefully maintain the original documents so that copies may be made when necessary. As Principal Investigator, you agree to uphold your responsibility to protect the rights and welfare of your subject at all times while adhering to all applicable federal regulations governing the conduct of clinical research trials.

Copernicus Group IRB reserves the right to visit your research site at any time with appropriate prior notice.

We are also enclosing a Copernicus Group IRB Investigator Guidebook that details the IRB's expectations, procedures and contact information. Please carefully read this Guidebook and have your study staff do the same. CGIRB forms and additional information regarding the conduct of clinical trials are available on our web site: www.cgirb.com.

If you have any questions regarding the contents of this letter or your working relationship with Copernicus Group IRB, please do not hesitate to call us at 1-888-303-2224 or email us at irb@cgirb.com. To avoid delay in locating your records we ask that you refer to the IRB Tracking number located in the header of this letter.

We look forward to working with you.

Copernicus Group IRB

cc: Tracy Berry, Social And Scientific Systems (Web Portal)

Copernicus Group IRB
One Triangle Drive Suite 100
P.O. Box 110605
Research Triangle Park, NC 27709

Experience and Innovation in Ethical Review™

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IRB APPROVAL DATED:
April 7, 2011
EXPIRATION DATE: April 5, 2012

Investigator: Susan J. Griffey PhD
Approval Includes:
Protocol dated March 20, 2011
Data Sources and Evaluation Questionnaire
Principal Investigator

Investigator Address: Susan J. Griffey PhD

Social & Scientific Systems, Inc
8757 Georgia Avenue 12th Floor
Silver Spring, MD 20910

Sponsor: Social & Scientific Systems

Protocol Title: Principal Investigator Survey for the Process Evaluation of the NIH Roadmap Epigenomics Program including Principal Investigator survey instrument

Approval is granted subject to the following considerations:

- Responsibilities of the Principal Investigator as found in the Investigator Guidebook
- In the event that non-English speaking subjects are recruited, a certified translation of the informed consent must be approved by the IRB before recruitment.
- If subjects who cannot read are recruited, there should be an impartial witness to attest to the adequacy of the consent process and to the subject's voluntary agreement to be in the study. This witness should also verify the subject's signature or mark on the consent form.
- Please note that if revisions are required for any approved item (particularly advertisements), they must be approved prior to use.
- If CGIRB has requested changes to your recruitment material, please forward a clean copy of the recruitment material, incorporating the changes noted. If the recruitment material is audio/visual, please provide an electronic copy via one of the following methods, email, CD or DVD for our files.
- If pediatric subjects are to be enrolled then they should be re-consented when they become of legal age.
- Please note that CGIRB requires the reporting of any unanticipated problems involving risks to subjects or others as soon as possible, but in all cases within 10 business days in accordance with the applicable regulatory standards and CGIRB requirements.

IF YOU HAVE ANY QUESTIONS, CALL COPERNICUS GROUP IRB AT 1-888-303-2224

This signature certifies that the information contained in this IRB Approval Notice is true and correct as verified by the minutes and records of The Copernicus Group, Inc. It also certifies that The Copernicus Group, Inc. is in full compliance with FDA Code of Federal Regulations (21 CFR Parts 50, 56, 312, and 812 and 45 CFR) and ICH Guidelines.

Signature See appended electronic signature page IRB TRACKING # SSS1-11-110


Authorized Signature

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	Signature Page	
	Title	SSS1-11-110_Griffey_Susan_J_Approvals_2011-04-07
	Summary	Griffey Susan J.

Signed By:	Reason:	Date/Time:
Rebecca Battista	Authorized Signature	April 7, 2011 2:56:59 PM EDT