6958

CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):
Susan J. Persky, Ph.D., NHGRI, 301-443-0098, 31 CENTER DR RM B1B36BETHESDA MD 20892, perskys@mail.nih.gov

PROTOCOL TITLE:
Patient Perspectives and Simulated Clinical Interactions

ABBREVIATED TITLE (30 characters or less):

PROPOSED START DATE: 5/1/2013 END DATE: 5/1/2016 TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 1200

MULTI-SITE COLLABORATION:
Is this a multi-site collaboration? ☐ Yes (complete this section) ☒ No
Will subjects participate on the protocol at the NIH CC? ☐ Yes ☐ No
Will subjects participate on the protocol at other sites? ☐ Yes ☐ No
If yes, are the sites ☐ Domestic ☐ Foreign ☐ Both
Is NIH the coordinating site?
☐ Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☐ No. Coordinating Site is_____

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None ☐ Asian
☒ Male ☐ Black or African American
☐ Female ☐ White
☒ Children <18 ☐ Hispanic or Latino
☐ American Indian/ Alaskan Native ☐ Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:
Minimum Age Permitted 18
Maximum Age Permitted 50
Pediatric ☒ None ☐ <2 Yr. ☐ 2-6 Yrs. ☐ 7-17 Yrs.
Protocol involves healthy volunteers? ☒ Yes ☐ No
Are Healthy Volunteers NIH Employees? ☒ Yes ☐ No
Does the protocol permit self referral? ☒ Yes ☐ No
Will the protocol involve adults unable to give informed consent? ☐ Yes ☒ No

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History – Disease Progression/ Physiology
☒ Natural History – Sample/Data Collection or Analysis (Recruiting Patients)
☐ Natural History – Sample/Data Collection or Analysis (Not Recruiting Patients)
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? ☐ Yes ☐ No ☒ N/A

KEY WORDS (Words or phrase that describe the protocol.)
1. Body weight
2. Virtual Reality Technology
3.
4.
5.

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
☒ None ☐ Medically indicated ☐ Research indicated*
*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.
FDA No. _____.
IND/IDE Name: _____.
Sponsor: _____.
Who is the manufacturer of the above entity: _____

Does the protocol involve a Tech Transfer Agreement? ☐ Yes ☒ No

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☐ Yes (Append a statement of disclosure)
☒ No

Has the NIH IRP COI Guide been distributed to NIH Investigators?
☒ Yes ☐ No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators?
☐ Yes ☐ No ☒ N/A

CONFLICTS OF INTEREST REVIEW:
Date submitted to IC DEC: 3/11/2013 Date cleared by IC DEC: 4/3/2013

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? ☐Yes ☒No
Name of Adjunct PI: _____

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:
Cynthia J Tifft, M.D., Ph.D., NHGRI/OCD, ...(See page 3)

LEAD ASSOCIATE INVESTIGATOR – Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☐ _____

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☐ Peter Hanna, NHGRI/SB

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.
1. ☐ Stephanie Browning, NHGRI, browningsn@mail.nih.gov
2. ☒ Rebecca Ferrer, Ph.D., NCI, 301-594-0437,...(See page 3)
3. ☐ Peter Hanna, NHGRI/SB
4. ☒ William Klein, M.D., NCI/AB, 301-435-6816, 6130 ...(See page 3)
5. ☐

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE	Susan J. Persky Principal Investigator	Susan J. Persky, Ph.D. Print/Type Name	Date e-Signed on 3/11/13 10:17 AM	Send to Accountable Investigator
RECOMMENDATION	Susan J. Persky Accountable Investigator	Susan J. Persky, Ph.D. Print/Type Name	Date e-Signed on 3/11/13 10:17 AM	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Colleen McBride Br. Chief/CC Dept. Head of Acct. Invest.	Colleen McBride, Ph.D. Print/Type Name	Date e-Signed on 3/19/13 7:10 AM	Send to Institute/Center Scientific Review Committee
APPROVALS	Ellen Sidransky For Institute/Center Scientific Review Comm.	Ellen Sidransky, M.D. Print/Type Name	Date e-Signed on 3/7/13 4:59 PM	Send to Clinical Director
	William A. Gahl Clinical Director	William A. Gahl, M.D., Ph.D. Print/Type Name	Date e-Signed on 5/28/13 3:15 PM	Send to Chair, Institutional Review Board
	Sara C Hull Chair, For Institutional Review Board	Sara C Hull, Ph.D. Print/Type Name	Date e-Signed on 6/5/13 9:40 AM Protocol & Consent Approval Completed	Send to Office of Protocol Services, through IRB Protocol Coordinator
PATIENT SAFETY/ RESOURCE REVIEW	Director, Clinical Center	Gallin Print/Type Name	Date 6/26/13	Return to Office of Protocol Services, (10/1S231B)
COMPLETION	Brianna Douglas Protocol Specialist	Date 6/25/13	PROTOCOL NO. T-HG-0093 13-HG-0158	

#852 on PRIA log

NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER Public Health Service

Warren G. Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center

Building 10, Room 1S231B
10 Center Drive, MSC 1192
Bethesda, MD 20892
Telephone: (301) 496-0744

Date: June 25, 2013

To: Susan Persky, Ph.D.
31/B1B54D

From: Bianca Duggins, RHIT, Protocol Specialist
Office of Protocol Services

Subject: Initial Protocol Approval

Title: Patient Perspectives and Simulated Clinical Interactions

Protocol Number: 13-HG-0158

The final patient safety and resource review was conducted by John I. Gallin, M.D., Associate Director for Clinical Research of the National Institutes of Health Clinical Center on 06/21/2013. The Office of Protocol Services has assigned your intramural research protocol, number **13-HG-0158** which will be due for continuing review on **05/08/2014**.

OPS or your IRB Office will notify you 120 days prior to the review. However, Federal regulation and NIH policy require that you report promptly any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to your IRB. In addition, substantive changes in research activities, during the period for which IRB approval has been given, may not be initiated by you without prior review and approval by your IRB, except where necessary to eliminate apparent immediate hazard to subjects.

If you have any questions regarding protocol review, approval or reporting procedures, please contact Victoria Willits, your Protocol Coordinator at (301) 496-1906.

cc: Protocol Coordinator