

IRB Approvals for iCOMPARE

39 Sites are using the University of Pennsylvania IRB for iCOMPARE. They are listed here.

ACGME Program ID Number	Program Name
1400321025	Banner Good Samaritan Medical Center Program (NEW NAME: University of Arizona
1400511046	UCLA Medical Center Program
1400521047	Olive View/UCLA Medical Center Program
1400521068	Stanford University Program
1400821085	Yale - New Haven Medical Center Program
1400831078	University of Connecticut Program
1401121100	Jackson Memorial Hospital/Jackson Health System Program*
1401221105	Emory University Program
1401221502	Morehouse School of Medicine Program
1401621130	Advocate Lutheran General Hospital Program
1401921139	University of Kansas School of Medicine Program
1402311150	Johns Hopkins University/Bayview Medical Center Program
1402311153	Johns Hopkins University Program
1402312156	St. Agnes HealthCare Program
1402321160	University of Maryland Program
1402331152	Greater Baltimore Medical Center Program
1402411181	Baystate Medical Center/Tufts University School of Medicine Program
1402421171	Tufts Medical Center Program
1402421184	University of Massachusetts Program
1402821215	Washington University/B-JH/SLCH Consortium Program
1403021224	University of Nebraska Medical Center College of Medicine Program
1403621320	Duke University Hospital Program
1403621325	Wake Forest University School of Medicine Program
1403811336	Case Western Reserve University (MetroHealth) Program
1403821330	Canton Medical Education Foundation/NEOMED Program
1403821334	University Hospital/University of Cincinnati College of Medicine Program
1403821335	Case Western Reserve University/University Hospitals Case Medical Center Program
1404111362	Geisinger Health System Program
1404111373	Lankenau Medical Center
1404112358	Abington Memorial Hospital Program
1404121374	Drexel University College of Medicine/Hahnemann University Hospital Program
1404121378	Temple University Hospital Program
1404121379	Thomas Jefferson University Program
1404121504	UPMC Medical Education Program
1404311400	Brown University Program
1405121432	Eastern Virginia Medical School Program
1405121433	Virginia Commonwealth University Health System Program
1405131431	Carilion Clinic-Virginia Tech Carilion School of Medicine Program
1405631445	Medical College of Wisconsin Affiliated Hospitals Program

* The execution of an Interagency Agreement for Jackson Memorial Hospital to use the Penn IRB has not yet been completed because of a technical routing issue at the University of Miami. That error was rectified and the executed agreement is expected soon. iCOMPARE is not collecting data from this site.

24 Sites are using their own IRB for iCOMPARE. They are listed here and communications from those IRBs are appended.

ACGME Program ID Number	Program Name
1403311235	Atlantic Health (Morristown) Program (IRB waiver)
1404821422	Baylor College of Medicine Program (Local IRB)
1402421162	Beth Israel Deaconess Medical Center (IRB waiver)
1400511040	Cedars-Sinai Medical Center Program (Local IRB)
1403812339	Cleveland Clinic (Local IRB)
1403021222	Creighton University Program (Local IRB)
1403611323	East Carolina University (Local IRB)
1401021093	George Washington University Program (IRB waiver)
1401011097	Georgetown University Hospital/Washington Hospital Center Program (Local IRB)
1402511189	Henry Ford Hospital/Wayne State University Program (Local IRB)
1402421511	Lahey Clinic Program (Local IRB)
1404111375	Mercy Catholic Medical Center Program (Local IRB)
1402421172 1402411169	Partners (Brigham and Women's Hospital Program and Massachusetts General Hospital Program) (IRB waiver)
1401611126	St. Francis Hospital of Evanston Program (Local IRB)
1404821426	Texas A&M College of Medicine-Scott and White Program*
1404821459	Texas Tech University (Lubbock) Program (Local IRB)
1400721073	University of Colorado (Local IRB)
1403321227	UMDNJ Robert Wood Johnson Medical School (Camden)/Cooper University Hospital Program (Local IRB)
1403621318	University of North Carolina Hospitals Program (IRB waiver)
1404121380	University of Pennsylvania Program (IRB of Record)
1405021429	University of Vermont/Fletcher Allen Health Care Program (Local IRB)
1405421434	University of Washington Program (Local IRB)
1405511440	West Virginia University (Local IRB)

* Final IRB approval by Texas A&M is pending at this writing. iCOMPARE is not collecting data from this site.



Atlantic
Health System

Institutional Review Board

475 South Street
Morristown, NJ 07960
Phone: (973) 660-3128
Fax: (973) 292-7923

Morristown Medical Center
Overlook Medical Center
Newton Medical Center
Chilton Medical Center
Goryeb Children's Hospital

TO: Donna Astiz, MD

PROJECT TITLE: [671957-1] iCompare Study

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS

DECISION DATE: 11/4/14

REVIEW CATEGORY: Exemption category # [1]

The above referenced study has been reviewed and found to be **EXEMPT** from the regulations that govern human subject research.

The research design submitted for review must be strictly adhered to. Any changes must be submitted and reviewed by the IRB.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Atlantic Health System IRB's records.

MEMORANDUM

TO: RICHARD J HAMILL
MEDICINE: RESIDENTS ONLY



FROM: GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

DATE: May 11, 2015

RE: **H-36645 - ICOMPARE STUDY**

Your amendment, detailed below, has been reviewed and approved. NOTE: Approved advertisement(s) should only be posted at the institution(s) where the research is being performed including approved recruitment site (s). This is not applicable to the following advertisement modes: billboards, radio, television, internet, or website.

Description:

The End of Year Survey for residents was changed; the new version is attached. Also attached is a letter that will be sent to residents along with the survey; the letter explains the purpose of the survey and the iCOMPARE Study. The new version of the End of Year Survey is much more extensive and better captures the information that will allow us to critically evaluate the impact of the 2 arms of this duty hour study. The old version of the End of Year Survey for the Residents was deleted.

H-36645 - ICOMPARE STUDY

APPROVAL VALID FROM 4/7/2015 TO 3/10/2016

Dear Dr. HAMILL

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

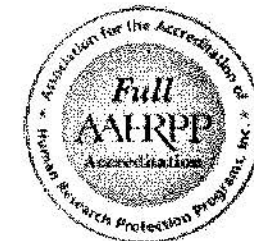
The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,



SHITAL MAHENDRA PATEL, M.D., B.A.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals



**DETERMINATION OF HUMAN SUBJECT RESEARCH**

All protocols involving both "research" or "clinical investigations" and "human subjects" must be reviewed and approved by the IRB before recruitment and data collection may start. The range of activities involving human **participants** at BIDMC comprises patient care, teaching and research; however, not all of these activities constitute human subject research. For example, training, education, quality improvement, and review of case reports are activities in which our faculty and staff are commonly engaged. However, for some activities it might be difficult to tell whether they qualify as human subject research. Furthermore, these activities may become research when an individual decides to take "accidental discoveries" and/or "innovative practices," a step further and engage in a systematic investigation with the intent to contribute to generalizable knowledge.

Please refer to the CCI Policy Manual for further definition of human subject research.
<http://research.bidmc.harvard.edu/OST/CCI/Documents/CCIPolicyManual.doc>

If it unclear whether the activities in question meet the definition of "human subject research," please complete the following questions and return the completed form as a Word document via email to Wendy Chau, CCI Protocol Coordinator at wchau@bidmc.harvard.edu for a determination.

PROVIDE A TITLE OF PROJECT

iCompare: Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education

WHO IS INVOLVED WITH THE PROJECT

Name of individual leading the project: Charles Christopher Smith, MD (BIDMC IM Program Director); Sanjay Desai, MD (Program Director at Johns Hopkins is the PI)		
Department: Medicine		Division: General Medicine
Telephone: 617-632-8269	Pager: 36638	Fax: 627-632-8261
Do you have other "collaborators" working on the project with you? If so, can you identify them at this time? Study is a multicenter trial approved by the ACGME.		

EVALUATION



Provide a brief description (one paragraph) of the purpose or goal of the project, the intent for conducting the project, and the procedures used to accomplish the purpose or goal:

In 2011, the Accreditation Council for Graduate Medical Education (ACGME) limited first year trainees (interns) to 16 hours of continuous duty. The implementation of these standards has raised safety concerns regarding fragmented continuity and increased patient handoffs between physicians, as well as educational concerns for trainees, given the same loss of continuity and the compressed time for learning and direct patient care.

The iCOMPARE study is the first national multicenter trial to address these pressing questions in internal medicine resident education. iCOMPARE is designed as a cluster randomized trial in a sample 59 Internal Medicine (IM) training programs that are randomly assigned to either the current duty hour standards (control programs) or with less restricted flexible duty hour standards (intervention programs). The study will evaluate the extent to which the intervention programs preserve clinical and educational goals. Randomization is at the level of the Internal Medicine (IM) training program. The intervention is technically one year, AY 15-16 (July 2015-June 2016). Pretrial work such as recruitment and collection of baseline data will begin in Winter 2014 and analyses and writing will extend into 2018.

BIDMC will **not** be an intervention site and will not change our current duty hours as part of this study. In discussions with the leaders of the study, because we have very few changes we were willing to make in our duty hours as part of this study, we will be in the control arm. Thus, there will be **no intervention at BIDMC**; however, routine data from our residency program will be used as part of the data analysis.

We will provide the iCompare team with data that are normally collected by the ACGME as part of our routine reporting including duty hour schedules and de-identified resident duty hour adherence data/logs.

Does the project include testing the safety and efficacy of a drug or device in a human subject?

Yes No

Do you intend that the information you learn from the project to be generalizable beyond BIDMC and BIDMC processes and practices? The intent is that the activity is undertaken to contribute to generalizable knowledge, not to provide immediate and continuous improvement and feedback in the local setting. Generalizable knowledge applies beyond a specific time and location.

Yes No

The information we provide will only be our local information; however the study is designed as a multicenter study.

Will you collect data from living individuals through some type of intervention?

Yes No

There will be no intervention at BIDMC; our duty hours will not change. Data collected about our residency program will be routinely reported information and will be used as comparison as part of the control arm.

Will you interact in any way with a living individual?

Yes No

If yes, describe:

There is no direct interaction with the residents. All data collected from residents are data collected as part of our residency expectations as an ACGME approved residency program.

Will you have access to individually identifiable information?

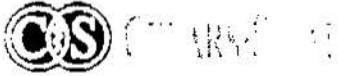
Yes No

If yes, describe:

Data collected on trainees will be obtained via direct survey and through deidentified data sets provided by APDIM (In Training Examination scores) and by ACGME (annual required and standard surveys conducted by ACGME).

Data collected on program directors and IM program faculty will be obtained via direct survey and through deidentified datasets provided by APDIM and ACGME (annual required and standard surveys conducted by APDIM and ACGME).

All program directors will communicate to their trainees that participation in the iCOMPARE surveys will have zero effect on their trainee assignments or evaluations. Additionally, program directors will not know the survey completion status or responses of individual trainees. This is all standard for any ACGME survey of residents.



Office of Research Compliance and Quality Improvement, 8383 Wilshire Blvd. Suite 742, Beverly Hills, CA 90211

CERTIFICATION OF EXEMPTION FROM IRB REVIEW

3/23/2015

To: AMANDA EWING
CC: AMANDA EWING
From: CSMC Office of Research Compliance
Subject: IRB Exemption for Pro00039219

Please note that the Cedars-Sinai Office of Research Compliance has determined that the proposed research referenced below is exempt from the requirements for IRB review and approval in accordance with federal regulations, 45 CFR 46.101(b).

IRB No.: Pro00039219
Study Title: Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education
Exempt Category: Category 1
Category 2
Exemption Date: 3/23/2015
Principal Investigator: AMANDA EWING
Co-Investigators:
Other Study Staff: AMANDA EWING
CSMC Federalwide Assurance No.: FWA 00000468
Funding Information: Internal CSMC Funding /

Below are the documents currently approved for this study:		
Document Type	Name	Version Description
Protocol	<u>iCOMPARE Study Protocol_03.19.2015.docx</u>	

March 30, 2015

Andrei Brateanu, M.D.

RE: IRB# 15-354: EXEMPT: Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education(iCOMPARE)

Dear Dr. Brateanu:

Your response on 3/27/2015 regarding your new study application is acceptable. This study is now **approved** under expedited review on 3/27/2015 as **Exempt Research** for the collection of data in an anonymous manner in which participants will not be identifiable nor linked to a code that could identify them.

Exempt status means that continuing IRB review and approval is not required. Only changes that no longer meet the criteria for exemption listed above will require submission to the IRB.

The PI is responsible to ensure research team members are knowledgeable of the study protocol and appropriately trained.

If you have any questions regarding study changes or modifications, please call the IRB office at 216-444-2924.

Sincerely,

Daniel Beyer, MS, MHA, CIP
Executive Director, IRB and Human Research Protections

DB:jl

This letter is available online under the Correspondence tab

DATE: February 12, 2015
TO: Tammy Wichman, MD
FROM: Creighton University IRB-02 Social Behavioral

PROJECT TITLE: [718335-1]iCOMPARE
REFERENCE #: Exempt (Category #2)
SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: February 12, 2015
EXPIRATION DATE: February 11, 2018

Thank you for your submission of New Project materials for this project. The following items were reviewed in this submission:

- Application Form - 2.9.15 Application for Determination of Exempt Status Educational Research.doc (UPDATED: 02/9/2015)
- Creighton - IRB Application Form - Creighton - IRB Application Form (UPDATED: 02/12/2015)
- Other - Porter e-mail (UPDATED: 02/11/2015)
- Questionnaire/Survey - Residents Survey - End of Year.doc (UPDATED: 02/10/2015)
- Questionnaire/Survey - PD Survey - End of Year.doc (UPDATED: 02/10/2015)

An IRB administrator has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations. All changes to approved research must be submitted to the IRB to access if the project continues to be exempt

If you have any questions, please contact Patsy Nowatzke at 402-280-3586 or nowatzke@creighton.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Creighton University IRB-02 Social Behavioral's records.

East Carolina University

From: [Kraemer, Suzanne](#)
To: [Amanda Bertram](#); [Katz, Joel Thorp, M.D. \(JKATZ@PARTNERS.ORG\)](#)
Subject: FW: Your Exempt study has been approved
Date: Monday, May 18, 2015 1:43:36 PM



ECU IM has been provided approval by our IRB to participate in iCOMPARE.

Suzanne Kraemer, MD, FACP
Program Director Internal Medicine Residency
Brody School of Medicine at East Carolina University
Vidant Medical Center
Greenville, NC

From: umcirb@ecu.edu [mailto:umcirb@ecu.edu]
Sent: Monday, May 18, 2015 9:39 AM
To: Kraemer, Suzanne
Subject: RX: Your Exempt study has been approved

EAST CAROLINA UNIVERSITY

University & Medical Center Institutional Review Board Office

? 4N-70 Brody Medical Sciences Building · Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914**  Fax **252-744-2284**  www.ecu.edu/irb

Notification of Exempt Certification

From: **Social/Behavioral IRB**
To: Suzanne Kraemer
CC:
Date: 5/18/2015
Re: UMCIRB 15-000586
iCOMPARE

I am pleased to inform you that your research submission has been certified as exempt on 5/18/2015. This study is eligible for Exempt Certification under category #2.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

The UMCIRB office will hold your exemption application for a period of five years from the date of this letter. If you wish to continue this protocol beyond this period, you will need to submit an Exemption Certification request at least 30 days before the end of the five year period.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418

IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

—

Study.PI Name:

Study.Co-Investigators:

February 2, 2015

Jillian Catalanotti, MD

Assistant Professor of Medicine and Health Policy

Director, Internal Medicine Residency Program

The George Washington University

Dear Dr. Catalanotti,

Regarding the Determination Worksheet submitted January 30, 2015 for the study entitled, "Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE)," a determination has been made that GWU is not engaged in research related activities. That is, recruitment, consenting, data collection, or identifiable data analysis involving human subjects.

This determination is being made as the GWU Internal Medicine Residency Program will serve as a participant in the study, rather than an investigator. This has been assured by Dr. Jillian Catalanotti, Director of the GWU Internal Medical Residency Program. Residents will be informed of program participation at the beginning of their residencies.

Further review by the GWU IRB is not required.

Should any future projects include the aforementioned research activities that involve human subjects, please contact our office before proceeding.

Best regards,

Cortni Romaine

Cortni Romaine, MS, CIP, CCRC

Education and Outreach Coordinator

Office of Human Research, GWU

cromaine@gwu.edu



MedStar Health
Research Institute

6525 Belcrest Road
Suite 700
Hyattsville, MD 20782
301-560-7300 PHONE
301-560-7348 FAX
medstarresearch.org

Exempt Determination Notice
Initial Review

14-May-2015

Washington Hospital Center
110 Irving St Room 2A-3BA
Washington, DC 20010

Protocol Number: **2015-046**
PI Name: **Christian Woods MD**
Protocol Title: **iCompare**


Dear Christian Woods MD,

The above-referenced **Initial Review** submission was reviewed by the Office of Research Integrity (ORI) on **11-May-2015**.

It has been determined that your study meets the criteria set forth in **[45 CFR 46.101(b), Category (1)1]** and qualifies for exemption from the requirements of **[45 CFR 46]** federal regulations. In the event changes are made to the protocol, which may affect this determination, please submit documentation of this change for review prior to implementation.

Please refer to the Office of Research Integrity website to review the **Principal Investigator's Responsibilities** as a MedStar researcher on <http://www.medstarresearch.org/Body.cfm?id=243>.

If you have any questions, please contact me at 301-560-7339.

rm 

Office of Research Integrity

Enclosure: IRB Stamped Participant Material (PD Email Invitation, Resident Email Invitation, PD Survey & Resident Survey)



RESEARCH ADMINISTRATION

March 20, 2015

Research Administration
CFP Basement 046
2799 West Grand Boulevard
Detroit, MI 48202-2689
(313) 916-2024 Office
(313) 916-2018 Fax

To: Sean Drake, MD
Internal Medicine

Fm: Timothy Roehrs, Ph.D., Chair
Jonathan Ehrman, Ph.D., Vice Chair
Adrian Ormsby, M.D., Vice Chair
Institutional Review Board (IRB)

Re: **Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (IRB No. 9491)**

Period of IRB Approval: **March 20, 2015 – March 19, 2016**

This is to apprise you that the above-named project was reviewed through the expedited procedure on **March 20, 2015**. The human rights aspects of the above-referenced protocol were reviewed and approved. This approval is based on Title 45, Section 46.110 of the HHS Code of Federal Regulations related to no more than minimal risk to the subject. In accordance with the HIPAA Privacy Rule Section 164.512(i), the IRB has determined that the criteria for waiver of patient authorization have been met. The approval of this project will be presented as an informational item at a subsequent IRB meeting.

The Institutional Review Board and Federal Regulations require that each research proposal involving human subjects be reviewed at intervals appropriate to the degree of risk but not less than once per year and that a final report is submitted at the termination of the project. **Therefore, a continuation or final report for this proposal is due in one year. The report must be submitted to and approved by the IRB by March 19, 2016 to avoid a lapse in your approval. As the Principal Investigator, you are ultimately responsible for timely submissions of continuation and final reports. You are encouraged to create a tracking mechanism to ensure timely submissions.**

Revisions to the protocol must be approved by the IRB prior to implementation. In addition, our IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. A copy of the signed and stamped application, indicating approval by the Institutional Review Board, is enclosed for your files.

Forms for progress reports, final reports, modification and adverse/unexpected event are available on the IRB website or in the Research Office (CFP-Bsmt). Please contact the Research Office at 916-2024 if you have questions regarding these matters.

Lahey Hospital Medical Center

INTERNAL NOTICE OF IRB APPROVED CLINICAL RESEARCH PROJECT - OR-5

The DR-5 is a Research Administration internal document notifying investigators that they may begin their research project. This document confirms that all pre-study regulatory, administrative, financial, and/or contractual issues have been resolved and/or completed.

Protocol LCID #: 2015-039

Consent ID: NIA Waiver of Documentation

IRBNet #: 728204

IRB Approval Date: 0610512015

Expiration Date: 0610512016

DR-5 Notification Date: 0611612015

PRINCIPAL INVESTIGATOR: *Elizabeth Nilson, M.D.* DEPARTMENT: *General Internal Medicine*

PROJECT TITLE: **iCOMPARE**

SUB INVESTIGATOR: *None Listed*

STUDY COORDINATOR: *None Listed*

SPONSOR/FUNDING: *Lahey Clinic, Inc. & ACGME*

Checks are to be made payable to: "Lahey Clinic, Inc." and sent to the Office of Research Administration, Lahey Hospital & Medical Center 41 Mall Road, Burlington MA 01805.

The TAX IDENTIFICATION NUMBER for Lahey Clinic, Inc. is: 04-2704683

PEOPLE SOFT PROJECT NUMBER (if applicable): *NIA*

CLINICAL TRIALS ID#(if applicable)www.clinicaltrials.gov: *NIA*

This notice serves as the Office of Research Administration's APPROVAL TO BEGIN this IRB-approved project

This study must be conducted in accordance with the IRB-approved submission and the executed budget and contract. All research must be in compliance with Federal regulations, the policies and procedures of Lahey Clinic, Inc. and the Lahey Clinic, Inc. Institutional Review Board.

RESEARCH SOPs, REGULATORY GUIDANCE, AND IRB SUBMISSION RESOURCES:

- *ECMS: Massnet!ECMS!Libraries!Research Department Manual*
- *Sharepoint: Massnet!Lahey Tools/Lahey Sharepoint Lobby/Search "Research"*
- *www.irbnet.org: Forms and Templates tab: IRBNet instructions, IRB submission forms and references*
- *Research Administration x 8027*

PLEASE NOTE THE FOLLOWING RESEARCH GUIDELINES AND REMINDERS:

1. INFORMED CONSENT: *(IRB-required method of consent is checked below)*

[gJ] Waiver of Documentation of informed consent approved per 45 CFR 46.117(c), however you are required:

Keep a list of the subjects (names, medical record number and date of enrollment) to be submitted with your Annual Continuation Report to the IRB; OR--

[8:1] Keep track of the total number of subjects to be submitted with your Annual Continuation Report to the IRB

Informed consent is a process beginning with a description of the project and assurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant.

1. SUBJECT BILLING/EPIC TASKS:

Insurance carriers or patients cannot be charged for tests, procedures or evaluations that are performed solely for research purposes. Specific procedures must be followed in EPIC for research study patients.

Reminder: In EPIC you must: 1) link yourself to the study, 2) link consented subjects to the study with the appropriate status, 3) ensure all study orders and appointments are assigned the correct research billing and, 4) at least twice weekly, perform a Charge Review to release charges correctly to the research account or insurance.

2. ANNUAL CONTINUATION:

This project requires continuing review by the IRB. You will receive a reminder before the project Expiration Date listed at the top of this form. Updated study-specific Conflict of Interest Disclosures are required from all study personnel at this time.

Reminder: Failure to submit the Annual Continuation Report will result in Administrative Suspension of your project per Federal regulations and the policies of the IRB.

4. FINAL STUDY CLOSURE:

The IRB must be notified when the study is completed by submitting a Final Study Closure Report in IRBNet. Any supporting documents for final data analyses, if available, should be included in the submission.

Reminder: You must first contact the Research Financial Analyst for approval to close a study.

5. RESEARCH CONFLICT OF INTEREST DISCLOSURE:

An updated study-specific COI disclosure is required for each study personnel at the time of annual IRB review. You will receive a reminder with instructions when these are due. Disclosures are reviewed by the Research Compliance Committee who will follow-up on any reported conflicts that require management.

Reminder: Any study personnel added to the study need to complete both a study-specific COI disclosure and complete the Lahey Clinic, Inc. Corporate Compliance Disclosure.

6. ADVERTISING AND MEDIA RELEASES:

Reminder: All advertising, internal or external, and/or media releases must be prior approved by the IRB.

7. AMENDMENTS TO PROTOCOL, CHANGES IN STUDY OR PERSONNEL, PROTOCOL DEVIATIONS OR UNANTICIPATED PROBLEMS:

Reminder: Any change to previously approved study material or personnel must be approved by the IRB prior to initiation of the change; major protocol deviations or unanticipated problems must be promptly reported to the IRB

9. MANUSCRIPTS, ABSTRACTS, PUBLICATIONS OR PRESENTATIONS:

Reminder: These must be reported to the IRB as received or at the time of annual continuation.

10. CITI COURSES:

Reminder: CITI courses must be kept current within 3 years while conducting research. You will receive a reminder if your certification is due for renewal.

11. ELECTRONIC IRB SYSTEM (IRBNet):

Reminder: All IRB submission forms are located, submitted, and reviewed through www.irbnet.org.

12. COMMENTS:


RESEARCH ADMINISTRATION

(o/f)(o/)
Date

cc: 1) Principal Investigator
2) Sub-investigators & Study Staff
3) Department Chairman

When applicable:
1) Laboratory Medicine
2) Diagnostic Molecular Pathology
3) Department of Diagnostic Imaging
4) Radiation Oncology

Research Administration:
1) Quality
2) Protocols
3) Web posting
4) Research Billing
5) CT.gov posting, if applicable


Mercy
Health System
Mercy Health System
Institutional Review Board

March 9, 2015

Eric Green, MD
Mercy Fitzgerald Hospital

Dear Eric:

This is written acknowledgement of the approval regarding your protocol.

- MHS #2015-10 "iCompare".

The protocol was reviewed and approved by Dr. James Roberts, Chairman, IRB and the IRB Board Members. You may start your research immediately.

All members of the MCMC Institutional Review Board have also been sent the Lay Summary and Informed Consent for their review and file.

An annual review of your study will be due on or before January 13, 2016.

Thank you for using the MCMC Institutional Review Board.

Sincerely,



Dianne Palomba
MHS Institutional Review Board Administrator

Cc: James Roberts, MD

From: Katz, Joel Thorp, M.D.
To: Amanda Bertram
Subject: FW: iCOMPARE IRB process
Date: Monday, March 02, 2015 6:23:38 PM

See below. Thanks, Joel

A digital signature block for E. Hohmann MD. It includes a name, a title, an email address (ehohmann@partners.org), a phone number, and a fax number.

From: Hohmann, Elizabeth, M.D.
Sent: Wednesday, January 28, 2015 4:56 PM
To: Katz, Joel Thorp, M.D.
Subject: RE: iCOMPARE IRB process

Hi Joel,

This is not necessary or appropriate. Our staff are subjects not researchers. And your role in the project is **not human subjects research**. We are not required to either provide IRB oversight, nor to authorize another IRB to do this for us. Thanks.

E. Hohmann MD

From: Katz, Joel Thorp, M.D.
Sent: Wednesday, January 28, 2015 4:33 PM
To: Hohmann, Elizabeth, M.D.
Cc: DeOliveira, Maria C.; Vyas, Jatin M., M.D., Ph.D.
Subject: FW: iCOMPARE IRB process

Dear Libby,

Many thanks for your helpful advice on the IRB process relative to the iCOMPARE study participation.

The study investigators are requesting a local IRB signature on the PENN master authorization agreement.

Who would be the most appropriate person to sign this?

Many thanks, Joel

From: Vyas, Jatin M.,M.D.,Ph.D.
To: Amanda Bertram
Subject: FW: iCOMPARE IRB process
Date: Thursday, February 19, 2015 11:22:02 AM

fyi

From: Hohmann, Elizabeth,M.D.
Sent: Thursday, February 05, 2015 3:19 PM
To: Vyas, Jatin M.,M.D.,Ph.D.
Subject: FW: iCOMPARE IRB process

Here is the response. We are subjects not researchers. Libby

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Many thanks, Joel

From: Sanjay Desai

Sent: Friday, January 23, 2015 12:40 PM

To: Aimee Zaas; Benjamin Mitchell Goodman III; Brandenburg, Suzanne; Brian Gable; Charles Schleupner; Charles Smith; Cheryl O'Malley; Cinnamon Bradley; Colleen Christmas; Curtis Mirkes; Darilyn Moyer V.; David Smith; Deb Bynum; Dominick Tammaro; Donna Astiz; Elizabeth Nilson; Eric Green; Eric Warm; Gretchen Diemer; Hal Atkinson; Harris, Mary E.; Harvey Friedman; James O'Dell; Jatin Vyas; Jennifer Bolyard; Jill Patton; Jillian Catalanotti; Jodi Friedman; Joel Katz; Keith Armitage; Kenneth Steinberg; Leigh Eck; Lisa Bellini; Lorenzo Di Francesco; Mark Noah; Mark Pasanen; Mark Siegel; Melvin Blanchard; Michael Frank; Michael McFarlane; Michael Phy; Michael Rosenblum; Paul Foster (pfoster@gbmc.org); Richard Forster; Richard Hamill; Richard Kopelman; Richard Paluzzi; Ronald Witteles; Sal Pindiprolu; Sanjay Desai; Sapna Kuehl; Sean Drake; Shanta Zimmer; Soma Wali; Stephanie Call; Stephen Symes; Steven Angus; Susan Wolfsthal; Suzanne Kraemer; Tammy Wichman; William Surkis

Cc: Alice Sternberg; Amanda Bertram; Judy Shea

Subject: iCOMPARE IRB process

Dear iCOMPARE Program Directors,

We are very excited about your participation in our iCOMPARE study! Now that we have gotten through randomization, **we have to get IRB approval for your institutions.**

There are two ways to obtain IRB approval depending on your institutions preferences:

1. **(preferred)**. Allow the University of Pennsylvania IRB to be the IRB of record. To do this, your IRB will need to sign the attached form entitled "UPenn IRB Authorization Agreement".
2. Submit a new application to your IRB. We have attached documents that should help you complete your application entitled "iCOMPARE Template IRB Text". Once you have submitted your application, please let us know so we can make a note for our records.

Should you have any problems or any questions with your IRB please contact our coordinator, Amanda Bertram (abertra3@jhmi.edu).

To see your program and other programs involved in iCOMPARE please click the following link:
<http://www.jhcct.org/icompare/showassignments.asp>

Many thanks,

The iCOMPARE Study Team

Sanjay V. Desai, MD FACP

Director, Osler Medical Training Program

Vice Chair for Education

Associate Professor
Johns Hopkins School of Medicine Johns
Hopkins Carey School of Business

Ashley Crenshaw

Administrative Coordinator for Sanjay Desai, MD FACP Department of
Medicine

9th floor; 1830 East Monument Street

Baltimore MD 21287

410-955-7963 (phone)

410-955-7910 (Dr. Desai direct line)

410-955-0374 (fax)

acrensh3@jhmi.edu

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Partners Compliance HelpLine at <http://www.partners.org/complianceline> . If the e-mail was sent to you in error but does not contain patient information, please contact the sender and properly dispose of the e-mail.

January 28, 2015

Harvey Friedman, MD, FACP, FACCP
Program Director, Department of Medicine
Presence Saint Francis Hospital
Evanston, IL 60202

Dear Dr. Friedman,

The Institutional Review Board approved by expedited review the following protocol for use at Presence Saint Francis Hospital.

Protocol: **IRB # SFH00298- iCompare IMResidentEducation/UPenn Study**

Principal Investigator(s): Harvey Friedman MD,

Date of Expedited Review Approval:

January 28, 2015

Annual Review Date:

January 28, 2016

Responsibilities of Principal Investigator:

1. Insure that any changes in approved research or consent form, during the period for which IRB approval has already been given, will be promptly reported and may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects;
2. Insure that unanticipated problems involving risks to human subjects are promptly reported in writing to the IRB, appropriate institutional officials, and the FDA
3. Review of the protocol on the designated review date.
4. Must place the IRB study protocol summary in the front of the patient chart.
5. View the Human Research Protections (OHRP) program on Informed Consent Interviews. <http://www.youtube.com/watch?v=wrtKtVllya8&feature=channel>

Sincerely,



Scott French, MD
Chairman, Institutional Review Board



INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
FWA # 00006767 LUBBOCK/ODESSA IRB #00000096

APPROVAL OF AMENDMENT REQUEST

May 07, 2015

IRB #: L15-127

STUDY #: Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) (CRI15-025 iCOMPARE)

PRINCIPAL INVESTIGATOR: Michael Phy, D.O.

SUBMISSION REFERENCE #: 054960

TYPE OF REVIEW: EXPEDITED

SUBMISSION ITEMS: Residents survey - end of year version 1.1
Resident email invitations version 1.1

Amendment description: Submission of final versions of the Resident Survey and Resident Email Invitation.

Reviewer comments: This is a national study being conducted by the ACGME to investigate the impact of resident duty hours on patient safety and resident satisfaction. The amendment includes revised versions of the invitation letter for residents to complete the baseline survey and the survey itself. **This study has a waiver of documentation of consent.** The standard letter from the investigators addresses issues of consent briefly. Although this is not our standard language, I find the letter to be acceptable.

RECOMMENDATION: This amendment was reviewed by the TTUHSC Lubbock/Odessa IRB and found to satisfy the requirements for approval in accordance with 45 CFR 46.111.

Study Personnel Currently Approved to Conduct the Research: Zachary Mulkey, Amanda West Romero, RN, BS, Catherine Lovett, RN, MSN, CCRC, CCRP, Chris Scott-Johnson, RNC, MSN, SANE CA/CP, CCRC, Melissa Leiker, BSN, RN, CCRC, Thu L Fenno, RN, Alyssa Tanhueco Sherry

Please retain this letter with your research records. Research records include all Institutional Review Board submissions and responses and must be kept in the principal investigator's file for a minimum of three (3) years after completion of the study.

The Texas Tech University Health Sciences Center (TTUHSC) IRB Policies and Procedures are available for reference on the TTUHSC Human Research Protection Program Website - (<http://www.ttuhsc.edu/research/hrpo/irb/>).

TTUHSC Lubbock/Odessa Institutional Review Board
3601 4th Street STOP 8146
Lubbock, TX 79430
806-743-4753



University of Colorado
Anschutz Medical Campus

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
[COMIRB Home Page](#) [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital

Denver Health Medical Center
Veteran's Administration Medical Center
Children's Hospital Colorado
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

18-Aug-2015

Investigator: Suzanne Brandenburg
Subject: COMIRB Protocol 15-0836 Initial Application
Review Date: 8/18/2015
Effective Date: 18-Aug-2015
Expiration Date: 07-Jul-2016
Sponsor(s): No Sponsor~
Title: Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE)
Expedited Category: 5,7

Submission ID: APP001-4

SUBMISSION DESCRIPTION:

Response to Minor Modifications

Your COMIRB Initial Application submission APP001-4 has been APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 45 days prior to the expiration date.

Study personnel are approved to conduct the research as described in the documents approved by COMIRB, which are listed below the REVIEW DETAILS section.

Please carefully review the REVIEW DETAILS section because COMIRB may have made red-line changes (i.e. revisions) to the submitted documents prior to approving them. The investigator can submit an amendment to revise the documents if the investigator does not agree with the red-line changes. The REVIEW DETAILS section may also include important information from the reviewer(s) and COMIRB staff.

COMIRB stamps the approved versions of documents in the top right hand corner. Stamped copies of documents are available for download through COMIRB's electronic submission website, eRA(InfoEd).

[Click here for instructions on how to retrieve stamped documents.](#)

REVIEW DETAILS:

The response to Minor Modifications were reviewed by the Chair, who determined that the issues raised by committee were adequately addressed with the exception of the following redline change:

End of Year Survey: 1. Please change version date to 8.18.15 2. Please change 'baseline (pre-study) survey' to 'post study survey'

Note: COMIRB administration will make the changes requested. The redlined and clean copies of the end of year survey will be uploaded into InfoEd. If the PI disagrees with the end of year survey changes, a change form should be submitted to COMIRB.

The following documents have been reviewed and stamped APPROVED as part of this approval:

Protocol, dated July 31, 2015

Application form with Attachments A, F, G, M, dated June 7, 2015

Personnel Form, dated April 26, 2015

Residents Survey Start of Year, dated July 31, 2015

Residents Survey End of Year, dated August 18, 2015

The following documents have been reviewed and stamped NOTED as part of this approval:

Response Submission Cover letter, dated July 31, 2015

HSR Portal Clearance letter, dated May 13, 2015

JAMA December 5, 2012 - Vol 308, No 21

If this protocol requires full-board review and includes attachment C and/or D, the PI will be required to complete GCP training. COMIRB will begin enforcing this new requirement on 9/1/15. It is highly recommended that you complete this training as soon as possible to prevent delays on approvals after the 9/1/15 deadline.

For the duration of this research the investigator must:

- Submit any change in the research design, personnel, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, ect.) to COMIRB and receive approval before implementing the changes.
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as required by COMIRB. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language or use a Consent Short Form, as approved for the study.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Maintain approval for the research. COMIRB approval is generally given in one year increments, but the period may be shorter. Research is required to be submitted for continuing review and re-approval at least 45 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning. For FDA-regulated research the investigator must sign the investigator line on the consent form prior to participants receiving study-related interventions.

Information on how to submit changes (amendments) to your study, requests for continuing review, and reports of unanticipated problems to COMIRB can be found on the COMIRB website <http://www.ucdenver.edu/COMIRB>.

Contact COMIRB with questions at 303-724-1055 or COMIRB@ucdenver.edu.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Sincerely,

UCD Panel B

Please provide your feedback on IRB processes and support

The Cooper Health System
Institutional Review Board
FWA #: 0000211

Notification of Expedited New Protocol Approval

Date: January 02, 2015

To: Principal Investigator
Cerceo, Elizabeth, MD

IRB#: 14-174EX
This number is a CHS IRB number which should be used on all correspondence.

Study Title: iCOMPARE
Study Number: 001
Sponsor:

Approval Date: 12/24/2014

Study Application Version: 1.2

This approval is for a period of 12 Months **Expiration Date:** 12/23/2015
(based upon date recommended for approval)

The dataset may include subject identifiers and/or a link to subject identity.

This protocol and supporting materials have been reviewed and approved by an IRB member designated by the Chair using the expedited procedures set forth in 45 CFR 46.110(b)(2) and 21 CFR 56.110(b)(2) and the expedited review categories specified in the Federal Register/Vol. 63, No. 216 dated 11/9/98. The reviewer determined that the study qualifies for expedited review because it involves no greater than minimal risk and involves only procedures in the following category.

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application is not required.
 - (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick or venipuncture.
- (3) Prospective collection of biological specimen by non-invasive means.
- (4) Collection of data through non-invasive procedures.
- (5) **Research involving materials collected solely for non-research purposes.**
- (6) Collection of data from recordings made for research purposes.
- (7) **Research employing surveys, interviews, etc.**

Items reviewed and approved in this action:

- Investigator-initiated protocol in Study Application version: []
- Sponsor's Protocol version: []
- Combined consent form and HIPAA authorization [date stamp/approved:]
- Waiver of informed consent per the regulations at 45 CFR 46.116(d)
- Waiver of HIPAA authorization per the regulations at 45 CFR 164.512(i) (2)
- Waiver of documentation of informed consent per the regulations at 45 CFR 46.117(c)(1)
- Waiver of documentation of informed consent per the regulations at 45 CFR 46.117(c)(2)
- Tissue/specimen banking form
- Declaration of De-identification
- External investigator (specify IIA/FWA above)
- Cooper is Data Coordinating Center and/or FWA/IRB approval from other sites required (specify above)
- Other (specify:)

The research meets the criteria and approval is granted for:

- Children as subjects per Subpart D at 45 CFR 46.404 and of 21 CFR 50.51
- Pregnant women or fetuses prior to delivery per Subpart B at 45 CFR 46.204.
- Other:

Consent Form and HIPAA Authorization (if applicable): The approved and stamped consent form and HIPAA authorization must be used when enrolling subjects. You are responsible for maintaining signed consent forms for a period of at least three (3) years after study completion. **Print out and use the currently approved and stamped consent form and HIPAA authorization when enrolling subjects.** Please note that the expiration date is stamped on consent and HIPAA authorization forms as well as the approval date.

Other IRB-Stamped Approved Documents (if applicable); If any documents other than the consent form and HIPAA authorization were stamped with the IRB approval stamp, use only the stamped versions of the documents when conducting the research project.

Continuing Review: Federal regulations require that research involving human subjects be reviewed at least every 365 days although the IRB has the authority to set more frequent review requirements. You should receive electronic notification 60 days prior to the expiration of this project's approval. However, it is your responsibility to insure that an application for continuing review approval has been submitted by the required time. If the research study is not re-approved before the expiration date, accrual of new subjects must be suspended until approval has been renewed.

Amendments: It is the principal investigator's responsibility to inform the IRB of any and all changes to the approved study, including but not limited to changes in investigators and study staff and revisions to the protocol and/or consent form. You must have IRB approval before initiating any changes to the study except changes that are necessary to eliminate immediate hazards to the subjects.

Unanticipated Risk Reporting:

The principal investigator must immediately report to the CHS IRB any unanticipated problems involving risks to subjects or others and any serious harm to subjects.

Study Closure: You are required to submit a Study Closure Report summarizing the study's activity at the completion of the project.

Sincerely,

Judith Finkelstein
IRB Coordinator

From: [Bynum, Debra L](#)
To: [Amanda Bertram](#)
Subject: FW: IRB Notice
Date: Monday, March 30, 2015 8:58:05 AM

Amanda:

We have official IRB exemption.

Thank you

Deb

From: IRB [mailto:irb_no_reply@unc.edu]
Sent: Monday, March 30, 2015 8:11 AM
To: Bynum, Debra L
Subject: IRB Notice

To: Debra Bynum
Med-Geriatric Medicine

From: Office of Human Research Ethics

Date: 3/30/2015

RE: Determination that Research or Research-Like Activity does not require IRB Approval

Study #: 15-0649

Study Title: iCOMPARE

This submission was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(1)] and does not require IRB approval.

Study Description:

Purpose: To determine if there are any improved patient safety outcomes or trainee education outcomes associated with the more strict ACGME work hour limitations enacted in 2011 for resident training

Participants: residents in the Internal Medicine program (our program is one of 70 IM resident programs nationally in this study)

Procedures (methods): Please see attached document for details of methods and outcomes

outcomes.

Study Design:

iCOMPARE is a cluster randomized trial comparing two alternative duty hour standards for interns in 58 programs in Internal Medicine. The intervention programs will have less restrictive standards and will be compared to the current ACGME mandated standards, which limits work duration to 16 hours. We will evaluate the extent to which the intervention programs preserve clinical and educational goals. Randomization is at the level of the Internal Medicine (IM) training program. The Data Coordinating Center (DCC) will randomize programs to control or intervention standards. Randomization will occur in the fall of 2014 to allow each program sufficient time to prepare training schedules. Assignment to duty hour schedule will be 1:1 and there will be no stratification.

Study Duration:

The intervention is technically one year, AY 15-16 (July 2015-June 2016). Pretrial work such as recruitment and collection of baseline data will begin in Fall 2014 and analyses and writing will extend into 2018.

Target Population:

For Aim 1 (safety) we will be using Medicare claims data. Our study population for evaluation of patient safety will be Medicare fee for service (FFS) beneficiaries at least age 65.5 at admission and admitted to one of the acute care hospitals affiliated with the 195 IM programs eligible for randomization to control or intervention duty hour standards between July 1, 2015 and June 30, 2016 with any of the eligible principal diagnoses -see attachment]. Data from before the intervention period will be used as a baseline for safety analyses before the paired data are available. Approximately 80% of hospital patients have claims from Medicare. The analyses are limited to FFS beneficiaries because CMS reports only Medicare fee for service patients. All FFS Medicare patients will have complete, linked data: inpatient (Medicare Part A), outpatient, physician (Medicare Part B), and associated denominator files. Patients will be included if they were not enrolled in a managed care program six months before admission and one month post discharge. The minimum age is 65.5 and FFS status in the 6 months prior to admission are required so that claims are available for 6 months prior to the qualifying admission. The diagnoses were chosen to reflect the vast majority of patients on the typical IM service. Examining all patients, rather than just Medicare aged FFS patients, would be ideal but is not feasible because 30day mortality, as well as the secondary outcomes, require linkable data to events occurring outside the hospital, something not practical to obtain outside the Medicare system (i.e., it would be impractical to consent patients to be able to see their data, or to rely on numerous insurance companies or various state databases due to the scale of this trial). No patients will be excluded based on gender or race/ethnicity. We expect very little change in year to year demographic and clinical characteristics of the patients admitted to each hospital as we observed in previous studies. Patients will not be recruited or contacted by iCOMPARE in any way for collection of data. Patient data will be obtained from CMS using the processes set up by CMS for leveraging their data for research purposes. For Aim 2 (education) we will recruit 58 internal medicine programs from the total of 379. New data for this study will come from the 58 program directors and the average of 80 trainees at each sites. We estimate a total of 4640 total trainees at the 58 participating IM programs, so with a 70% response rate we estimate at least 3248 trainee respondents. We assume there are 10 faculty per program so a total of 580; with a 60% response rate to surveys we expect 348 participants.

The role of the UNC PI: The PD at UNC will help to ensure that the researchers involved

with the icompare study have access to resident contact information for survey purposes.
Patient outcomes will be determined only by medicare claims data as above.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

IRB Informational Message - please do not use email REPLY to this address

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

07-Oct-2014

David A Asch
asch@wharton.upenn.edu
Blockley Hall
Room 1223
Philadelphia, PA 19104-6021
Attn: Judy A Shea
sheaja@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR : David A Asch
TITLE : Individualized Comparative Effectiveness of Models Optimizing Patient Safety
and Resident Education (iCOMPARE) (PRIME)
SPONSORING AGENCY : Accreditation Council for Graduate Medical Education
PROTOCOL # : 821156
REVIEW BOARD : IRB #8

Dear Dr. Asch:

The above referenced protocol and was reviewed and approved by the Executive Chair (or her authorized designee) using the expedited procedure set forth in 45 CFR 46.110, category 5.7, on 07-Oct-2014. This study will be due for continuing review on or before 06-Oct-2015.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

The following documents were included in this review:

- HS ERA Initial Application, conf code: bgegifai, submitted 10-05-14
- Email Correspondence, dated 10-06-14
- CITI Training Report of Completion for Lisa Bellini, passed 10-06-14
- CITI Training Report of Completion for Orit Even-Shoshan, passed 05-22-13
- CITI Training Certificate of Completion for Jeffrey Silber, dated 12-08-12
- iCOMPARE Information Sheet, dated 10-2014
- PD Email Invitations (Baseline and End of Intervention), received via email 10-06-14
- Trainee Email Invitations (Baseline and End of Intervention), received via email 10-06-14
- CITI Training Report of Completion for James Tonascia, passed 03-10-14
- CITI Training Report of Completion for Dave Shade, passed 10-10-12
- CITI Training Report of Completion for Lea Drye, passed 08-17-12
- CITI Training Report of Completion for Alice Sternberg, passed 08-14-12
- John Hopkins University - Data Coordinating Center (DCC) List, uploaded 10-02-14
- iCOMPARE Program Enrollment Form, uploaded 10-02-14
- The iCOMPARE Trial Institutional Participation Agreement Form, uploaded 10-02-14
- Appendix 4B. End-of-Year Survey to Program Directors, dated 01-25-14
- Appendix 3B. End-of-Year Resident Perceptions of Educational Experience, dated 01-25-14
- Cover Letter, dated 10-01-14
- Study Protocol, version dated 08-29-14

Please Note: Penn IRB is willing to serve as the IRB of record, should the other sites be willing to rely on Penn IRB.

Please Note: Waiver of HIPAA authorization for CMS data is under purview of CMS and will be determined by the CMS privacy board.

Please Note: As indicated earlier in email communication dated 10/06/14, please ensure to submit protocol modifications when linkage methodology is finalized for ACP, ACGME, and APDIM data (with iCOMPARE data).

Please Note: The IRB reviewed and approved a waiver or alteration of the required elements of consent under § 46.116(d) as it was determined that (1) the study is no greater than minimal risk, (2) conducting the study would be impracticable without the waiver, (3) waiving does not adversely affect subjects and, if applicable, (4) pertinent information will be provided to the subjects later.

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,

David
Heagerty



The
UNIVERSITY
of VERMONT

Committees on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)656-5040 ph
www.uvm.edu/irb/

Protocol Exemption Certification

TO: Mark Pasanen, MD
FROM: Gale Weld, Research Review Administrator
DATE OF CERTIFICATION: 18-May-2015
SUBJECT: CHRMS: 15-566
iCOMPARE (Part A - Survey)

A handwritten signature in cursive script that reads "Gale Weld".

Following IRB review of your project, it has been determined that it qualifies for exemption, as indicated below.

Exemption Category: 2

Federal Exemption: "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 subjects' financial standing, employability, or reputation."

This exemption is effective for the duration of the project UNLESS modifications are made that affect the original determination of exemption.



Committees on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)656-5040 ph
www.uvm.edu/irb/

Certification

Not Human Subjects Determination

TO: Mark Pasanen, MD
FROM: Gale Weld, Research Review Administrator
DATE OF CERTIFICATION: 18-May-2015
SUBJECT: CHRMS: 15-569
iCompare (Part B - existing data)

Gale Weld

The IRB has determined that IRB review of the project is **not** required because it does not constitute human subjects research as described below and recognized by 45 CFR 46.102(f) and OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens.

The definition of "human subject" includes, but is not limited to, human organs, specimens, and body fluids from living individuals, as well as private graphic, written, or recorded information about living individuals, if

- (1) there is interaction or intervention with a living individual to obtain the data or specimens for research purposes, or
- (2) the identity of the subjects can be readily ascertained by the investigator or other members of the research team.



UNIVERSITY of WASHINGTON

HUMAN SUBJECTS DIVISION

Date: 25 June 2015

PI: Dr. Kenneth P. Steinberg
Professor of Medicine and Program Director, Internal Medicine Residency Program
Department of Medicine

RE: HSD study #49956
"iCOMPARE: Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education"

Dear Dr. Steinberg:

The University of Washington Human Subjects Division (HSD) has determined that your research qualifies for exempt status in accordance with the federal regulations under 45 CFR 46.101/ 21 CFR 56.104. Details of this determination are as follows:

Exempt category determination: 1 and 2

Determination period: June 25, 2015 through June 24, 2020

Although research that qualifies for exempt status is not governed by federal requirements for research involving human subjects, investigators still have a responsibility to protect the rights and welfare of their subjects, and are expected to conduct their research in accordance with the ethical principles of *Justice, Beneficence* and *Respect for Persons*, as described in the Belmont Report, as well as with state and local institutional policy.

Determination Period: An exempt determination is valid for five years from the date of the determination, as long as the nature of the research activity remains the same. If there is any substantive change to the activity that has determined to be exempt, one that alters the overall design, procedures, or risk/benefit ratio to subjects, the exempt determination will no longer be valid. Exempt determinations expire automatically at the end of the five-year period. If you complete your project before the end of the determination period, it is not necessary to make a formal request that your study be closed. Should you need to continue your research activity beyond the five-year determination period, you will need to submit a new *Exempt Status Request* form for review and determination *prior to implementation*.

Revisions: Only modifications that are deemed "minor" are allowable, in other words, modifications that do not change the nature of the research and therefore do not affect the validity of the exempt determination. **Please refer to the SOP on Exempt Determinations for more information about what are considered minor changes.** If changes that are considered to be "substantive" occur to the research, that is, changes that alter the nature of the research and therefore affect the validity of the exempt determination, a new *Exempt Status Request* must be submitted to HSD for review and determination *prior to implementation*.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events or any problem that may increase the risk to the human subjects and change the category of review, notify HSD promptly. Any complaints from subjects pertaining to the risk and benefits of the research must be reported to HSD.

Please use the HSD study number listed above on any forms submitted which relate to this research, or on any correspondence with the HSD office.

Good luck in your research. If we can be of further assistance, please contact us at (206) 543-0098 or via email at hsdinfo@uw.edu. Thank you for your cooperation.

Yours sincerely,

Laura A. Henderson
Human Subjects Review Administrator



Office of Research Integrity and Compliance

Approval Letter Expedited

Action Date 05/29/2015
To Nathan Lorfald
From WVU Office of Research Integrity and Compliance
Approval Date 05/29/2015
Expiration Date 05/28/2016
Subject Protocol Approval Letter
Protocol Number 1504668191
Title iCompare

The above-referenced research study was reviewed by the West Virginia University Institutional Review Board IRB and was approved in accordance with 46 CFR 46.101b.

It has been determined that this study is of minimal risk and meets the criteria as defined by the expedited categories listed below:

- " This is an expedited category 7.

Documents reviewed and/or approved as part of this submission:

UPenn IRB Authorization Agreement.doc: 2015-05-04-04:00

iCOMPARE Template IRB Text.docx: 2015-04-21-04:00

UPenn - IRB Approval.pdf: 2015-05-04-04:00

icompare Resident Email Invitations 4 20 15.docx: 2015-05-04-04:00

UPenn IRB Authorization Agreement - West Virginia University.pdf: 2015-05-04-04:00

iCompare Residents Survey - End of Year 4 20 15.pdf: 2015-05-04-04:00

Documents for use in this study are available in the WVUkc system in the Notes and Attachments section of your protocol.

The Office of Research Integrity and Compliance is here to provide assistance to you from the initial submission of an IRB protocol and all subsequent activity. Please feel free to contact us by phone at 304.293.7073 with any question you may have. Thank you.

WVU Office of Research Integrity and Compliance

Date:05/29/2015

Signed:

A handwritten signature in black ink, appearing to read "Lilo Ast". The signature is written in a cursive, flowing style.

Lilo Ast
Senior Program Coordinator

Once you begin your human subject research, the following regulations apply:

1. Unanticipated or serious adverse events/side effects encountered in this research study must be reported to the IRB within five (5) days via the Notify IRB action.
2. Any modifications to the study protocol or informed consent form must be reviewed and approved by the IRB prior to implementation via submission of an amendment.
3. You may not use a modified informed consent form until it has been approved and validated by the IRB.

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

20-Oct-2015

David A Asch
Attn: Kelsey Gangemi
kgangemi@mail.med.upenn.edu
Asch@Wharton.Upenn.Edu

PRINCIPAL INVESTIGATOR : David A Asch
TITLE : Individualized Comparative Effectiveness of Models Optimizing Patient
Safety and Resident Education (iCOMPARE) (PRIME)
SPONSORING AGENCY : Accreditation Council for Graduate Medical Education
PROTOCOL # : 821156
REVIEW BOARD : IRB #8

Dear Dr. Asch:

The documents noted below, for the above-referenced protocol, were reviewed using the expedited procedure set forth in 45 CFR 46.110 and approved on 10/19/2015.

Documents included:

- HSERA modification submission (confirmation # bjdddjdc) submitted 10/13/15
- Cover letter dated 10/13/15
- iCOMPARE Data and Safety Monitoring Plan, dated 10/6/15

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,

Stephanie Lesage

IRB Administrator

Digitally signed by Stephanie Lesage
DN: cn=Stephanie Lesage, o=ORA, ou=IRB,
email=lesages@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this
document
Date: 2015.10.20 12:32:29 -04'00'

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

21-Jul-2015

David A Asch
asch@wharton.upenn.edu
Attn: Judy Shea
sheaja@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR : David A Asch
TITLE : Individualized Comparative Effectiveness of Models Optimizing Patient
Safety and Resident Education (iCOMPARE) (PRIME)
SPONSORING AGENCY : Accreditation Council for Graduate Medical Education
PROTOCOL # : 821156
REVIEW BOARD : IRB #8

Dear Dr. David Asch:

The documents noted below, for the above-referenced protocol, were reviewed using the expedited procedure set forth in 45 CFR 46.110 and approved on 20-Jul-2015.

The following documents were included with this submission:

- HS ERA Modification Submission, (Confirmation Code # bigcchj), submitted 07/9/2015
- Daily Just-In-Time Surveys, dated 7/9/14
- Status Update for PD's, uploaded 7/9/2015
- Cover Letter, dated 7/9/2015

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,



Digitally signed by David
Asch:
DN: cn=David Asch, o=IRB,
ou=ORA,
email=dsr@wharton.upenn.edu,
c=us
Reason: I am the signer of this document.
Date: 2015.07.21 10:21:41-0400

IRB Administrator

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

21-Jul-2015

David A Asch
asch@wharton.upenn.edu
Attn: Judy Shea
sheaja@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR : David A Asch
TITLE : Individualized Comparative Effectiveness of Models Optimizing Patient
Safety and Resident Education (iCOMPARE) (PRIME)
SPONSORING AGENCY : Accreditation Council for Graduate Medical Education
PROTOCOL # : 821156
REVIEW BOARD : IRB #8

Dear Dr. David Asch:

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If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,



Digitally signed by David
Asch:
DN: cn=David Asch, o=IRB,
ou=ORA,
email=dsasch@upenn.edu,
c=us
Reason: I am the signer
and integrity of the document
was 20150721 10:21:41-0400

IRB Administrator

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

28-Sep-2015

David A Asch
asch@wharton.upenn.edu

Attn: Judy Shea
shea1@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR : David A Asch
TITLE : Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) (PRIME)
SPONSORING AGENCY : Accreditation Council for Graduate Medical Education
PROTOCOL # : 821156
REVIEW BOARD : IRB #8

Dear Dr. Asch:

The above referenced protocol was reviewed and re-approved using the expedited procedure set forth in 45 CFR 46.110(b) (5,7), on 9/24/2015.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for obtaining any relevant committee approvals.

This approval is for the period 24-Sep-2015 to 23-Sep-2016.

The following documents were included in this review:

- HS-ERA Continuing Review (confirmation code bjhheide), submitted 09/21/15
- Informed Consent Form, version 1.2, dated 09/11/15
- DSMB Roster, dated 09/16/15

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>

Thank you for your cooperation.

Sincerely,

Stephanie Lesage

Digitally signed by Stephanie Lesage
DN: cn=Stephanie Lesage, o=ORA, ou=IRB,
email=lesages@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this
document
Date: 2015.09.28 12:41:51 -04'00'

IRB Administrator