

Form for Determining Whether a Project Involves Human Subjects Research

Version: 3.0

Date: 5/10/2013

The Northwestern University IRB is required to review and approve all research involving human subjects. This application is intended to help you determine if your project requires IRB approval. If you require written documentation from the IRB Office, complete the entire form, and email the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to irb@northwestern.edu. You should receive an IRB response within 10 business days.

Current Status of the Project

Has the project already been conducted (i.e., data has already been collected and analyzed)?

Yes No

SECTION I: Activities Determined by the NU IRB Office Not to Represent Human Subjects Research

A. **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual's protected health information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

B. **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

NOTE: IRB approval is required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

C. **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

- i. the use will be solely for research on the information of a decedent; and
- ii. the Principal Investigator has documentation of the death of the individual about whom information is being sought, and
- iii. the information sought is for the purposes of the research

Note, however, that this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse

D. **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

NOTE: IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

E. **Oral History:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

NOTE: IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories).

F. **Program evaluation /Quality Improvement/Quality Assurance Activities:** The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

Note: Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur.

G. **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Below are examples of data sources that qualify as not-human subjects research (unless the researcher has received the restricted use data):

- Data files downloaded from the ICPSR (Interuniversity Consortium for Political and Social Research): <http://www.icpsr.umich.edu/icpsrweb/ICPSR/> or the Roper Center for Public Opinion Research <http://www.ropercenter.uconn.edu>.

- American National Election Studies, (ANES) 1948-2010 <http://www.electionstudies.org/>
- Bureau of Economic Analysis: <http://www.bea.gov/>
- Bureau of Labor Statistics (BLS): <http://www.bls.gov/>
- Center for Disease Control (CDC): <http://www.cdc.gov/>
- Consumer expenditure Survey: <http://www.bls.gov/cex/>
- Current Population Survey: <http://www.bls.gov/cps/>
- FBI Uniform Crime Reporting Program: <http://www.fbi.gov/about-us/cjis/ucr/ucr> or National Archive of Criminal justice data: <http://www.icpsr.umich.edu/icpsrweb/NACJD/index.jsp>
- General Social Survey: <http://www3.norc.org/GSS+Website/>
- National Center for Education Statistics (NCES): <http://nces.ed.gov/>
- National Longitudinal Surveys (NLS): <http://www.bls.gov/nls/>
- Survey of Income and Program Participation: <http://www.census.gov/sipp/>
- Government sites that bring data files together: [Data.gov](http://www.data.gov/) (<http://www.data.gov/>); [FedStats](http://www.fedstats.gov/) (<http://www.fedstats.gov/>); and [USA.gov](http://www.usa.gov) (http://www.usa.gov/Topics/Reference_Shelf/Data.shtml)

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.

H. **Coded* Private Information and/or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if all of the following conditions apply to the project:

- i. (1) The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
- (2) The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased;
 or

(c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased, **and**

- ii. Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**
- iii. The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008:

**Coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

***Investigator* includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

I. **De-Identified Private Information or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:

- i. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
- ii. The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; **and**
- iii. The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to

identifiers. **and**

- iv. Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

- v. The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

Instructions: If your activity did not fall into the categories described in Section I, continue to Section II and III to assess if you are engaged in human subjects research per the regulations set forth by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

SECTION II. Activities subject to HHS human subject research regulations (45 CFR 46)

1. Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?

TIP: If the investigation characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research.

Yes, Go to #2

No, Go to FDA section III

2. Does the research involve obtaining information about LIVING individuals?

Yes, Go to #3

No, Go to FDA section III

3. Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact between investigator and person) with the individuals?

Yes, **IRB review required.**

No, Go to #4

**Go to FDA section III to assess if
FDA regulations apply to your study.**

4. Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?
 Yes, Go to #5 No, Go to FDA section III

5. Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)
 Yes, IRB review required
Go to FDA section III to assess if
FDA regulations apply to your study. No, Go to FDA section III

SECTION III. Activities subject to FDA human subject regulations: If your answer is “yes” to any of the 3 questions below, IRB approval is required and the FDA regulations apply to your study.

1. Is this is an experiment that involves a test article * and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A subject is an individual (either health or a patient) who is a recipient of the test article or a control.

*Test article *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

Yes , IRB review required No

2. Is this is a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.

Yes, IRB review required No

3. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.

Yes, IRB review required No

Instructions:

If IRB Review is required, you will need to submit NEW STUDY application eIRB.

SECTION IV: Complete this section if you have determined that your activities do not constitute human subjects research and you require written confirmation of this determination from the IRB Office. E-mail the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to irb@northwestern.edu.

Investigator Information

Name (Last, First) BILIMORIA, KARL Y.	Degree(s) MD, MS	University Status/Title ASSISTANT PROFESSOR
Department DEPARTMENT OF SURGERY	College FEINBERG	
Phone Number +1 (312) 695-4853	E-mail Address k-bilimoria@northwestern.edu	

Project Information

Project Title Modification of Surgical Resident Duty Hours Study: A Cluster-Randomized Pragmatic Trial
Name of Funding Source (i.e., Department, NIH, Foundation) Self-Funded
Grant Number (if applicable) -----
Project Description (describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens)

Summary of Study Design Features That May Influence Whether Proposed Study Constitutes Human Subjects Research

- Aim is to evaluate the effect of a **policy change** (resident duty hour restriction policies) on patient outcomes and resident perceptions/wellbeing
- **Units of randomization are organizations (residency programs), not individual persons**
- **Interventions are at the level of organizations (residency programs), and will involve a change of resident duty hour restrictions**

- The intervention will involve a change in selected ACGME resident duty hour restrictions. Half of the participating residency programs will be randomized to usual care (current duty hour restrictions). Half of the participating residency programs in this study will be randomized to the intervention arm (relaxed duty hour restrictions).
- Apart from an informational webinar to recruit residency programs, there will be no direct interaction between Study Team members and participating residency programs/organizations.
- There will be **no direct contact/interaction/intervention between Study Team and human subjects**
- This study has been sanctioned, supported and approved by the Accreditation for Graduate Medical Education, the American Board of Surgery, and the American College of Surgeons
- Data for evaluation will come from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). These data are collected as part of an ongoing process through hospitals' prior and ongoing participation in ACS NSQIP (participation is independent of the proposed study). The Study Team will only have access to **coded private information** for the purposes statistical analyses. The coded dataset will not contain any direct patient identifiers or dates. These data will be made available in a coded, private dataset to the Study Team by the ACS NSQIP.
- Additional data for evaluation will come from a module to be added to the American Board of Surgery In-Training Examination (ABSITE). The ABSITE is a compulsory examination administered annually to all residents in the month of January. The ABS will include a special module in the January 2015 ABSITE that asks residents questions regarding their perception of the effectiveness of training, as well as their satisfaction with training. The Study Team will only have access to **coded private information** for the purposes of statistical analyses. The data will be collected by the ABS, and then made available to the Study Team in the form of a coded, private dataset that does not include any direct individual-level identifiers.

Signature of Investigator: _____



Date: 11/19/2013_____

SECTION V: IRB Determination (to be completed by IRB Office)*

The activities as described in the submitted protocol and/or materials and description of activities provided by the investigator,

Do not constitute research with human subjects in accordance with 45 CFR 46 and 21 CFR 50 & 56. IRB approval is not required.

For activities involving decedents and their Protected Health Information (PHI), the conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(1)(iii), have been met.

- the use or disclosure sought is solely for research on the protected health information of decedents;
- documentation can be provided, at the request of the covered entity, of the death of such individuals; and
- the protected health information for which use or disclosure is sought is necessary for the research purposes.

Authorized IRB Personnel Printed Name: Kathleen E. Murphy, PhD, CIP

Authorized IRB Personnel Signature: 

Title: Manager, Social and Behavioral IRB, Northwestern University, Evanston, IL

Date: 11-21-2013

*If any activities completed were or possibly were not in compliance with federal regulations regarding prior IRB review, please forward the form to the IRB Compliance Manager for review. For example, the investigator reports activities which are already completed but initially required IRB approval.