Institutional Review Board
NYU School of Medicine

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INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH:

Research on Medical Education Outcomes (ROMEO) Trainee Registry

A. PURPOSE OF THE STUDY:

You are being asked to volunteer as a participant in a research registry – a de-identified database of educational and quality outcome data collected throughout your graduate, and if a graduate of NYU School of Medicine, your undergraduate experience, at NYU School of Medicine. This consent/authorization form includes information about this registry.

The purpose of this registry is to create a de-identified database of educational and quality outcome data on trainees throughout their medical education training at NYU SOM. This registry will permit research on the effectiveness of medical education.

B. SUBJECT PARTICIPATION:

All residents and fellows in participating programs will be recruited for participation in the Registry.

We estimate that we will enroll up to 360 residents in the first year of the study (all incoming interns and housestaff as of June 2007) and approximately 100 residents and fellows each year thereafter (incoming interns and fellows).

Your participation does not involve any visits. Instead, participation involves giving us permission to access your graduate and undergraduate (if a graduate of the NYU SOM) medical education evaluation and performance data for the purpose of creating a research registry. Data collected in this study will span your medical career at NYU SOM – if you graduated from NYU SOM, the registry will include both undergraduate and graduate medical education and performance data and if you did not graduate from NYU SOM, the registry will include only data from your time in the residency and/or fellowship program.

C. DESCRIPTION OF THE RESEARCH:

Participation in the ROMEO (Research on Medical Education Outcomes) Trainee Research Registry is limited to linkage of your educational outcome information across your education/training career at NYU SOM, placement of this de-identified information in a research database (i.e., the Research Registry), and the use of this information for research studies directed at evaluating the effectiveness of medical education.

We are asking you to provide written informed consent to allow educational and outcome data that is or has been collected from you as part of your educational and training experience at NYU SOM to be linked, de-identified, and then placed in the ROMEO Trainee Research Registry.

We are asking you to provide their permission for the use of this information for research studies so that we can assess the quality of educational outcome assessment and the effectiveness of medical education; such research will be conducted by ROMEO investigators as well as those investigators who apply for and receive permission from ROMEO investigators and from the NYU SOM IRB to conduct particular studies. Trainees will not be recruited for future research studies via the ROMEO Trainee Research Registry.

Participant data will be indefinitely stored electronically within the ROMEO Trainee Registry. All identifiable information, including name, social security number, KerberosID, and student ID number, will be deleted and replaced with a unique study identifier.

The ROMEO Trainee Registry principal investigator will approve all retrospective research studies being conducted on medical education outcomes using educational outcomes contained with the Registry. All approvals will be obtained prior to providing investigator access to the information. Approval shall be based upon considerations of scientific quality and validity; shall be granted only for research studies related to medical education outcomes; and shall be documented.

De-identified data contained within the Research Registry may be provided to secondary research investigators (i.e., research investigators who are not affiliated with medical education outcomes research). ROMEO Investigators shall require secondary investigators to obtain IRB approval of an "exempt" research application prior to its provision of de-identified information to the secondary investigator. Participants will not be informed of the results of retrospective research studies involving the use of their information contained with the Research Registry. ROMEO investigators will not have access to the ROMEO Research Registry for the purpose of determining potential eligibility of registry participants for additional research studies.

D. COSTS/REIMBURSEMENTS:

There is no anticipated cost to participate in this research registry.

E. POTENTIAL RISKS AND DISCOMFORTS:

There are no anticipated risks and discomforts related to your participation in this educational research study. Participant data will be stored electronically within the ROMEO Trainee Registry without any identifiable information except for a unique identifier generated for this study. Access to the Registry data will be restricted to ROMEO investigators.

F. POTENTIAL BENEFITS:

There is no direct benefit to you expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

This is not a study related to diagnosis or treatment of a disease or condition in eligible subjects. You are free to choose not to participate in the study.

H. CONFIDENTIALITY:

Private information about you that identifies you will not be used or shared for the purposes of this research project. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality.

If you agree to be in this research program, Dr. Adina Kalet and her study team will obtain your permission to access your graduate medical education performance outcomes data and, if a graduate of NYU SOM, your undergraduate medical education performance outcomes data. Such data may include OSCE performance and evaluation, clinical evaluation (inservice performance evaluations), clinical knowledge assessments (USMLE Step exam scores), online evaluations (Resweb); graduation questionnaires, report cards, quality assurance data (quality monitoring), clinical practice indicators, and other performance outcomes. All data are collected as part of the standard NYU SOM curriculum. If you graduated from NYU SOM, we are also asking for your permission to access educational and quality outcomes data from your undergraduate NYU SOM career including: admissions data (GPA, MCAT); Physician Patient and Society I and Physician Patient and Society II course evaluations and OCSE performance; Physical Diagnosis course evaluations and OSCE performance; clerkship performance; preclinical knowledge assessments (shelf-exam scores, USMLE Step exam scores); Comprehensive Clinical Skills Exam performance and evaluation; USMLE Step 2 Clinical Skills exam scores; professionalism portfolio data; and graduation questionnaires.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

All data will be de-identified upon entry into the Registry.

Confidentiality of Your Study Information

Your study records will include some information that identifies you and that is kept in research files until it is encrypted and fed into the Registry – these records will be kept in a secure location if paper-based and in password-protected, encrypted files if computer-based. We will try to keep this information confidential, but we cannot guarantee it. We will report and publish the data in ways that ensure that no individuals can be identified.

Retention of Your Study Information

The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your record will be destroyed or information identifying you will be removed from such study results at NYU.

I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

Participating in this educational data registry involves no risk of injury.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:

Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled. Whether you choose to participate or not will not be known to anyone other than study personnel.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. If you do decide to withdraw your consent, we ask that you contact Dr. Adina Kalet and let her know that you are withdrawing from the study. Her address is [redacted] New York, NY 10016.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study.

L. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-[redacted].

If you have any questions or sustain any injury during the course of the research, please contact the Principal Investigator Dr. Adina Kalet at the following telephone number (212) [redacted].

I have been given a copy of this Consent/Authorization form to keep and I understand that I am entitled to and will be given a copy of this signed form if I request it.

_____

PLEASE INDICATE WHETHER YOU CONSENT OR DO NOT CONSENT BY PRINTING AND SIGNING YOUR NAME AND DATE IN THE APPROPRIATE SPACE BELOW.

***Please initial and date each page of this consent/authorization form.**

I CONSENT

I voluntarily consent to participate in the ROMEO Research Registry and therefore give permission for the educational and performance data that has been or will be collected throughout my undergraduate and graduate experience at NYU SOM to be included in the ROMEO Research Registry.

_____ _____/_____
Print Name Signature of Participant Date

I *DO NOT* CONSENT

I DO NOT consent to participate in the ROMEO Research Registry.

_____ _____/_____
Print Name Signature of Participant Date

(IRB Official Use Only)
This Consent Document is approved for use by the New York University's Institutional Review Board (IRB). Only the IRB-stamped approved form may be used.

Approved: From: ***3/11/2013 To:*** **3/10/2014**
The study expiration date applies for this form
Template rev. date: 2006-03-16
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NYUSOM IRB APPROVED