



For NU IRB use:

Date Received: _____ NU IRB No. _____

Review Category: _____ Approval Date _____

APPLICATION FOR APPROVAL FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

Before completing this application, please read the [Application Instructions](#) and [Policies and Procedures for Human Research Protections](#) to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. The document, *Application Instructions*, provides additional assistance in preparing this submission. **Incomplete applications will be returned to the investigator. You may complete this application online and save it as a Word document.**

If this research is related to a grant, contract proposal or dissertation, a copy of the full grant/contract proposal/dissertation must accompany this application.

Please carefully edit and proof read before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator.

REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN SUBJECTS

Under the direction of the [Office of the Vice Provost for Research](#), Northeastern University is now requiring completion of the NIH Office of Extramural Research training for all human subject research, regardless of whether or not investigators have received funding to support their project.

The online course titled "Protecting Human Research Participants" can be accessed at the following url: <http://phrp.nihtraining.com/users/login.php>. **This requirement will be effective as of November 15, 2008 for all new protocols.**

Principal Investigators, student researchers and key personnel (participants who contribute substantively to the scientific development or execution of a project) must include a copy of their certificate of completion for this web-based tutorial with the protocol submission.

- Certificate(s) Attached
- Certificate(s) submitted previously – on file with the NU's Office of Human Subject Research Protection

A. Investigator Information

Principal Investigator (PI cannot be a student) David Lazer

Investigator is: NU Faculty X NU Staff _____ Other _____

College College of Computer & Information Science; College of Social Sciences & Humanities

Department Political Science

Address 132 Nightingale Hall, Boston, MA 02115

Telephone (617) 496-0102 _____ Email d.lazer@neu.edu



Is this student research? YES ___ NO X If yes, please provide the following information:

Student Name _____ Undergrad ___ MA/MS ___ PhD ___

Mailing Address _____ Anticipated graduation date _____

Telephone _____ Primary Email _____

Cell phone _____ Secondary Email _____

B. Protocol Information

Title Online Laboratory for Behavioral Experimentation

Projected # subjects 100,000 (this protocol is for a web-based laboratory, and therefore while we can report the exact number of participants afterwards, it is difficult to project with any precision)

Approx. begin date of project 4/1/2013 Approx. end date 4/1/2017

month, day, year

month, day, year

It is the policy of Northeastern University that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).

- Anticipated funding source for project (or none) Army Research Office, Army Research Laboratory
- Has/will this proposal been/be submitted through:
- NU's Office of Research Administration and Finance (RAF) X
 - Provost _____
 - Corp & Foundations _____

C.

Will Participants Be:	Yes	No	Does the Project Involve:	Yes	No
Children (<18)	_____	X	Blood Removal?	_____	X
Northeastern University Students?	X	_____	Investigational drug/device?	_____	X
Institutionalized persons?	_____	X	Audiotapes/videotapes?	_____	X
Prisoners?	_____	X			
Cognitively Impaired Persons?	_____	X			
Non or Limited English Speaking Persons?	_____	X			



People Living outside the USA?	<u> X </u>	<u> </u>	
Pregnant Women/Fetuses?	<u> </u>	<u> X </u>	
Other? (Please provide detail)	<u> </u>	<u> </u>	

Please answer each of the following questions using non-technical language. Missing or incomplete answers will delay your review while we request the information.

D. What are the goals of this research? Please state your research question(s) and related hypotheses.

Traditionally, behavioral experimentation within academic science is done in brick and mortar facilities – participants complete surveys or computer based experiments on campus in computer laboratories and designated testing facilities. These traditional facilities limit the type of science that can be done in two ways. 1) The number of simultaneous participants is limited by the number of available computers or space in one facility. 2) The diversity of the participants, through measures of age, race, socioeconomic status, political beliefs, and other demographic qualities is limited by the population of students or size and diversity of the surrounding city.

Our goal is to develop an online behavioral experimentation laboratory that solves both of these problems, while providing a plethora of additional advantages over traditional brick and mortar facilities. We are building a website platform that will allow for hundreds of participants in a single experiment concurrently, while recruiting and enrolling participants from around the world. This website will also allow rapid prototyping of new experiments and reduced costs for investigators, allowing for faster and cheaper data gathering for academic pursuits. Therefore our goal is to harness the power of the internet to push behavioral experimentation forward, allowing both novel hypotheses that could never before be asked and provide more efficient data collection.

E. Provide a brief summary of the purpose of the research in non-technical language.

Network science is a blossoming field that combines researchers from a wide-ranging set of disciplines who are interested in studying the interconnectedness of life. Sociologists, political scientists, psychologists, economists, computer scientists and physicists (among others) are currently working together at Northeastern and other top research schools to answer some of the most pressing questions in network science. However, like any research, they are limited by the strength of their research tools. Behavioral experimentation in network science has inherently been limited by the number of individuals who can participate at any one time – the size of the network is limited by physical space needed to connect individuals. Traditional psychological or behavioral economic experiments involve no more than 2-4 participants interacting at any given time. Network scientists would like to develop hypotheses and conduct experiments with 20 to 100+ participants interacting at any given time. This proposal is for an online experimentation platform that would allow for such experiments.



The purpose of this research is therefore to provide new tools for network scientists to be able to test hypotheses that have previously been unanswerable due to limited technology and the barriers of physical lab space.

F. Identify study personnel on this project. Include name, credentials, role, and organization affiliation.

David Lazer, Ph.D. Principal Investigator. Professor, Depts of Computer Science & Political Science, Northeastern University

Brooke Foucault Welles, Ph.D. Co-Investigator. Assistant Professor, Dept of Communication Studies, Northeastern University.

Jeff Hoye. Lead Engineer. External Consultant to Northeastern University

Ceyhun Karbeyaz. Co-Investigator. Graduate Student, Dept of Computer Science, Northeastern University

Brian Keegan, Ph.D. Project Manager. Post-Doctoral Research Fellow, Dept. of Political Science, Northeastern University.

Waleed Meleis, Ph. D. Co-Investigator. Professor, Dept of Computer Science, Northeastern University

Alan Mislove, Ph.D. Co-Investigator. Assistant Professor, Dept of Computer Science, Northeastern University

Skyler Place, Ph.D. Psychologist. External Consultant to Northeastern University

G. Identify other organizations or institutions that are involved. Attach current Institutional Review Board (IRB) approvals or letters of permission as necessary.

H. Recruitment Procedures

Describe the participants you intend to recruit. Provide all inclusion and exclusion criteria. Include age range, number of subjects, gender, ethnicity/race, socio-economic level, literacy level and health (as applicable) and reasons for exempting any groups. Describe how/when/by whom inclusion/exclusion criteria will be determined.

Exclusion Criteria:

If a participant is under 18 years of age.

If a participant is unable to read & write in conversational English.



Inclusion Criteria:

A participant must have an active Facebook account.

Our goal is to recruit a wide variety of individuals of different ages, genders, SES and geographic locations. We will use Facebook as a means of validating the identity of potential participants. Therefore any individual who is over 18 and can read English will be allowed to participate if they have a Facebook account.

Before an individual can participate in an experiment, they will have to link the experimental site to their Facebook account. Our website will automatically read a subset of relevant data from the individual’s Facebook profile to determine if they are eligible to participate. Because the data is read before the consent step to both authenticate users and ascertain their eligibility, if the participant is not eligible to participate this data will be discarded immediately. Eligible participants will then be provided with an informed consent form that will be delivered and executed electronically. If the participant elects not to consent, the data collected up to that point would also be discarded immediately.

Describe the procedures that you will use to recruit these participants. Be specific. How will potential subjects be identified? Who will ask for participation? If you intend to recruit using letters, posters, fliers, ads, website, email etc., copies must be included as attachments for stamped approval. Include scripts for intended telephone recruitment.

Participants will be recruited through three means, all of which are conducted via the internet. Examples of ads to be placed on Google and Facebook are shown below.

1. Advertisements will be placed on google.com using certain keywords (such as “psychology experiments” or “Facebook research”) These advertisements will be for participating in the experimental website.
2. Advertisements will be placed on Facebook using certain keywords & other demographic attributes (such as education and geographical location). These advertisements will be for participating in the experimental website.
3. When a participant finishes an experiment on the website, they will have an opportunity to share their results on Facebook. This opt-in, voluntary sharing will provide a link back to the website. Therefore these shared results could act as a recruitment mechanism for individuals who are friends with a participant on Facebook.
4. Announcements will be made on academic e-mail lists to invite other researchers to have their students participate and spread the information to their colleagues.



Volunteer Science



Participate in free online experiments to help scientists at Northeastern.

Volunteer Science



Farmville with a purpose – free online experiments help researchers at Northeastern University.

Volunteer Science



Complete fun online experiments while helping scientists at Northeastern University.

Examples of advertisements for recruiting participants on Facebook.

[Help advance science – VolunteerScience.com](#)

www.volunteerscience.org/

Free online experiments help scientists at Northeastern University.

[Free online experiments – VolunteerScience.com](#)

www.volunteerscience.org/

Online experiments help Northeastern University researchers.

[Farmville with a purpose – VolunteerScience.com](#)

www.volunteerscience.org/

Free online experiments help Northeastern University scientists.

Examples of advertisements for recruiting participants using Google Ads.



John volunteered his time for science!
apps.facebook.com

John completed the Traveling Salesperson Experiment. Join John in completing other experiments to help Northeastern University researchers!

Example of notification posted to the Facebook wall of a hypothetical person named John.

Reminder

Now that you completed an experiment for science, do you want to let your friends know about it?

Your friends will see which experiment you completed, but they won't see how you performed.

Tell my Friends **Don't tell my friends**

Example of a notification participants will receive on Volunteer Science after completing an experiment offering them the option to recruit friends to participate.

What remuneration, if any, is offered?

Participants will not be paid for participation.



I. Consent Process

Describe the process of obtaining informed consent*. Be specific. How will the project and the participants' role be presented to potential participants? By whom? When? Where? Having the participant read and sign a consent statement is done only after the researcher provides a detailed oral explanation and answers all questions. Please attach a copy of [informed consent statements](#) that you intend to use, if applicable.

If your study population includes non-English speaking people, translations of consent information are necessary. Describe how information will be translated and by whom. You may wait until the consent is approved in English before having it translated.

When a potential participant first comes to the laboratory website, there is a series of events that take place before they can participate. As mentioned above, participants are required to have a Facebook account to both assess the criteria for inclusion and exclusion as well as to participate in the experiments themselves.

Upon entering the website, participants are provided with a brief statement explaining the website. When an individual clicks the join button, a new window is generated that asks the individual to allow our website to access their Facebook information. This window is generated by Facebook.com, so we cannot control the text on this page. The individual has to click "accept" in order to move on. At this point, the exclusion criteria are checked, based on the data provided from Facebook. If an individual is approved to participate, they view the consent form and other instructions before they can access or participate in the experiments.

Experiments are sorted into categories that could include a variety of types, including single-person experiments, multi-person experiments, etc. The categories have brief explanations that explain the types of experiments that fall into each category. When an individual clicks on (chooses) a category, the informed consent form is brought up on the screen. This consent form has two aspects. 1) Consenting for the storage of Facebook information that is required as authentication for joining the website and 2) consenting for the actual content of the experimental category. The individual will read through the consent form, and have the option of printing the form. At the bottom of the form they will have to click the "Accept" button. At this point they are automatically assigned to one of the experiments in the category, and are now a participant in an experiment.

The website will record the consenting information for later use. If a participant returns to the website at a later time, there are two possible consenting conditions. 1) If a participant selects a category of experiments they have previously consented for, they will be given a brief reminder about the kind of experiments, and the types of data and confidentiality they can expect. If 2) the participant selects a category of experiment they have never consented to before, they will be provided with the full consent form for that experimental category.



For each category of experiments on this website, an amendment to this protocol will be provided that has both a description of the category, the full consent statement, and the reminder consent statement.

We have attached to this submission the overall consent statement for joining the website, as well as the information for one experimental category.

Reminder – Multiplayer Experiment

You previously consented to participate in a similar multiplayer experiment on Volunteer Science.

- **You must be 18 to participate.**
- **This experiment will take about 10 minutes to complete.**
- **You will be interacting with other people anonymously.**
- **Only data related to your performance will be collected.**
- **You can stop at any time by closing the browser.**

Continue **Quit**

This experiment has been approved by Northeastern University (IRB #13-03-09). If you have questions or concerns, please contact irb@volunteerscience.com or irb@neu.edu

Example of a consent reminder participants will see when attempting another experiment of the same category to which they have previously consented.

If your population includes children, prisoners, people with limited mental capacity, language barriers, problems with reading or understanding, or other issues that may make them vulnerable or limit their ability to understand and provide consent, describe special procedures that you will institute to obtain consent appropriately. If participants are potentially decisionally impaired, how will you determine competency?

N/A

If incomplete disclosure during the initial consent process is essential to carrying out the proposed research, please provide a detailed description of the debriefing process. Be



specific. When will full disclosure of the research goals be presented to subjects (e.g., immediately after the subject has completed the research task(s) or held off until the completion of the study's data collection)? By whom? Please attach a copy of the written debriefing statement that will be given to subjects.

There is no deception on this website, for any of the experimental categories. Although explanations & instructions will be provided at the beginning of each experiment, the design of some experiments may require manipulating and hiding the condition to which participants are assigned. However, the researchers will make published papers, presentations, and other research results available on a section of the Volunteer Science website.

J. Study Procedures

Provide a detailed description of all activities the participant will be asked to do and what will be done to the participants. Include the location, number of sessions, time for each session, and total time period anticipated for each participant, including long term follow up.

While there will be a variety of experimental categories on the website, the overarching procedures will be the same. This application is for the overall study framework for obtaining consent, collecting data, and storing it using a Facebook application, website, and database. Amendments will be filed to detail the specific procedures and variables to be obtained in each experiment.

Individuals will go through the consenting process as described above. They will then participate in an experiment, that is housed entirely on the Volunteer Science website and platform. The experiments will take no more than 30 minutes to complete. When the experiment is over, the participant will have the option of sharing their participation in the experiment with their Facebook friends via a post on their Facebook wall. Participants will then be directed back to the homepage of the website, where they can choose to participate in additional experiments if they so wish.

The website assigns unique IDs to participants to (1) keep track of which experiments each individual has participated in and (2) prevent researchers from linking participants back to identifiable information such as their Facebook IDs. These unique IDs and the Facebook accounts they map to will only be available to site administrators. Site administrators will not access these data for research purposes as these data will only be used for system administration and software development. Facebook IDs and other administrative data will not be accessed will remain encrypted and protected on a server secured by password and additional access restrictions. Only administrators will have access to administrative data.

Amendments will be provided that describe in detail each of the experimental categories, however all experiments will share the following characteristics.

1. There will be no deception.



2. There will be no payment for participation.
3. All sharing of participation on Facebook is opt-in, meaning by default there is no sharing, and each participant has to decide at the end of each experiment if they would like to share whether they participated on Facebook.
4. There will be no more than minimal risk.

Reminder

Now that you completed an experiment for science, do you want to let your friends know about it?

Your friends will see which experiment you completed, but they won't see how you performed.

Tell my Friends

Don't tell my friends

Example of a notification participants will receive on Volunteer Science after completing an experiment offering them the option to recruit friends to participate.

Who will conduct the experimental procedures, questionnaires, etc? Where will this be done? *Attach copies of all questionnaires, interview questions, tests, survey instruments, links to online surveys, etc.*

All experimental procedures will happen on the website. All procedures will be designed and implemented by the research staff listed in this protocol. Details about the experimental design, surveyed variables, and other supporting material will be filed in amendments to this application.

K. Risks

Identify possible risks to the participant as a result of the research. Consider possible psychological harm, loss of confidentiality, financial, social, or legal damages as well as physical risks. What is the seriousness of these risks and what is the likelihood that they may occur?

There are no physical, legal, or financial risks for participating in this study. There is a risk of psychological discomfort from answering survey questions as a part of experimental protocols.



This risk will be mitigated by participants being able to skip any question, and to stop the experiment at any time with no penalty.

The major risk in this protocol is the loss of confidentiality. The Facebook data we will gather is inherently identifiable. We will take every precaution to securely store this data, and to store identifiable data separately from anonymized experimental responses. All participant experimental data will be stored with randomly generated user IDs. Demographic data gathered through Facebook will only be linked to this ID when demanded by research questions driven by experimental hypotheses. The information linking user IDs to Facebook identities will be stored in a separate database that is only accessible by website administrators. Demographic information available from the Facebook API such as age, location, gender, and number of friends will be binned so that researchers will only be able to link experimental behavior to these binned variables by user ID. Thus, identifiable information such as Facebook IDs and names will only be able to be linked to performance in experiments by site administrators, not researchers themselves.

However, in the unlikely event of a security breach of the website or databases, participants may suffer a loss of confidentiality of the personal information on their profiles gathered through this website and their behavior on the experiments. However, the identifiable data will be stored on the servers in encrypted format, minimizing the risks in this scenario.

Describe in detail the safeguards that will be implemented to minimize risks. What follow-up procedures are in place if harm occurs? What special precautions will be instituted for vulnerable populations?

The website will run from a secure server and will use industry standards for encrypting and securing the transmission of information between servers. The servers hosting the website and databases are physically located in a server farm owned and operated by Amazon Web Services. The only individuals who have physical access to the server are the IT administrators for Amazon. Details about the security of these facilities are described by Amazon here: <http://aws.amazon.com/security/>

Access to the full files on the server is limited to the Principal, Co-Investigators, and Lead Engineer listed on this protocol each of whom have completed the NIH Course on “Protecting Human Research Participants”. The data on these servers will be secured to prevent them from being downloaded or transmitted to unsecured computers. There will be no research or analysis of the raw files and data available to administrators.

L. Confidentiality

Describe *in detail* the procedures that will be used to maintain anonymity or confidentiality during collection and entry of data. Who will have access to data? How will the data be used, now and in the future?



There are two types of data gathered through the website: 1) Facebook data and 2) Experimental data.

Facebook data is inherently identifiable. This data includes the unique Facebook ID as well as self-reported name, email address, age, gender, political affiliations, education level, relationship status, and other information from the Facebook profile of an individual. Users consenting to and participating in an experiment will transmit their Facebook account data to our database using OAuth 2.0, an industry standard for security authentication and the only method for compliant with Facebook's standards for information retrieval and transmission. At a minimum, users' "basic" personal data such as Facebook ID, name, picture, gender, and location are temporarily stored (cached) in the database because this is the minimum amount of information that can be retrieved. Some of this information such as picture is discarded afterwards while other data such as Facebook ID, name, gender, and location are stored for later use. Experiments on the website can access additional user information contingent upon its experimental necessity as determined by the PI as well as users' consent to provide this information. Both the "basic" and "additional" Facebook data will be stored in its own database, in an encrypted format. Only Principal, Co-Investigators, and Lead Engineer listed on this protocol have access to this data. The database housing this identifiable Facebook information will be locked to prevent the information from being transmitted to or stored on non-secure computers.

Users' real name, Facebook ID, and photo are only used on the client-side to improve the user experience (e.g., "Welcome back John Doe") and are not directly accessible by researchers. During experiments, users' real names are not used and random pseudonyms (e.g., "Player 1") are assigned instead. Facebook IDs and IP addresses are not revealed or used to link data, we employ an alternative unique identifier instead to obfuscate this identifying information. User-level gender is reported and user-level age is bucketed into 5-year pools (e.g., "20-24 years")

The other type of data is experimental data. Unique participant IDs will label all experimental data at the individual level to de-identify individuals and for administrators to track their participation across experiments. This experimental data will be stored in a database separate from the Facebook data. Details about the types of data collected and stored for these experiments will be filed in addendums to this application.

This website and the database which records both the Facebook data and experimental data are built using a platform called Django which uses industry-standard security and authentication procedures. In addition to built-in protection against common security mistakes and threats (e.g., SQL injection and cross site request forgery) when creating an interactive web framework, the project is compliant with the recommended Django security procedures (<http://www.djangobook.com/en/2.0/chapter20/>). To the extent that these databases need to be linked, unique and de-identified codes will be used. While these databases are distinct, they will reside on the same secured computer and transmission of this information will be entirely internal to the machine (occurring in memory). These databases are encrypted on disk and can only be accessed by the web server with a password possessed by the system administrators. De-identified but fine-grained and multi-dimensional data about individuals such as the Facebook is susceptible to de-anonymization attacks by intersecting and combining these data with other



datasets (Narayanan & Shmatikov 2008). To diminish the threat of such attacks, demographic and other personal information in this study is de-identified and stored on secured databases to make re-identification of individuals extremely difficult.

The experiments run on this website will be added via amendment before any experimentation occurs. Each experiment will have a designated investigator, who might not be currently listed on this protocol yet but will be included in any amendment. These investigators would only have access to a) the data gathered from their own experiments and b) the necessary relevant demographic data about only those individuals who participated in their experiments. Other investigators will only access anonymous ID of participants; they will not have access to names, email addresses or other identifiable information. For example, if a researcher is running an experiment, and they want additional demographic data on their participants that includes age, gender and number of Facebook friends. These values could be collected from the pre-existing Facebook database. However, the specific number of friends could be an identifiable feature. Therefore, the resolution of this feature would be thresholded or otherwise reduced to a level determined by the PI to be safe to qualify as deidentified. In this example, the exact number of Facebook friends (429) might be rounded to the nearest 50 (i.e., 400 friends) to de-identify the research participant. The researcher would only have access to this demographic data for the specific individuals who participated in their specific experiment. Each researcher would have to justify why they needed the demographic attributes captured from the Facebook profiles by our website for their analyses.

These measures allow the website to gather confidential, identifiable information in a secure fashion, and then only share it with researchers in a safe, controlled, deidentified manner.

References:

Narayanan, Arvid & Shmatikov, Vitaly. (2008). "Robust De-anonymization of Large Sparse Datasets." In Proc. 29th IEEE Symposium on Security and Privacy, Oakland, CA, USA. Pp. 111-125. IEEE Computer Society, 2008.

How and where will data be stored? When will data, including audiotapes and videotapes, be destroyed? If data is to be retained, explain why. Will identifiers or links to identification be destroyed? When? Signed consent documents must be retained for 3 years following the end of the study. Where and how will they be maintained?

Data will be stored on a secure server hosted by Amazon Web Services. The data on this server is encrypted and can only be decrypted by users possessing credentials to access administrative portions of the site. Administrators will have access to the databases to perform maintenance tasks. Principal investigators will not have direct access to the databases containing Facebook data, but will have access to a dashboard for preparing and monitoring experimental data.

Research participants will be able to access the website using only their Facebook ID. To the extent data is transmitted from the server to clients, communication is secured by HTTPS. In the future, a user account may provide a private web page where participants can see the history of their participation and performance in prior experiments, "points" or "badges" they have earned



from this participation, or other potential features. At this time, these pages and features have not been introduced and user accounts simply refer to the unique IDs and the permission to participate in experiments. Future addendums will describe research involving user accounts and pages in more detail.

All Facebook, experimental, link data and consent forms will be retained for the life of the website, and/or the length of the approval of this protocol, whichever is shorter, with the following exceptions.

1. If a participant asks to have their information deleted, all of their identifiable Facebook data will be deleted immediately. However, their anonymous experimental data will be retained, as its removal could adversely affect published and in-progress scientific results.
2. If a participant does not login to the website for a period of one year, his or her Facebook data is deleted from the database but his or her previously collected experimental data is retained.

**M. If your research is HIPAA-protected, please complete the following;
Individual Access to PHI**

Describe the procedure that will be used for allowing individuals to access their PHI or, alternatively, advising them that they must wait until the end of the study to review their PHI.

N/A.

N. Benefits

What benefits can the participant reasonably expect from his/her involvement in the research? If none, state that. What are potential benefits to others?

There are no individual benefits a participant can expect from his/her involvement in the research, except for possible enjoyment of the various experiments on the platform. The potential benefit to others is advancement in our scientific understanding of group behavior in psychology, sociology, political science, and computer science.

O. Attachments

Identify attachments that have been included and those that are not applicable (n/a).

	Copy of fliers, ads, posters, emails, web pages, letters for recruitment *
n/a	Scripts of intended telephone conversations*
	Copies of IRB approvals or letters of permission from other sites
XX	Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization *
	Debriefing Statement*
	Copies of all instruments, surveys, focus group or interview questions, tests, etc.
XX	Signed Assurance of Principal Investigator Form <i>(required)</i>



XX NIH Human Subject Training Certificate(s) *(required if not already on file at HSRP)*

**(Approved forms must be stamped by the IRB before use)*

P. Health Care Provision During Study

Please check the applicable line:

XX I have read the description of HIPAA “health care” within [Section 3.0 of the Policies & Procedures for Human Research Protection](#). I am not a HIPAA-covered health care provider and no health care will be provided in connection with this study.

_____ I am a HIPAA-covered health care provider or I will provide health care in connection with this study as described in [Section 3.0 of the Policies & Procedures for Human Research Protection](#). This health care is described above under “Study Procedures,” and the Informed Consent and Health Information Use and Disclosure Authorization form will be used with all prospective study participants.

If you have any questions about whether you are a HIPAA-covered health care provider, please contact Nan C. Regina, Director, [Human Subject Research Protection](#) at n.regina@neu.edu or (617) 373-4588.

Please return the completed application to: Nan C. Regina, Director
Human Subject Research Protection
960 Renaissance Park
Northeastern University
Boston, MA 02115-5000
Tel: 617.373.7570; Fax: 617.373.4595
n.regina@neu.edu

The application and accompanying materials may be sent as [email attachments](#) or in hard copy. A signed [Assurance of Principal Investigator Form](#) may be sent via fax or in hard copy.