Sample IRB

The following IRB was developed by Jean Amaral from Borough of Manhattan Community College as part of the Community College Libraries & Academic Support for Student Success (CCLASSS) project. For more information on the project and additional resources, please see https://sr.ithaka.org/our-work/cclasss-toolkit.

ITHAKA S+R

Initial Application
2018-0133
Jean Amaral

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1. Summary

Protocol Title

Community College Libraries and Academic Support for Student Success (CCLASSS)

Primary College	Borough of Manhattan Community College
PI relationship to CUNY	Full-time Faculty

Application Initiated By	Jean Amaral
Are you seeking an approval for a project that is lacking definite plans for involvement of human subjects (45 CFR 46.118)?	No
Research Type	Social Behavioral
Research Type	Social Behavioral
Are you seeking an exemption from IRB review?	Yes

Lay Summary

Through semi-structured interviews and surveys, the researchers will develop and assess a series of concepts for innovative library services with the goal of improving support of community college success.

Do you have a scientific protocol or a sponsors protocol?	No

![CUNY — The City University of New York]

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2. Summary - Exemption

Select all categories that apply. If all of your procedures do not fit within exemption categories, your protocol does not qualify for exemption from IRB review.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation

3. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Jean Amaral / Borough of Manhattan Community College	PI /		Yes		███████	
███████ LaGuardia Community College	Co-Investigator /				███████	
███████ / Temp Department	Co-Investigator /					
███████ / Queensborough Community College	Co-Investigator /					

4. Other Personnel

None

5. Research Sites

Name	CUNY
Sub-Location	LaGuardia Community College
Site PI	▮▮▮▮▮
Role of the site in research	9999999
Has IRB?	No
Permission Granted?	No

Name	CUNY
Sub-Location	Bronx Community College
Site PI	▮▮▮▮▮
Role of the site in research	9999999
Has IRB?	No
Permission Granted?	No

Name	CUNY
Sub-Location	Queensborough Community College
Site PI	▮▮▮▮▮
Role of the site in research	9999999
Has IRB?	No
Permission Granted?	No

Name	Northern Virginia Community College
Sub-Location	
Site PI	▮▮▮▮▮
Role of the site in research	data collection and analysis
Has IRB?	No
Permission Granted?	No

Name	Monroe Community College
Sub-Location	
Site PI	▮▮▮▮▮
Role of the site in research	data collection and analysis

Has IRB?	No
Permission Granted?	No

Name	Pierce Community College District (Washington State)
Sub-Location	
Site PI	██████████
Role of the site in research	data collection and anaylsis
Has IRB?	No
Permission Granted?	No

Name	Ithaka S+R
Sub-Location	
Site PI	████████████████
Role of the site in research	data collection and analysis
Has IRB?	No
Permission Granted?	No

Name	CUNY
Sub-Location	Borough of Manhattan Community College
Site PI	████████
Role of the site in research	9999999
Has IRB?	No
Permission Granted?	No

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6. Research Design - Overview

Research Purpose and Hypothesis

The vast majority of research on how to adapt library services to support new priorities has been conducted at four year colleges and universities. And, the definitions of student success used in these projects have often derived from higher education institutions, state boards of education, and the federal government, thus omitting the perspective of the student in what defines success. This project will take an important step to address these imbalances.This study is an exploratory qualitative analysis of the practices, perspectives, and needs of community college students in order to understand and determine the resources and services these students need to be successful. This information will be used to generate a series of concepts for services that community college libraries might seek to offer.

Research Design and Methodology

The research methodology includes semi-structured interviews with students which will be used to develop service concepts, and these service concepts will then be tested with a survey. Students will participate in one-on-one semi-structured interviews with a researcher. The interviews will be approximately 45-60 minutes and take place at a convenient location on campus or by telephone. These interviews will be conducted by Ithaka S+R Researcher ███████████████████ Ithaka S+R is a not-for-profit service that helps the academic and cultural communities serve the public good and navigate economic, technological, and demographic change. The research team will use the interview data to develop a survey testing service concepts that emerge from the interviews. The collected data from the seven participating community colleges will be analyzed thematically, and the findings will be released in a public research report on student perspectives, practices, and needs.

Retrospective Data Review ONLY	No

Funding Requested/Obtained	Yes
Will you obtain informed consent from participants?	Yes
Compensation for participation	Yes
Will participants incur any research related costs?	No
Is compensation available for research related injury?	No

Surveys or Questionnaires	Yes
Will the survey or questionnaire be self administered by the participants?	Yes
Do you intend to give feedback to participants based on survey/ questionnaire results?	No
Attach survey(s) / questionnaire(s)	

Title	Survey Information
Upload	CCLASSS-survey.docx

Interviews	Yes
Who will conduct the interview	████████████
Will any individual(s) other than the research personnel be present during the interview?	No
Attach interview questions	

Title	Interview Questions
Upload	CCLASSS-interview-protocol.docx
Observation	No
Audio or Video Recording or Photograph	Yes

Please be sure to insert template language regarding recordings and/or photographs in the consent document
Check all that apply

Audio Recording	Yes

List the procedures that will be recorded

Semi-structured interviews will be recorded.

State the purpose of recording

Recordings will be transcribed in order to complete thematic coding.

Will participants be permitted to review, edit and/or erase the recording?	Yes
Will participants be identified in the recording?	No
Who will have access to the recordings?	████████████
Video Recording	No
Photograph	No
Deception	No

Access to or use of pre-existing non-medical records, including student records	No
Access or use of medical records	No
Will participants be screened?	No

Prospective Biological Sample Collection and Existing Biospecimens	No
Drugs or Vaccines	No
Devices	No

7. Research Design - Procedures and Risks

Participant Group

List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.

Procedure	Semi-structured interviews will be conducted with three to seven students at each of the seven participating community colleges.
Where it will take place?	In office or other private room on campuses of participating institutions.
When it will take place?	Spring semester 2018, as scheduled with participants.
Frequency	Each student will be interviewed once.
Is procedure optional for participants?	Yes
Associated risk or discomfort	There are no known risks associated with participating in this study.
Anticipated severity of risk or discomfort	no anticipated risk
Expected frequency of risk or discomfort	not applicable
Risk reduction or mitigation method	not applicable

Participant Group

List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.

List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.

Procedure	Survey will be administered by email at the seven participating community colleges.
Where it will take place?	Online
When it will take place?	Fall semester 2018
Frequency	One time

Is procedure optional for participants?	Yes
Associated risk or discomfort	There are no known risks associated with participating in this study.
Anticipated severity of risk or discomfort	no anticipated risk
Expected frequency of risk or discomfort	not applicable
Risk reduction or mitigation method	not applicable

8. Research Design - Risks and Benefits

Does your research claim to present a therapeutic benefit to the participants?   No

Expected Direct Benefit(s)

Participants may experience benefits in the form of increased insight and awareness into their own practices and needs.

Benefit to Society

Community colleges nationwide will have access to two research reports which will support the development of new services to students: one on student perspectives, practices, and needs, and a second providing specific assessments of service models.

Will data safety monitoring be done?   No

9. Funding - Sources

Grant or Contract Title	Community College Library Support for Student Success
Grant or Contract Number	▮▮▮▮▮▮▮▮▮
Funding Status:	Funded
Grant/Contract PI:	▮▮▮▮▮▮
Department	Borough of Manhattan Community College
Division	
Phone	▮▮▮▮▮▮▮▮
Email	▮▮▮▮▮▮▮▮▮▮
Funding Source:	Institute of Museum and Library Services
Contact	
Funding Category:	Federal
Do the protocol and funding proposal match?	Yes
Identify the substantive differences	

10. Funding - Federal Details

Is CUNY the prime awardee and/or   Yes
coordinating center?

Please outline your procedures for oversight of the conduct of this research at the external collaborating sites:

The research at each site will be coordinated by the campus PI and conducted by Ithaka S+R. Oversight will be jointly shared between the CUNY lead, Jean Amaral, and the grant lead, Dr. Braddlee. Ithaka S+R will be in close contact with both the campus contacts and the leads as the research progresses.

Please outline your procedures for ensuring timely communication amongst the collaborating sites with regards to i) modifications to the protocol & related documents; and ii) unanticipated problems involving risks to participants or others:

The project team, which includes representatives of the seven colleges and Ithaka S+R, holds regularly scheduled conference calls, and also communicates frequently through a project team email distribution list.

  You will maintain with your research records for this study: Documentation of Federalwide Assurance (FWA) for each of the collaborating sites engaged in human participants research. Documentation of current IRB approval and IRB approved documents from the designated IRB of all collaborating sites engaged in human participants research. Collaborative agreements/contracts with all collaborating sites, when applicable

I certify   Yes

Will any participating sites or   Yes
individual investigators rely on
CUNY UI IRBs?

Attach letter from relying sites institutional official agreeing to comply with CUNY policies and procedures.

Attach executed IRB Authorization Agreement or Individual Investigator Agreement

11. Participants - Populations

Age Range(s)   18 years of age or older

Targeted Population(s)   CUNY Students

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12. Participants - Projected Enrollment
Please provide the upper limit of anticipated enrollment
Projected Enrollment   15,000

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13. Participants - Eligibility

Inclusion Criteria and Rationale

Approximately 500 students (random sample) at each participating institution will receive an email invitation to participate in the study. Students who are interested in participating will fill out a form to indicate their interest and availability. From those who indicate interest in participating, approximately 3 to 7 will be randomly selected to participate in the interviews. The data from the semi-structured interviews will be used to develop a survey. The survey will be sent to a random sample of 10,000 to 15,000 students at each campus, with an anticipated response rate of 15%. Students must indicate that they are 18 years or older to participate.

Exclusion Criteria and Rationale

Students must be at least 18 years of age to participate in the study.

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14. Participants - Recruitment

Method(s)   Broadcast emails

Outline the recruitment process in a step-by-step fashion

Approximately 500 students (random sample) at each participating institution will receive an email invitation to participate in semi-structured interviews. Students who are interested in participating will fill out a form to indicate their interest and availability. From those who indicate interest in participating, approximately 3 to 7 will be randomly selected to participate in the interviews. An email invitation to participate in the survey developed from the interview data will be sent to approximately 15,000 randomly selected students on each campus. The broadcast email text for the survey will be uploaded when the survey is developed in summer 2018.

Identify the group(s) to whom email will be sent

For the interviews, 500 randomly selected students on each campus. For the survey, 15,000 randomly selected students on each campus.

Indicate how you have access to these email addresses

Access will be through the campus institutional research offices.

Attach email text you will use

Type   Broadcast emails
Title   Recruitment Email

15. Participants - Consent

Documented informed consent and/ or parent or guardian permission   Yes

Are you requesting Broad Consent

Oral or internet based informed consent and/or parent or guardian permission   Yes

Waiver of Informed Consent Involving Public Benefit and Service Programs

Alteration of Informed Consent Involving Public Benefit and Service Programs

Documented informed consent and/or parent or guardian permission

Identify the research personnel who will obtain consent   Jean Amaral

Identify where and when consent will be obtained from potential participants

For the semi-structured interviews, consent will be obtained at the time of the interview. For the surveys, consent will be obtained online before participants begin filling out the survey. The interview consent form is attached. The survey protocol will be provided when the survey is developed after the data from the interviews has been analyzed; this is scheduled for summer 2018.

Attach Consent/Permission Document(s)

Title   Interview Consent Form

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16. Participants - Compensation

Type	Monetary
Amount	$50.00
Justification	Time
Description (Address the compensation schedule for participants that withdraw from the research protocol.)	For the semi-structured interviews, there is no compensation for non-participation, as the time spent would have been the interview itself.
When will participants be compensated?	End of each visit
Explain when	
Describe mechanism in place to ensure confidentiality when distributing compensation	Participants will receive an Amazon gift card at the end of the interview, which does not include any identification.

Type	Monetary
Amount	$100.00
Justification	Time
Description (Address the compensation schedule for participants that withdraw from the research protocol.)	As incentive to take the survey, students who complete will be entered in a raffle.
When will participants be compensated?	Other
Explain when	The raffle winners will be drawn after the survey has closed.
Describe mechanism in place to ensure confidentiality when distributing compensation	The collection of contact information for the raffle will be separate from the survey data.

17. Participants - Privacy and Confidentiality

Describe the mechanisms in place to protect the privacy of participants during recruitment, consent process and research procedures

Participants will sign informed consent forms but these forms will in no way be linked to the collected data because there will be no key that corresponds the participants to their responses. Informed consent forms will be stored as paper copies in a locked file cabinet only accessible to the investigators. Ithaka S+R will store digital copies on a private protected drive which will only be accessible to the Ithaka S+R project team and ITHAKA network domain administrators.

Describe the mechanisms in place to maintain confidentiality of participant data

Interviews will be recorded and transcribed, and only the investigators will have access to the recordings and transcriptions. Following the interviews, Ithaka S+R will store the recordings and transcriptions on a private protected drive which will only be accessible to the Ithaka S+R project team and ITHAKA network domain administrators.

How will you store participant data   Without any identifiers or codes

What will you do with the data once the research has been completed?   Retain data for three years, or longer when required by the study sponsor, then destroy it.

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18. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Interview Question(s)	CCLASSS-interview-protocol.docx	1	New	CCLASSS-interview-protocol.docx	02/02/2018
Email Text	CCLASSS-email-recruitment.docx	1	New	CCLASSS-email-recruitment.docx	02/02/2018
Informed Consent Document	CCLASSS-consent-form.doc	1	New	CCLASSS-consent-form.doc	02/02/2018
Survey(s)	CCLASSS-survey.docx	1	New	CCLASSS-survey.docx	02/02/2018
Curriculum Vitae	███████████	1	New	███████████	02/09/2018
Curriculum Vitae	███████████	1	New	███████████	02/09/2018
Curriculum Vitae	███████████	1	New	███████████	02/09/2018
Curriculum Vitae	███████████	1	New	███████████	02/09/2018
Curriculum Vitae	███████████	1	New	███████████	02/09/2018

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