Date: 4-25-2024

IRB #: IRB-FY2024-8734
Title: Network Adequacy and Market Competition
Creation Date: 3-7-2024
End Date:
Status: Approved
Principal Investigator: Daniel Waldinger
Review Board: New York University
Sponsor:

Study History

Submission Type Initial	Review Type Expedited	Decision Approved

Key Study Contacts

Member Daniel Waldinger	Role Principal Investigator	Contact dw120@nyu.edu
Member Jinglin Wang	Role Primary Contact	Contact jw5469@nyu.edu
Member Jinglin Wang	Role Investigator	Contact jw5469@nyu.edu
Member Jinglin Wang	Role Co-Principal Investigator	Contact jw5469@nyu.edu

Initial Submission

Screening Questions

*required

Are you requesting a ".118 determination?"

See the ? to the right for a description of a .118 determination. No human subjects activities may be conducted for a project given a .118 determination until the complete IRB protocol has been reviewed and approved by the IRB.

Do NOT select Yes if the protocol is not externally-funded or if the full protocol is developed and ready for IRB review.

- Yes
- ✓ No

*required

Does the study fit any of these criteria:

1. Involve the use of NYU Protected Health Information (PHI) subject to HIPAA;
2. Involve the use of NYU Langone Health clinical data (identified or de-identified);
3. Enroll NYU Langone Health patients, takes place within an NYU Langone Health facility, or uses NYU Langone resources or funding; *OR*
4. Engage investigators whose primary appointment is with GSoM and draw their salary from GSoM, including WSQ student investigators with GSoM advisors/faculty sponsors.

- Yes
- ✓ No

DO NOT SELECT. FOR INTERNAL IRB PURPOSES ONLY.

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*required

Is this a ***federally-funded, cooperative*** study requiring single IRB review under 45CFR46.114 ?

Any institution located in the United States that is engaged in federally-funded, cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The following research is ***not*** subject to this requirement:

1. Cooperative research for which more than a single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
2. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Yes

✓ No

Unsure

*required

Will your research be conducted under the auspices of NYU Washington Square (WSQ), including the Tandon School of Engineering and NYU in Brooklyn?

The NYU IRB reviews research only when conducted under an investigator's affiliation at NYU WSQ, e.g., dissertation research, research in which NYU WSQ receives funding, faculty-led research when conducted under their NYU affiliation.

✓ Yes

No

*required

Will potential participants be located in the United Arab Emirates (UAE) at the time of data collection, including online data collection in which participants are located in the UAE?

Yes

✓ No

*required

Will your study:

1. involve research (i..e, systematic investigation intended to contribute to generalizable knowledge) AND,
2. involve human subjects (i.e., involve obtaining information about a living individual via interactions/interventions *or* using identifiable, private information)?

(Please see IRB decision tree here).

Select Yes if you are unsure if it includes human subjects research and/or if you are required to obtain a formal Not Human Subjects Research determination (e.g., from an external funder or data repository providing access to data).

✓ Yes, the study involves human subjects research and/or it requires a formal Not Human Subjects Research determination from the IRB.

No, the study does not involve human subjects research.

*required

If this is an Initial submission to the NYU IRB for this study, has it been reviewed and approved by another IRB?

Yes

✓ No

*required

Will the study require NYC Department of Education IRB approval?

The NYC DOE IRB reviews studies conducted within NYC DOE schools, including charter schools, or that involve contacting individuals via their association with the NYC DOE (e.g., via DOE email addresses, staff at DOE central office) .

Yes

✓ No

*required

Do any research personnel have a conflict of interest (COI) related to this research?

Conflicts of interests are those circumstances in which an investigator's personal interests conflicts with, may affect, or has the appearance of affecting the protection of human subjects or the integrity of human subjects research

See the ? to the right for more information about what constitutes a conflict of interest.

Yes

✓ No

NYU Research Personnel

Add all engaged NYU research personnel to this section.

******Can't find a member of the NYU research team below? Have them register for a Cayuse Research Suite account here. After submitting the registration request, it may take up to three business days for names to appear in the search.******

---

*required

Primary Contact

If you are responsible for the completion of this form and are NOT the PI, please select yourself here to avoid being locked out of the application. Note that the Primary Contact will be included on most emails from the IRB about this study.

Name: Jinglin Wang
Organization: FAS - Economics
Address:
Phone:
Email: jw5469@nyu.edu

*required

Is this a student-led or postdoc-led project?

For instance, is the project being completed in fulfillment of a thesis or dissertation?

- ✓ Yes
- No

*required

Identify the student/postdoc:

Name: Jinglin Wang
Organization: FAS - Economics
Address:
Phone:
Email: jw5469@nyu.edu

*required

Student/Postdoc status:

Undergraduate

Masters

✓ Doctoral

Postdoc

*required

Principal Investigator

Name: Daniel Waldinger
Organization: FAS - Faculty of Arts and Science (FAS)
Address: , New York, NY 10012-2331
Phone: 2129928967
Email: dw120@nyu.edu

****** YOU HAVE IDENTIFIED THIS STUDY AS A STUDENT-LED OR POSTDOC-LED PROJECT. PLEASE SELECT THE NAME OF THE FACULTY SPONSOR AS THE PRINCIPAL INVESTIGATOR ******

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*required

Is the Principal Investigator (PI) a full-time NYU faculty member or professional research personnel (e.g., tenure/tenure-track faculty, continuing contract faculty, assistant/associate/senior research scientist)?

Select No if the PI has an appointment as an adjunct faculty or staff member/administrator. These appointments do not fit the criteria for PI status without approval from the department chair and/or supervisor.

✓ Yes

No

Co-Investigator

Can't find a member of the research team? Have them register for a Cayuse Research Suite account here. After submitting the registration request, it may take up to three business days for names to appear in the search.

Name: Jinglin Wang
Organization: FAS - Economics
Address:
Phone:
Email: jw5469@nyu.edu

Other Personnel

Can't find a member of the research team? Have them register for a Cayuse Research Suite account here. After submitting the registration request, it may take up to three business days for names to appear in the search.

*required

Please describe what role all personnel will have on the project.

Include the name(s) and responsibilities for each person. When describing responsibilities, do not use nouns or titles, e.g., PI, researcher. Instead, use action statements, e.g., obtain consent, distribute and collect surveys, analyze identifiable data.

Jinglin Wang will analyze data under the supervision of Daniel Waldinger. Daniel Waldinger will advise Jinglin Wang on the analyses performed but will not be directly performing any data analysis.

*required

Training in human subjects research ethics is required for all personnel. The only acceptable trainings are the CITI Social & Behavioral Basic/Refresher Course or the CITI Biomedical Basic/Refresher course.

Please affiliate with New York University in CITI. The IRB can confirm CITI training only for users affiliated with New York University. (See CITI)

In order for CITI training to display in Cayuse IRB, please ensure the email address in your CITI account matches the email address listed in Cayuse (typically netid@nyu.edu).

The training previously offered by NYU (NYU Human Subjects tutorial and NIH training) are outdated and no longer valid.

✓ Please confirm that all NYU research personnel have completed an acceptable CITI training course in human subjects research ethics.

*required

Are any external (non-NYU Washington Square Campus) investigators or personnel engaged in this research?

Generally, "engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research purposes. See OHRP Engagement Guidance for information.

External (non-NYU) personnel are subject to their own institutional review and/or local oversight requirements. Investigators are responsible for determining if other requirements apply and are encouraged to maintain documentation of any additional approvals/determinations for this study.

Do NOT select Yes if this study is **a federally-funded, cooperative study requiring single IRB review under 45CFR46.114 and NYU is serving as the single IRB.**

- [ ] Yes
- [x] ✓ No

Project Information

*required

Summary of the Research

Summarize the ***purpose*** and ***procedures*** of the proposed research using non-technical language that can be readily understood by someone outside the discipline.

This project studies how insurance network regulations affect the healthcare market in Colorado. To quantify the tradeoff between improving healthcare access, containing costs, and promoting competition, I will study how insurer market participation, networks, and prices respond to the regulation. First, I will use statistical methods to estimate the causal effect of network adequacy on various measures of market competitiveness in both the health insurance and the healthcare provider market. The results will be used to build and estimate economic models of consumer, insurer, and provider behavior. The estimated model will be used to simulate counterfactual policies to inform the design and regulation of healthcare markets in Colorado and beyond.

Funding or Other Support

*required

Is the proposed project being supported by any **external (non-NYU) funding** or has such funding been applied for?

- Yes
- ✓ No

*required

Is the proposed project being supported by an **NYU competitive research program** or has such funding been applied for?

- ✓ Yes
- No

*required

What is the name of the NYU department/program/fund sponsoring the competitive research program?

Department of Economics (C.V. Starr Center for Applied Economics and Center for Research in Applied and Theoretical Econometrics)

*required

Has/will the funding proposal be submitted through the NYU Office of Sponsored Programs (NYU OSP)?

Yes

✓ No

*required

Explain why the funding proposal is not being submitted through the NYU Office of Sponsored Programs:

For instance, it's an NYU internal grant that is not managed via Cayuse SP.
It is an NYU internal grant that is not managed via Cayuse SP.

If applicable, attach documentation.

For instance, attach documentation from the funder stating that it funds individuals directly, rather than going through the University. If this documentation is not available, then you do not need to attach a file.

*required

What is the title of the project as it appears in the submission for funding or award?

Quality Regulation of Insurance Networks with Endogenous Entry

*required

Attach the **complete** submitted grant/funding application:

Wang_Jinglin_CIVHCProjDescription.pdf

CRATE_Proposal_JinglinWang.pdf

*required

Please confirm that the information regarding human subjects research (methods, data collection, participants, etc.) in the funding proposal matches the information in this IRB protocol.

Yes, the information regarding human subjects research (methods, data collection, participants, etc.) in the funding proposal matches the information in this IRB protocol.

✓ No, the information regarding human subjects research (methods, data collection, participants, etc.) in the funding proposal does not match the information in this IRB protocol.

*required

Explain what information from the funding proposal does not match the IRB protocol and why there is not congruency.

In the funding proposal for CRATE, I stated that the fund would be used to purchase data from Washington. For reasons unrelated to the IRB protocol, the fund will instead be used to purchase similar data from Colorado.

*required

Will any part of the research be conducted with the collaboration of a site/organization/department not engaged in conducting the research?

Select 'Yes' if a department/organization/institution will assist with recruitment or enrollment of participants, such as having them distribute recruitment materials on your behalf or providing space to conduct research activities, including collaborating with NYU departments or offices.

Select 'No' if research activities may occur at an organization/site but you will not be collaborating with it to facilitate the research procedures, e.g., interviews at a coffee shop or in a city park.

Yes

✓ No

*required

Will any research procedures be conducted with participants located outside the United States?

Yes

✓ No

Data Collection & Procedures

*required

Will you be conducting secondary analysis of human subjects data?

Secondary analysis of data includes the use of information that is originally created for purposes other than the proposed research, e.g., educational records/grades, medical records, posts on Internet message boards or social media, existing human subjects research data from another study.

✓ Yes

*required

Will you be using any other form of data collection (e.g., surveys, interviews, observations) or research activity (e.g., treatment or intervention) besides the secondary analysis of data?

Yes

✓ No

No

Secondary Analysis of Data/Biospecimens

*required

What type of information/biospecimen will be used?

Private information is information that an individual can reasonably expect will not be made public. Generally, data sets that require specific permission from the data owner or are restricted access are considered "private."

✓ Private information

*required

Will investigator(s) *access* potentially *identifiable* information?

Select Yes if an investigator will access/view/use identifiable information at anytime, even if identifiable information is never recorded in a research dataset that the investigator is responsible for securing/maintaining.

✓ Yes

No

*required

Will investigator(s) *record* potentially *identifiable* information?

Select No if identifiable information is accessed but the research records will never include the data in an identifiable format, e.g., accessing identifiable medical records, but recording only de-identified data in a research spreadsheet. Select Yes if identifiable data will be recorded at any time during the research, even if the data are later de-identified, e.g., an investigator uses identifiable information to match two data sets for research purposes or an investigator receives and downloads a dataset with identifiers, even if it's later transformed to be de-identified.

✓ Yes

No

If applicable, attach a data security plan.

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data_security_plan.pdf

*required

Attach a data use agreement/letter from the data/biospecimen owner.

Most data use agreements (DUAs) are first drafted by the data owner; please contact the data owner to see if it requires such an agreement. For initial submissions, the DUA does NOT need to be signed; it can be a draft agreement from the data owner. If the data owner does not require a DUA, then upload an email/letter/website text from the data owner stating that a DUA is not required.

A data use agreement is not required if participants will provide prospective consent for the use of the data (e.g., obtaining consent from

students/parents to use their educational records). In these cases, attach a "dummy" document noting that participants will provide prospective consent for the use of their data.
DUA_draft_IRB.pdf

*required
Will the execution of the data use agreement be processed by NYU's Office of Sponsored Programming (OSP)/Research Contracts Office (i.e., Cayuse SP will be used to process the execution of the agreement)?

NYU's OSP *is responsible for processing the execution of most DUAs related to research studies. Please contact it at osp.agency@nyu.edu if you have any questions about executing data use agreements.*

✓ Yes

*required
What is the Cayuse SP proposal number used to process the execution of the agreement?

24-1426

No

Not applicable (e.g., there is no DUA or similar agreement that requires execution/signature).

*required
Please identify the source of the data/biospecimens, i.e., name of data/biospecimen owner.

Include the URL, if applicable.
Center for Improving Value in Health Care (https://civhc.org/get-data/co-apcd-info/)

*required
Please describe the nature of the data/biospecimens, e.g., type of information and/or specimens, types of identifiers.

If available, include a comprehensive list of data variables/fields. The IRB needs as detailed information about the dataset as possible to determine whether it includes identifiable, private information and the necessary data security procedures.

The CO-APCD is an administrative dataset that contains the near-universe of insurance enrollment and claims for residents in Colorado. For each individual in the sample, the data include information on their choice of insurance plan, the start and end dates of coverage associated with the plan, as well as the member's age (date of birth), gender, race, and location of residence (5-digit zip code). For each claim record, the data include information on the procedure filed, the total amount charged, the amount paid by the patient and the insurer, and the facility or provider associated with the reported service.

*required

Will the investigator *access* identifiable information from educational records covered by FERPA, e.g., final grades, exam scores?

Select Yes if the investigator will ever access/view/use identifiable educational records for research purposes, including those that they may hold in their possession as a course instructor, even if the investigator will not record any identifying information.

Yes

✓ No

*required

Were the data/biospecimens originally collected for research purposes, e.g., another research project, a research data repository?

Yes

✓ No

Public information

*required

Will NYU personnel handle any human biospecimens , e.g.,blood, saliva, hair, nail clippings?

Yes

✓ No

Description of Study Procedures

Complete the text box(es) below.

*required

For the secondary analysis of data, please describe:

- how you will gain access to the data and
- whether you will be combining data sets from multiple sources.

I will gain access to the data through a data use agreement with the Center for Improving Value in Health Care. The data will be combined with several other public datasets, including 1) data on population characteristics, such as the American Community Survey; 2) data on the characteristics of plans sold in different geographical markets, such as HIX Compare (https://hix-compare.org/); 3) data on provider characteristics, such as the CMS Hospital Provider Cost Report Data (https://data.cms.gov/provider-compliance/cost-report/hospital-provider-cost-report). The datasets will be combined using geographical identifiers, such as zip code or fips code, and provider identifiers, such as NPI.

Participants & Recruitment

Participant Population

*required

Participant Populations

Specify the participant population(s) to be included (check **ALL** that apply):

- Adults
- Children
- Students
- Subject pools
- ✓ Secondary data (research using collected data/specimens for purposes other than the proposed research)
- Individuals with impaired decision-making capacity, e.g., participants with dementia
- Individuals who are economically or educationally disadvantaged
- Prisoners
- Other population

*required

Will any materials be translated to a language other than English?

If any participant and/or parent/guardian/legally authorized representative cannot complete the applicable study procedures in English, then the appropriate materials must be translated to a language that is understandable to them.

- Yes
- No
- ✓ Not applicable to this study

*required

Explain why it is not applicable to this study:

For instance, there is no interaction with participants and they will not read or be read any documents, such as studies involving only participant observation or secondary analysis of data and consent will not be obtained.
There is no interaction with participants and they will not read or be read any documents as this study only involves secondary analysis of data and consent will not be obtained.

*required

Total number of participants:

Provide the **maximum total number** of participants (or number of participant records, specimens, etc.) for whom you are seeking NYU approval. ***The number of participants is defined as the number of individuals who agree to participate, i.e., those who provide consent or whose records are accessed, including those who complete the screening but are deemed ineligible or do not complete the study. Please overestimate the number of participants to avoid over enrollment.***
5,800,000

*required

What are the eligibility criteria for potential participants (i.e., inclusion and exclusion criteria)?

Address any criteria that will be used to determine if an individual may be included or excluded from the study. Examples include specific age ranges, country of birth or native language, medical status, grade in school, membership in a particular organization, marital or parental status. These criteria should relate to the study's scientific requirements and/or issues of safety; they should not relate to the recruitment procedures. For instance, if the study design does not require that individuals be NYU students but the recruitment procedures happen to target only NYU students, then being an NYU student should not be included as eligibility criteria.

If applicable, describe any quotas or stratification targets based on specific criteria, e.g., equal number of students and non-students.
Since I will be using an existing dataset at NYU (through a separate data use agreement), I do not have control over the sample of individuals included. The sample in this dataset contains individuals who purchased any commercial, Medicaid, or Medicare Advantage health insurance plans in Colorado from 2015 to 2018.

*required

What are the procedures for determining that participants meet the eligibility criteria?

Examples include recruitment material describing the eligibility criteria and having participants self-confirm meeting the criteria; having participants complete a screening survey; recruitment procedures occurring at locations or via mechanisms that would include only individuals that meet the eligibility criteria, such as asking an online recruitment platform to recruit only individuals that meet criteria; accessing records or using data collected for other purposes.

Provide enough details about the procedures so it's clear exactly how it will occur. If applicable, include the URLs for any screening surveys.

Per the above, since I will be using an existing dataset at NYU (through a separate data use agreement), I do not have control over the sample of individuals included.

If applicable, attach any materials that will be used to determine eligibility.

Examples include screening surveys or variables/field list from existing records (do NOT include the actual records themselves). Do not attach recruitment materials as they will be attached below.

*required

If applicable, will participants provide consent before any information is collected to determine if they are eligible?

For instance, if participants will complete a screening survey or if private records will be accessed, then will participants give prospective consent for this?

Yes

No

✓ Not applicable. (No information will be obtained about participants in order to determine eligibility).

Participant Recruitment

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*required

Describe how potential participants will be identified, e.g., advertising, individuals known to investigator, record review. Use of one's own students or employees is strongly discouraged. Explain how investigator(s) will gain access to the population, as applicable.

This study will not be recruiting participants as it only involves secondary analysis of data.

*required

Describe the recruitment process, including the setting in which recruitment will take place and the mechanisms used to recruit participants. Explain how the process respects potential participants' privacy and how it will minimize coercion or undue influence. ***Attach copies of proposed recruitment materials below, e.g., ads, flyers, website postings, recruitment letters, videos/digital recordings and oral/written scripts.***

This study will not be recruiting participants as it only involves secondary analysis of data.

*required

Recruitment Materials

********MUST BE PDF DOCUMENT WITH ONE INCH MARGIN AT BOTTOM OF EACH PAGE********

Upload copies of proposed recruitment materials, e.g., flyers, social media postings, email/letter text, oral scripts, Mechanical Turk HIT descriptions, study descriptions on Sona.

If no recruitment materials will be used, then upload a document explaining why not (e..g., study involves only secondary analysis of data). Note that almost all studies in which participants will actively complete procedures (surveys, interviews, etc.) and/or provide prospective consent for the secondary analysis of their information require recruitment materials.

no_recruitment_explanation.pdf

Compensation for Research Participants

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*required

Will participants receive compensation for participating in the research , e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement?

Examples of payments that are NOT compensation for participating in research are:

1. *Payments to groups/organizations/entities for assistance, such as for allowing researchers to recruit their members/employees/etc. or to use their facilities.*
2. *Subject referral fees, which are payments to individuals that refer people to participate in the study.*
3. *Payments to members of advisory boards (if these members are also receiving payments for completing activities as research participants then only these should be accounted for here).*

These payments should not be included here as compensation for participants. Instead, if the payments relate at all to the recruitment process, then they should be listed in the description of the recruitment procedures above.

Yes

✓ No

Consent/Assent/Parental Permission

*required

Will you obtain informed consent/assent from all participants or their legally authorized representatives?

Select 'Yes' if participants will be presented with consent/assent language, but they will not sign the consent/assent form (e.g., online surveys). This procedure constitutes obtaining consent/assent even if the participants do not sign a form. Do not select No if the study involves children and you are not obtaining parental permission (i.e., waiver of parental permission); this will be addressed in the research involving children section. Also, do not select No if the study involves deception/incomplete disclosure, as the request of waiver of consent/assent will be addressed on the use of deception/incomplete disclosure section.

Yes

✓ No

*required

Does your research meet **all** of the criteria below?

- The research involves no more than minimal risk to the participants.
- A waiver will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver or alteration of consent/assent.
- If identifiable private information or identifiable biospecimens will be used, then the research could not practicably be carried out without using the information or specimens in an identifiable format.
- If appropriate, participants will be provided with additional pertinent information after participation.

✓ Yes

No

*required

Explain how the research involves no more than minimal risk to the participants.

The research involves no more than minimal risk to the participants because it involves data that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained.

*required

Explain how a waiver will not adversely affect the rights and welfare of the participants.

The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.

*required

Explain why the research could not practicably be carried out without the waiver or alteration of consent/assent.

The research could not practicably be carried out without the requested waiver because it would require contacting all individuals in the data, and contact information is not readily available.

*required

If identifiable private information or identifiable biospecimens will be used without obtaining consent/assent, then please explain why the research could not practicably be carried out without using the information in an identifiable format.

If identifiable private information or identifiable biospecimens will *not* be used, then please write "Not applicable - No identifiable private information or biospecimens will be used".

The research could not practicably be carried out without using identifiable private information because the identifiers cannot be removed from the source data.

*required

Will the participants be provided with additional pertinent information after participation (e.g., debriefing)?

Yes

✓ No

*required

Explain why it is not appropriate to provide participants with additional pertinent information after participation.

We are prohibited from using the data to deduce an individual's identity or contact individuals, hence no participant will be provided with additional information.

*required

Please provide the rationale for the waiver.

- The research involves no more than minimal risk to the participants.
- A waiver will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver of consent/assent.
- The research could not practicably be carried out without using the information in an identifiable format.

*required

Indicate the process(es) and document(s) to be used in the study. *Provide copies of documents, as applicable.*

Please use the language and templates available under Forms & Guidance or the Consent Form Generator. Do not use old templates or examples of consent/assent/parental permission forms. Departmental/school subject pools may have their own templates; please contact the pool administrator for these templates.

Informed Consent (for adults)

Parental/Guardian Permission

Assent (for minors age 12 - 17 and persons incapable of consenting)

Oral Assent (for minors under age 12)

✓ **Consent will not be obtained for all participants.**

*required

Privacy of Participants

Describe the provisions to protect the privacy interests of the participants. For instance, describe the circumstances under which information will be obtained (e.g., at a person's home, in a public setting, via an existing data set/records, etc.) and the nature of the information, taking into account factors that may influence participants' expectations of privacy (e.g., age, gender, ethnicity, organizational affiliation, etc.).

Privacy refers to individuals' desires to control who has access to them and to their private information. Important considerations for protecting individuals' privacy include the methods used to recruit potential participants, the settings in which information will be collected, and the relationship of person(s) collecting or accessing the information to the individual (e.g., non-research relationship between the investigator and participant or the relationship among participants in a focus group). In focus groups, it is often appropriate for participants to introduce themselves so that participants can decide whether they want to disclose information to certain individuals.

This study only uses secondary data. See the data management section below for our data security measures.

Data Management (Security & Confidentiality)

*required

Explain the security and confidentiality measures for all phases of the data lifecycle (e.g., data collection, transfer/download, analysis, and final storage).

Be sure to address:

1. *The data security for all types of data (electronic, hard/paper copies, audio/video recordings, researcher notes, etc.).*

2. *If applicable, whether some data will **not** be kept confidential (e.g., participants will give explicit consent for their identities to be included in publications/presentations).*
3. *Whenever possible, name the specific devices/platforms that may be used (e.g., researchers' personal phone for audio recordings, NYU Box, NYU Qualtrics).*
4. *How identifiable data will be managed throughout the data lifecycle (e.g., Identifiable data collected on NYU Qualtrics in order to compensate participants, and the downloaded data file from Qualtrics will be immediately de-identified and the data will be deleted from Qualtrics after compensation).*
5. *Who will have access to study data (e.g., only NYU researchers, non-NYU researchers, leaders at collaborating site, etc.) and what types/forms of study data each group will have access to (e.g., only NYU researchers will have access to identifiable data and collaborating sites will be given only aggregate data).*
6. *If using a non-NYU platform/service to manage data, then describe the data security/management features of the platform/service. If applicable, provide a URL for the service's description of its data security procedures or attach a description of the services data security procedures under the Attachments section. This item does not need to be addressed for NYU supported platforms/services, such as* NYU Qualtrics, NYU Drive, NYU REDCap, NYU Box, NYU Zoom, NYU Secure Data Research Environment, etc.

Please review these NYU policies/resources: File Storage Services Comparison, Electronic Data and System Risk Classification Policy, Data and System Security Policy, Retention of and Access to Research Data, Data Services.

This study does not involve data collection as it only uses secondary data. The only type of data involved will be electronic data.

The data will be transferred and downloaded from the data provider via SFTP. The data will be stored and accessed using a Secure Research Data Environment (SRDE) set up by NYU's Information Technology Office. The data will be accessible only to the Principal Investigator and the Co-Principal Investigator. This study will not involve collaborators outside of NYU.

Once the project is complete, we will work with NYU Research Technology Services to destroy the data according to NYU's security policies and the requirements of the data use agreement.

*required

Will personally identifiable information be linked to the research data at *any time*?

Examples of personally identifiable information (PII) are names, contact information, platform assigned unique IDs (e.g., Prolific IDs or Amazon MTurk Worker IDs), IP

addresses, voice/visual recordings, and demographic information that may be combined to identify an individual (e.g., combining name of employer, age, and gender). ***This includes linking personally identifiable information (PII) to data via codes, even if the PII and data are stored in separate files.*** *Usually, if participants will be compensated, then PII is linked to study data in some way. For online surveys, this includes having participants complete a separate survey to provide their contact information, as the completion timestamp on the two surveys can be used to link data to contact information.*

When determining if PII will be linked to data, please consider the participant population and recruitment strategies, in addition to the data being collected. For instance, if participants are recruited from one specific organization then demographic information may be used to personally identify individuals at that organization versus if recruitment occurred from a larger population. If applicable, also consider whether any open-ended/free response questions could elicit responses that are unique to an individual and could be used to personally identify them (e.g., open-ended question asking for unique job title or interview questions asking about specific experiences that could be unique to an individual).

✓ Yes

*required

Please explain:

- what identifiers or potentially identifiable information will be linked to the data (e.g., names, contact information, demographic information that may be combined to identify an individual) and
- why identifiable data must be collected (e.g., to link individual responses for pre- and post-surveys, to compensate participants, demographic information is necessary to answer research questions).

The data include potentially identifiable demographic information, including date of birth and 5-digit zip code. This information is necessary to answer research questions. Demographic information, such as age and gender, will be used to characterize how different demographic groups value different insurance networks. 5-digit zip codes will be used to calculate the distance between an individual's residence and health care providers, which will also be used to characterize how people living in different places value insurance networks.

Moreover, as mentioned above, I am reusing an existing dataset at NYU, so I do not have control over the specific variables included.

No

*required

Indicate what will happen to the identifiable data at the end of the study.

✓ Identifiers permanently removed from the data and the data completely de-identified.

*required

Describe the procedures for de-identifying the data.

The DUA requires that all data be destroyed upon project completion, hence no identifiable data will be retained.

Identifiable/coded (linked) data are retained.

*required

May de-identified versions of the data be used for future research, shared with other researchers, or placed in a data repository?

As applicable, NYU expects researchers to make de-identified data available for future research, especially if the study is externally funded and the funder has data sharing requirements, unless there is a compelling reason to not share de-identified data or use it for future research. Note that select Yes here does not require you to share de-identified data, it only means that you will have the option to do so.

Yes, de-identified data may be used for future research, shared with other researchers, or placed in a data repository.

✓ No, data will not be used for future research, shared with other researchers, or placed in a data repository.

*required

Explain why the de-identified will *not* be used for future research, shared with other researchers, or placed in a data repository.

Per the above, the DUA requires that all data be destroyed upon project completion, hence no identifiable data will be retained.

*required

Will audio or video recordings that may include identifiers be transcribed by non-research personnel (e.g., transcription company)?

Yes

✓ No

General Data Protection Regulation

Applies to the European Union, European Economic Area, and the United Kingdom.

*required

Will data be obtained from participants *while they are in the* European Union (EU), the European Economic Area (EEA), or the United Kingdom (UK), including data collected from Internet surveys, OR will data be processed by an organization established in the EU/EEA/UK, such as data transferred to EU-based researchers?

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*Select No if all data will be collected from participants while they are **outside** the EU/EEA/UK and the data are not processed by an EU/EEA/UK organization, e.g., data collected from EU resident who is an NYU student in NYC. Also select No if the **only** data from individuals in the EU/EEA/UK will be publicly available. In this case, please see the* Guiding Principles on the Applicability of the GDPR when Using Publicly Available Data for Research; *these publicly available data are not human subjects data and do not require IRB approval.*

Yes

✓ No

Risks & Benefits

*required

Describe the degree and likelihood of any reasonably foreseeable risks or discomforts to participants that may result from participation in the study. If applicable, describe how these risks will be minimized.

Risks or discomforts vary greatly by study procedures, and include, but are not limited to such things as:

- *embarrassment or emotional discomfort from answering sensitive questions during a survey or interview;*
- *harm from a loss of confidentiality;*
- *motion sickness/simulator sickness;*
- *muscle or joint pain/soreness from exercise;*
- *pain, bruising, light-headedness and possible infection from a blood draw;*
- *allergic or other reactions caused by stimuli or devices (e.g., headaches, seizures, etc.);*
- *skin irritation from application of sensors or wearing activity trackers.*

Note that there's a risk of a breach of confidentiality any time personally identifiable information is linked to study data.

The primary risk is the breach of confidentiality as the data include personally identifiable information and protected health information, and we will minimize these risks by following data management best practices appropriate for data at this level of risk. See the data management section above for the data security measures we plan to take.

*required

Does any part of the study present more than minimal risk to research participants?

Minimal risk means that the probability and magnitude of harm of discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Yes

✓ No

*required

Describe the degree and likelihood of any benefits to the participants or others, which may ***reasonably*** be expected from the research.

Include both benefits that participants may directly realize and benefits to society from the knowledge gained. If the benefits may be different based on different groups (e.g., individuals are randomly assigned to a treatment vs. control group), then please note this.

This project will directly contribute to our understanding of the design and regulation of the health insurance market. Managed care plans make up a vast majority of plans in the commercial US healthcare market; with patients typically paying significantly less for care provided in-network, networks are a central characteristic of insurance plans. On the other hand, insurers have incentives to provide narrow networks to negotiate lower reimbursement prices, steer patients away from expensive providers, as well as attract low-utilization consumers, hence the rise in narrow networks. In response, there have been various federal and state policies aimed at limiting the presence of narrow networks through network adequacy regulations, yet the wide variation in these policies attests to a lack of consensus on whether and how to regulate insurance networks. This project will provide insights into the pros and cons of candidate policies; in fact, I plan to write a policy brief to communicate the insights from this project to policymakers and the general public.

Review Type

*required

Which review type do you believe your study qualifies for?

Under the revised Common Rule, the exempt categories have changed; some research which previously qualified for expedited review may now qualify as exempt or exempt requiring limited IRB review. Please review these categories when making a selection.

- ✓ Exempt (Administrative review)
- Exempt - Limited IRB review
- Expedited
- Full board (Please select only if your study does not qualify for exempt or expedited)
- Not human subjects research determination (Please only select if you are requesting that the IRB make a determination of not human subjects research)

*required

Which of the following exempt categories do you believe your research falls under? (Select all that apply).

Your research must include only activities that fall into one or more of the following categories. Research involving student subject pools in which students will receive course credit for participation do not qualify as exempt.

Please select 'Expedited' above if your entire study does not fall under one or more of the exempt categories or if it involves a student subject pool.

Category 1:
Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods.

Category 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 are met:** (*Please select all conditions that apply)*

(i) The information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through the use of identifiers linked to the subjects; or

(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.

The following restrictions apply to exempt category 2:

- *It may be applied to research with children only if the research is limited to observation of public behavior when the investigator does not participate in the activities being observed or to educational tests.*

Category 3:
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording***if the subject prospectively agrees to the intervention and information collection*** and **at least ONE of the following criteria is met** (select all that apply):

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(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.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

The following restrictions apply to exempt category 3:

- *It may not be applied to research with children.*

Category 4:

✓ Secondary research uses of identifiable private information or identifiable biospecimens, **if at least ONE of the following criteria is met:**

*required

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under
✓ 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category 5:

Research and demonstration projects that are conducted or supported by a ***Federal department***

or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 6:
Taste and food quality evaluation and consumer acceptance studies:
(*Please select all that apply)*

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

*required

Describe how the proposed research meets the criteria for exemption.

Reference the category or categories and why the research meets the criteria for the categories' corresponding requirements

The research involves only analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purpose of "research" as defined at 45 CFR 164.501.

Attachments

Research Involving Prisoners

Recruitment & Consent/Assent/Parental Permission

Recruitment material(s)

no_recruitment_explanation.pdf

Other Materials

Other attachment(s)

Data security plan

data_security_plan.pdf

Data use agreement and\or letter from owner of the data granting access

DUA_draft_IRB.pdf