Cornell University
Office of
Research Integrity and Assurance

East Hill Office Building, Suite 320
395 Pine Tree Road
Ithaca, NY 14850
Phone: 607-254-5162
Fax: 607-255-0758

Request For Exemption From IRB Review

Part 1 - Administrative Information

1. Title of protocol

Attitudes to Health Data Privacy and Quality

2. Contact information

2.1. Principal Investigator (PI) (Please refer to the IRB policy on PI Roles and Responsibilities.)

Name	Lars Vilhuber
Net ID	lv39
Email address	lars.vilhuber@cornell.edu
College/Division	ILR School
Department/Unit	Economics Department

Status ☐ Undergraduate Student ☐ Graduate Student ☐ Post Doctoral Fellow ☐ Faculty ☒ Staff

2.2. Co-PIs and members of the research team:

Name	Email address	Cornell/ Non Cornell	Net ID (if Cornell)	College and Dept (if Cornell)	Name of organization (if Non Cornell)	State and Country (if Non Cornell)
Ian Schmutte	schmutte@uga.edu	Non Cornell			University of Georgia	GA, USA
John M. Abowd	john.abowd@cornell.edu	Cornell	jma7	ILR/Econ		
					Add	Remove

3. Funding information

3.1. Is this research being funded by an external funding agency? ☒ Yes ☐ No

3.1.1. External funding:

Name of funding agency	Sloan Foundation
Sponsor's Project ID number	G-2015-13903

Part 2 - Exemption Category Self-Assessment

While ORIA and/or the IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are asked to make an initial determination of the appropriate exemption category. Please select all the categories that apply from the list below.

Note: Research projects involving prisoners or the collection of biological samples cannot be granted exemption.

☐ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: regular and special education instructional strategies, or effectiveness or comparison of instructional techniques, curricula, or classroom management methods.

☐ (2) Research involving one or more of the following:

i. Educational tests (cognitive, diagnostic, aptitude, achievement):

a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

ii. Survey or interview procedures (*this exemption category does not apply to research activities with minors/children*):

a. If the information is recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

iii. Observation of public behavior:

For minors/children: Observation of public behavior of minors is eligible for exemption only if the researcher **does not** participate in the activities being observed.

For non-minors: Generally considered exempt from IRB review as follows:

a. If the information is recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

***Note:** Risks of criminal or civil liability, or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB staff based on experience, past precedent and bench marked best practices. The IRB staff welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, the research is not exempt.

Note: ***Exemption category #2 does not apply to research with children, unless the research is exclusively limited to activities described in 2.i (educational tests) and/or 2.iii (observation of public behavior and the investigators do not participate in the or manipulate the activities being observed).***

☐ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, but is not eligible for the above exemption (2), can be exempted if the research participants are **elected or appointed public officials or candidates for public office**, or federal statute requires that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ (4) Research involving the collection or study of existing *(i.e., existing before the request for exemption is submitted to ORIA to determine whether the research is exempt)* data, documents, records, pathological specimens, or diagnostic specimens:

i. If these sources are publicly available; OR

ii. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

****Example:** A PI who receives restricted access data, but stores the data in a secure environment such as the Cornell Restricted Access Data Center (CRADC), may be eligible for exemption under this category if s/he is not recording identifiable private information into her/his own research records, or is not merging datasets that may lead to identification of individuals. However, PIs should be advised that the owner of the dataset or funding agencies may have their own policies requiring IRB review.

☐ (5) Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and are designed to study, evaluate, or otherwise examine public benefit or service programs, 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.

☐ (6) Taste and food quality evaluation and consumer acceptance studies:

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.

Part 3 - Study Design, Methods and Procedures

1. Type of project/study: Please select ALL of the categories of work that apply to this proposed project.

☒ Active collection of data (not human biological materials or physiological data)

☐ Use of existing data (not human biological materials)

☐ Use of existing human biological materials

2. Please provide a lay summary of the study, including the purpose and the research questions and hypothesis to be evaluated.

The purpose of the survey is to elicit preferences relative to the quality of health care services as a function of sharing of data. The setting is a hypothetical setting - no information on actual health care services or health status are collected.

3. Please describe briefly how this study will contribute to existing knowledge in the field.

The tradeoff between privacy and data accuracy is the an important policy-setting parameter, for which very little information is available. Our previous research relies on a single setting. This survey is designed to validate, using a different setting, some of our prior results.

4. Active collection of data (*not human biological materials or biomedical procedures*).

Please select ALL the methods of data collection that will be employed in this study (select all that apply)

- ☐ In person interviews
- ☐ Paper surveys
- ☐ Telephone surveys
- ☒ Internet surveys (including online and email based data collection)

Please refer to IRB SOP on Computer- and Internet-based Human Participant Survey Research for guidance and requirements, including consent language and security considerations.

Please provide the name of the survey service provider

Google Consumer Surveys

- ☐ Use of Social Networking Sites
- ☐ Data collected using other communication/electronic devices (e.g., cell phones, pagers and texting devices)
- ☐ Observation
- ☐ Cognitive or behavioral measures, including daily diaries (Note- if surveys will also be administered, please select the appropriate option above.)
- ☐ Focus groups
- ☐ Audio/Video recording
- ☐ Anthropometric measures (e.g., height, weight, waist circumference, etc.)
- ☐ Self health monitoring (e.g., pedometers, food diaries, etc.)
- ☐ Other activities or interventions

Please include all applicable survey instruments, scripts, directions, etc., for IRB review.

Please provide details of all the procedures selected above. If none are selected, enter N/A.

See attached PDF.

Please select ALL the geographical locations where data will be collected (select all that apply)

- ☒ New York State
- ☒ Other US territories and states, specify

Nationwide

- ☐ International location, specify

Please select ALL the specific locations where data will be collected (select all that apply)

- ☐ Participants' homes
- ☐ Elementary, secondary or high school, specify
- ☐ Cornell campus, specify location

☐ Other university campuses, specify

☐ Hospitals, specify

☐ Community clinics, specify

☐ Prisons/halfway houses, specify

☐ Nursing homes, specify

☐ Other locations not indicated above, specify

Part 4 - Participants, Recruitment and Compensation

1. Please indicate the estimated number of participants you plan to recruit.

1250

2. Please provide the age range of the participants.

18 and older

3. Please select all the categories of participants that will be included in your study.

☐ Healthy adult volunteers
☐ Children under 18
☐ Employees of the investigating group
☐ Cornell students
☐ Cornell employees
☒ None of the above

Please describe your participant pool:

General US population, 18 and older.

4. Please select all of the tools that you plan to use to recruit your participants.

☐ Flyers
☐ Notices
☐ Mailers (U.S. Post)
☐ Online Advertisements
☐ Email
☐ Use of Internet social media or online networking sites

- ☐ TV, radio, print advertisements
- ☐ Cornell participant pool recruiting methods (such as Sona Systems or other Cornell-affiliated web-based participant pool management software)
- ☐ Face to face public intercept
- ☐ Presentations at meetings
- ☒ Other (Please describe below)

Google Consumer Surveys

Please include copies of all recruiting and advertising material that you propose to use.

Please refer to IRB policy on Recruitment and Payment of Human Participants.

5. Please describe each recruitment method to be used.

See attached document.

6. Describe the inclusion or exclusion criteria for participants as applicable in this study.

See attached document.

7. Will participants be compensated for their participation? ☒ Yes ☐ No

Please explain:

Google Consumer Surveys participants either get access to micro-paywall news articles, or credits in the Google Play Store. We pay Google Consumer Surveys. We do not pay participants directly.

8. Please describe the tasks that the participants will be asked to perform for each phase of the study.

Fill out a short (3-question) questionnaire.

9. Please provide an estimate of the time commitment from each participant for each phase of the study.

less than 5 minutes.

Part 5 - Privacy and Confidentiality

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

- ☐ Name
- ☐ Date of birth
- ☐ Mailing or email address
- ☐ Phone or fax numbers
- ☐ Social Security number
- ☐ Medical records
- ☐ License, certificate or Vehicle ID
- ☐ IP address

☐ Biometric identifiers

☐ Photos/images/audio recording

☐ Signatures, handwriting samples

☐ Any unique identifier not mentioned above:

☒ No member of the research team will have access to any personal identifiers. *This option is valid only if none of the other options in this question are selected.*

Part 6 - Informed Consent Process

Please refer to the IRB policy on Informed Consent Options, Processes, and Documentation

Please indicate the informed consent process(es) and/or document(s) to be used in the study. Click here for a Consent Template that you can modify to use for your study. Check all that apply. ***Provide copies of documents, as applicable.***

☐ Not Applicable (existing data or specimens)

☐	Informed Consent – form	☒	Informed Consent – oral script/online/unsigned
☐	Assent (participants under 18) – form	☐	Assent – oral script/online/unsigned
☐	Parental Permission – form	☐	Parental Permission – oral script/online/unsigned
☐	Translated Consent/Assent – form(s), script(s), etc.	☐	Other – please explain below
☐	Debriefing script		

Describe the consent process. Explain when and where consent will be obtained:

See attached PDF

Part 7 - Financial Conflict of Interest Disclosure

Cornell Policy 1.7 Financial Conflicts of Interest Related to Research requires that personnel conducting research involving human participants at Cornell must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict be managed prior to their engagement in the research with human participants. Significant financial interests include:

- An equity interest in an external entity that, when aggregated for the investigator and the investigator's spouse/ same sex partner and dependent children over the past 12 months and expected over the next 12months exceeds $5,000 in value, or represents more than 5% ownership interest.
- Salary, royalties, or other payments from an external entity that, when aggregated for the investigator, the investigator's spouse/same sex partner and dependent children over the past 12 months and expected over the next 12 months are expected to exceed $5,000.

1. **Have all Cornell faculty listed on this protocol (including faculty supervisor)** completed the Annual Disclosure for your external commitments and financial interests as required by Cornell Policy 1.7? ☒ Yes ☐ No

2. **Have all Cornell faculty listed on this protocol (including faculty supervisor)** disclosed all significant financial interests (as described above) that are reasonably related to this research project? ☒ Yes ☐ No

3. **For all personnel listed on this protocol:** Do any of the personnel, their spouses/same sex partners, or dependent children have any significant financial interests that are reasonably related to this research? ☐ Yes ☒ No

4. **For all personnel listed on this protocol:** Do any of the personnel, their spouses/same sex partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors or supports this research? ☐ Yes ☒ No

If you answered "Yes" to either #3 or #4, please contact Cornell's COI office at coi@cornell.edu for guidance on next steps regarding disclosure, review of the financial interest and resolution of any real or apparent conflict of interest. The IRB is not able to review this project until it has been determined by the COI office that no investigator involved in this research activity has a conflict of interest related to this research.

Reminder Check List

☒ Include all applicable survey instruments, scripts, directions etc. for IRB review.
☒ Include copies of all recruiting and advertising material that you propose to use.

You have now completed this form. Please review it to ensure that it is filled out completely and accurately. Please save this form and proceed to the signature page for submission instructions. If you have any questions or need assistance, please contact the IRB staff.

Phone: 607-254-5162
Email: irbexemptions@cornell.edu

Signature

This page is to be signed by the principal investigator. If the principal investigator is an undergraduate or graduate student, the faculty supervisor must also sign in the lower box.

OPTIONAL: You may submit an electronic copy of this application by clicking on the attestation box below and entering your name and today's date. After clicking on the attestation box, please save a copy of the form before emailing it to irbexemptions@cornell.edu. The email submission must come from your Cornell email account.

Principal Investigator

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.

☒ Attestation of Principal Investigator

Lars Vilhuber	Oct 4, 2017
Name / Signature of Principal Investigator	Date