

Upload this form with your eIRB submission. This form serves as the Protocol for applicable projects.

Contact the Tufts Health Sciences IRB office with any questions about whether to use this form or how to complete it at IRBoffice@tuftsmedicine.org or (617) 636-7512.

- Some projects do not involve Human Subjects as defined by [45 CFR 46.102\(e\)](#). Analysis of Coded or De-Identified data/specimens often does not involve Human Subjects.
- At Tufts, only the IRB may make the determination that a project does not constitute human subjects research; an investigator must not make this determination. This form will be used to assist the IRB with this determination. **Completing the form does NOT guarantee a determination of Not Human Subjects Research.**
 - If the IRB determines that this project meets the definition of Human Subjects Research (or that it does not meet the definition of Research at all), a different protocol form may be required.
- This form serves as the Protocol for Not Human Subjects Research projects, so a separate protocol document is not required. Section A will help you determine whether to use this form or a different protocol form
- This form must be completed by or reviewed by the project's Principal Investigator before it is submitted to the IRB.

Principal Investigator (PI): Shikhar Shrestha, PhD

Project Title: Impact of COVID-19 on ADHD-related health expenditures using MEPS dataset

Section A: Choosing the Right Form

1. Is the project a systematic investigation designed to develop or contribute to generalizable knowledge?

Systematic: Having or involving a system, method, or plan

Investigation: A searching inquiry for facts; detailed or careful examination

Generalizable: Universally or widely applicable (*i.e. not only applicable to Tufts*)

- No:** Instead of this form, use [Form 13: Non-Research Projects](#) or the [Quality Improvement / Quality Assurance Self-Assessment Tool](#).

- Yes:**

2. Are Tufts employees or agents assisting or collaborating on **another institution's study**, or are you **conducting your own** study by analyzing data/specimens provided by the other institution?

Employees or agents of Tufts includes staff, students, contractors, volunteers, or others, *regardless of whether the individual is compensated*, if they act on behalf of the institution, exercise institutional authority or responsibility, or perform institutionally designated activities.

- Conducting your own study:**

3. Are you interacting or intervening with living humans in order to collect information about them?

Yes

No

Interaction: Communication or interpersonal contact

Intervention: Physical procedures or manipulations of individuals or their environment

4. Will you access private, identifiable data or specimens of living humans?

Yes

No

Private information: Information which meets either definition below:

- Data provided for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record, **OR**
- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place

Identifiable information or specimens: the investigator (or the investigator's collaborator/s) can readily ascertain the identities of the individuals to whom the information or specimens belong.

Please note: TRDW identifiers (from CTSI's Tufts Research Data Warehouse) count as identifiable.

BOTH No: [Click here](#) to skip to Section B.

EITHER Yes: This project is Human Subjects Research.

Instead of this form, submit a full **Protocol** (see [instructions for Expedited & Full Committee Review](#)) or a **Form 7** (see [instructions for Exempt Review](#)).

5.

Collaborating on another institution's project:

6. Will researchers at **any** institution(s) interact with subjects and/or access private, identifiable data or specimens?

No: Continue to Section B.

Yes:

7. Is this a federal award where Tufts is *directly* receiving federal funding? (i.e. *not a subcontract*)

Yes: Tufts is engaged in Human Subjects Research.
Instead of this form, submit a full **Protocol** (see *instructions for Expedited & Full Committee Review*) or a **Form 7** (see *instructions for Exempt Review*).

No: Instead of this form, use [Form 15: Engagement](#).

Section B: Study Information

Research involving secondary analysis of coded private information or de-identified data/samples are not considered human subjects research if Tufts investigators (or the investigators' collaborator/s) cannot readily ascertain the identities of the individuals to whom the data or samples belong.

Note: If the *only* identifiers that Tufts investigators or collaborators can access are dates, age, state, city, and/or zip code, then the data or samples are generally not considered readily identifiable.

1. Describe the activities and intended purpose of the project: See attached
2. Describe which activities will take place at Tufts University Health Sciences, Tufts Medical Center, Lowell General, and/or MelroseWakefield (specify which institution/s): Tufts University Health Sciences
3. What is the source of the data/specimens? Medical Expenditures Panel Survey
4. What purpose were the data/specimens **originally** collected for? (e.g. clinical care, a previous research study) MEPS is the most complete source of data on the cost and use of health care and health insurance coverage.
5. I confirm that Tufts investigators will NOT have any interaction or intervention with study subjects for research purposes
6. I confirm that Tufts investigators will NOT have access to the code linking the data/specimens with identifying information, if any code exists

7. Are you receiving de-identified data from [CTSI's Tufts Medical Center Research Data Warehouse \(TRDW\)](#)?

- Yes, and I confirm I will only receive a unique identifier created for my study, and not the TRDW identifier.
 No

*If you will receive the **TRDW identifier** or if CTSI is doing a **manual chart review** for this study, switch to the [Form 7](#). If you are unsure how to respond to questions about CTSI, please discuss with CTSI Informatics before submitting this form.*

8. Is the data publicly available? (Note: data is **not** considered publicly available if a login or data use agreement is required to access it, or if it needs to be purchased.)

- Yes, and confirmation of this can be found on the following webpage or attachment:
 No, and I am including a completed [Letter of Support Form – Providing De-identified Specimens or Data](#) from each source of the data/specimens.
- A **dated** policy memo confirming the points on the Letter of Support Form may be acceptable for institutions that routinely provide data or specimens to outside researchers.
- No, I am only requesting de-identified data from [CTSI's Tufts Medical Center Research Data Warehouse \(TRDW\)](#). A letter of support is NOT required from TRDW.

Section C: Submission Instructions

Detailed instructions for eIRB can be found on the [eIRB Submission Worksheet](#), the [Step-by-Step Guide to Submitting a New Study](#), and on <https://viceprovost.tufts.edu/eIRB-Tips-HS-IRB-Studies>

- **Question #4** on the Basic Study Information page is “*What kind of study is this?*” Choose “Single-Site Study” if a single Tufts institution is the only institution involved. Choose “Multi-Site/Collaborative” if more than one institution is involved.
- **Question #5** on the Basic Study Information page is: “*Will an external IRB act as the IRB of record for this study?*” Choose **No**, even if another IRB has reviewed and approved the research. This question is asking whether Tufts will need to formally cede review to another IRB with a reliance agreement. If this project is not human subjects research, a reliance agreement will not be necessary and will lead you to the wrong submission type.
- **Attach this form in place of a Protocol** (at the bottom of the Basic Study Information page). You do not need to include a full Protocol.
- Attach all **letter of support forms** and other **supporting documents** on the Local Site Documents page.
- After you click Finish, remember to **click ‘Submit’** on the left side of the study workspace. This button will only show up for the PI (or PI Proxy if one is assigned.)

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IRBOffice@tuftsmedicine.org or (617) 636-7512!