



RESEARCHER INFORMATION

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|---|--|
| Principal Investigator Name | Gretchen Brion-Meisels |
| Affiliation (check all that apply) | <input checked="" type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Post-Doc <input type="checkbox"/> Undergraduate <input type="checkbox"/> Extension School Student <input type="checkbox"/> Staff <input type="checkbox"/> Visiting Scholar <input type="checkbox"/> Other (specify): |
| Faculty Sponsor (if PI is not PI Eligible) | |
| Other Advisor Name (if applicable) | |

STUDY INFORMATION

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| Study Title | A study in engaging youth, school and community in participatory action research in Lowell, MA in support of the Portrait of a Graduate initiative. |
| ESTR Number | |
| Version Number | May 7, 2020 |
| Is this a re-submission of a previous Harvard IRB-approved study that has been closed? | <input type="checkbox"/> Yes - Include previous IRB submission # here: <input checked="" type="checkbox"/> No |

1. FUNDING INFORMATION

- 1.1 Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?
- Yes
 No
- 1.2 Is your study funded (or will it be) by the National Institutes of Health (NIH)?
- Yes
 No **(please go to next section)**
- 1.3 Does your study meet the NIH definition of a [“Clinical Trial”](#)?
- Yes
 No

2. RESEARCH COLLABORATIONS AND LOCATIONS

LOCATIONS

Locations refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.



2.1 Where will this study take place?

- Harvard University
- At another location in Massachusetts
- In another US state (*see below*)
- Internationally (*see below*)

If you chose “in another US state” or “Internationally” describe the laws that will need to be considered:

Please ensure that what you have marked above matches what has been indicated in the ESTR SmartForm, section “Research Locations.”

2.2 Do you plan to obtain data from individuals located in the European Economic Area (EEA)*?

- Yes – Please go to next question
- No – Skip to #2.4

If “YES” the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click [here](#) for more information.

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway, and Switzerland. Note that this regulation may also apply to data obtained over the internet.***

2.3 Will data collected from individuals located in the EEA include any of the following? (mark all that apply)

- Racial or Ethnic Origin
- Political Opinions
- Religious or Philosophical Beliefs
- Trade Union Membership
- Sexual Orientation
- Data concerning a person’s sex life
- Biometric Data
- Genetic Data

2.4 Are there any U.S. state laws, international laws, or other laws that the IRB will need to consider when reviewing this study?

- Yes (*see below*)
- No

If “Yes” describe the laws that will need to be considered:

Laws that apply to public schools (e.g., FERPA) would apply here. We will also have to follow mandated reporting guidelines, as outlined by the state of Massachusetts.

2.5 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source*



of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.

Yes (*see below*)

No

If “Yes” describe and if available, upload any permission documents to the ESTR SmartForm section “Local Site Documents.”

Permission will need to be obtained from the Lowell Public School’s superintendent’s office and school committee before we collect any data. A partnership letter is attached, to indicate their interest in this work.

2.6 Are there any community or cultural differences for the local population of participants that require consideration? *For example, cultural or gender dynamics or social structure considerations.*

Yes (*see below*)

No

If “Yes” describe:

COLLABORATIONS/SITES

Collaborations, known as “sites” in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.

2.7 Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.*

Yes

No (**skip to next section**)

2.8 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?

Yes

No (**skip to next section**)

2.9 Will these collaborators receive their own IRB review?

Yes, all will receive their own IRB review (skip to next section)

No, none will receive their own IRB review

Some will receive their own IRB review and some will not

2.10 Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record (“Reviewing IRB”) for that institution’s or that researcher’s activities on the study?

Yes

No (*see below*)

If you chose “No” describe the compliance/ethical oversight that this researcher will have in place:

2.11 If the Harvard University Area IRB will be providing review for the non-Harvard affiliated collaborating researchers, indicate which institutions they are affiliated with and their role and activities on this study (are they involved in recruitment, data collection, analyzing data, etc.) Add additional lines as necessary.



| Name | Institution | Role on Study | Description of Activities that They will be Conducting |
|------|-------------|---------------|--|
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| | | | |

3. STUDY TEAM QUALIFICATIONS AND TRAINING

3.1 Describe the Principal Investigator’s experience with the proposed research procedures, population, and local context.

I have experience both as an educator working with middle school students and a researcher in urban schools. I worked as a middle school humanities teacher in the cities of Baltimore, MD, Cambridge, MA, and Berkeley, CA, between 1999 and 2007. In this capacity, I communicated daily with middle school students of multiple cultural, socioeconomic and familial backgrounds. In addition, as a teacher I was involved in student support processes regularly, often working to connect with school-based mental health practitioners and staff members to support the complex needs of my students. Between 2005 and 2007, I was also involved in organizing a case-management system for a middle school in Berkeley, CA; in this capacity, I worked with students across the school in need of universal learning supports.

Over the past 12 years I have engaged in educational research at the Harvard Graduate School of Education. I have conducted research in many different elementary, middle and high schools around the topics of teacher-student relationships, school culture/climate, student supports, learning supports, bullying prevention and social emotional learning. These studies have been related to both student support/success and organizational equity/inequity. In 2009, I conducted a small photovoice study with middle school students at two urban middle schools; here, I looked at the learning supports that students identified as helpful with school, and then conducted interviews with a subset of students to better understand what “worked” in terms of adult support. In 2011, I conducted a collaborative project with a group of adolescents in a nearby city, looking at the same topic. This project mirrored Youth Participatory Action Research, in that the students and I collaborated in the study design, data collection and data analysis. My dissertation involved a secondary analysis of this data, where I also interviewed the youth researchers about the process itself.

Between 2015-2019, I collaborated with an educator working with over-age and under-credited youth at a local public high school. Between 2018 and 2020, I have been working with educators from three districts in the Boston area, collaborated with educators who are conducting their own CPAR projects. As such, I have already done three years of work with youth similar to that which I am proposing here.

3.2 Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.

There are two groups of people who will be working on this critical participatory action project (CPAR): educators and community partners. For the purpose of my research, I consider both groups to be “participants” because I am collecting data on their experiences with the project. With that said, these folks are also study staff, to some degree, because they will be trained in research methods and they will be implementing their own research studies. As a part of our work, I will be providing some basic training in research ethics for both groups of people.



Educators will ultimately bound by the ethical code of the teaching profession, as well as the rules of their organization, but they will work together to balance these requirements with the ethics of being a researcher.

Community partners will ultimately be bound by the ethical rules set out in their organizational policies; but, again, they will work together with me to balance these requirements with the ethics of being a researcher.

Both me and two members of my research team (TBD) will be looking at data collected from the teacher and youth researchers, which are the data of concern in this study of the process of CPAR. However, if any of the educator or community partners want to collaborate on this part of the project, they will be invited to do so. **In that case, I would de-identify the data before sharing it with them.**

- 3.3 Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?

Yes (*see below*)

No

If “Yes” describe:

4. RESEARCH PURPOSE

- 4.1 Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.

The purpose of this research is to amplify the voices of marginalized youth, parents and educators in a small, urban school district in the Northeast. The project will engage community partners (educators, adults & youth) in the process of critical participatory action research (CPAR). CPAR is an approach to research where a university researcher partners with community members to investigate questions of interest to these local community members. In this case, the CPAR project will look at how different community members visualize and imagine what they dream for graduates of their district.

Critical participatory action research (CPAR) is a form of critical, collective inquiry that provides youth and adults with opportunities to identify problems affecting their lives, to gather and analyze data about these problems, and to determine actions that will begin to rectify these problems (Cammarota & Fine, 2008; Cahill & Torre, 2007; Mirra, Garcia & Morrell, 2016; Torre, 2005, 2008, 2012). Typically, a researcher partners with a group of community members to investigate questions that are of significance to their lives. Once a question has been chosen, the researcher trains team members in a variety of methods, often including: interviewing, surveying, conducting focus groups, and using photovoice or other visual methods. Team members then practice these methodological approaches, discuss research ethics, and think through the strengths and weaknesses of each approach. Then, together with their research partner, they design and execute research projects.

CPAR projects are rooted in histories of popular education, critical theory, and participatory research. Epistemologically, projects are built on the assumption that what is seen as real has been shaped by social, political, cultural economic, ethnic and gender values. As such, CPAR



projects do not seek to discover immutable truths; rather, projects investigate the social patterns which function as truths in peoples' everyday lives. Unlike traditional post-positive approaches which seek to control for bias or mitigating factors, CPAR researchers strive to name and explore the different ways in which positionality, context, and power impact their findings. To be valid, findings must be situated, participatory, transformative and authentic for the local context.

The purpose of this CPAR project, specifically, is to amplify the voices of educators, parents and youth in a small urban school districts, particularly in terms of what they want from their school-based experiences. What is the portrait of the graduate that they imagine emerging from their public schools?

As such, the purpose of this research is best described in two parts.

(PART A) Part A of this study, which is the part submitted for review by the Harvard University IRB, is an exploration of the CPAR process that the Lowell Public Schools and Dr. Brion-Meisels will undergo, together. Part A seeks to investigate the process of critical participatory research with educators, parents and youth in a small, urban school districts and the extent to which such research might: (a) shift relationships between school-based educators and community members, including parents and youth; (b) shift feelings of agency or the desire to advocate for educational change among community members; and, (c) shift understandings of purpose and approach on the part of educators. In addition, this study seeks to understand how, if at all, CPAR can help illuminate and address inequities within a community or school system. In this first part of the study, where Dr. Brion-Meisels will be the PI, we ask: How, if at all, does partnering with educators and community member (including parents & youth) in studying their multiple "portraits of a graduate" shift relationships, understandings, or feelings of agency/motivation among participants? How do the community members involved in this project make meaning of their involvement? And how, if at all, do district leaders take-up the ideas generated by their research?

(PART B) Part B of this study, which will be reviewed by the Lowell Public School district office of research and evaluation, will collect data to support the development of the *Portrait of a Graduate Project*. This part of the study seeks to answer the questions: *How would we reimagine success for graduates from our district, including the values, knowledge, skills, and work habits they will need to thrive as learners, workers, and leaders in the 21st century? How might this re-envisioning impact our work moving forward?*

To answer this question, the school district is partnering with a set of local organizations to engage in research that will collect data about this question from local communities and sub-communities. The individual methods conducted by community-based partners will be determined by those community partners, and the school district will review each of these study designs as a part of their "continual improvement process."

Below is a description of Part B, as articulated by the school district and community partners:

Over the coming year, Lowell Public Schools will bring together our students, families, educators, employers, and community partners to create a bold new vision for Lowell's



graduates: *Portrait of a Graduate 2020* will emerge from a community-driven process that redefines success for Lowell students, including the values, knowledge, skills, and work habits they will need to thrive as learners, workers, and leaders in the 21st century.

To ensure that this process is community-driven and equitable, the Office of Equity & Engagement of the Lowell Public Schools is seeking trusted community organizations to conduct authentic community engagement that will connect communities in Lowell to the Portrait of a Graduate Initiative. The Community Engagement service providers will provide outreach and engagement, facilitate community circles/focus groups, interview community members and engage in other forms of data collection inspired by the Critical Participatory Act Research approach.

Critical participatory action research (CPAR) is a form of research that relies on both traditional and next-generation methodological approaches; CPAR projects typically investigate questions of interest to local communities, including an explicit analysis of how systems of power may be influencing everyday people. Although it is an approach to research, CPAR is also a form of youth and adult development. The individuals involved in CPAR projects typically benefit from feelings of connection, motivation, and empowerment as they work collaboratively to create positive change in their school or community contexts (e.g., Cammarota & Fine, 2010).

The goal of the Portrait of a Graduate initiative is to engage the community and ensure that diverse voices are included in this important visioning process, as well as future decision-making processes, within the Lowell Public Schools. The Lowell Public Schools also views this as an opportunity to grow the capacity of our community partners by providing training for and increasing the use of a relevant form of authentic engagement in educational systems.

- 4.2 Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.

Over the last fifty years, one of the most persistent and harmful aspects of public schooling in the United States has been the existence of achievement or opportunity gaps across racial, gender, linguistic and socio-economic lines. Countless research has taken up this issue, providing much insight into the strategies that schools and teachers can use to improve their curriculum, build positive teacher student relationships, address holistic student needs, and provide equal access. However, despite this, public school districts continue to underserve their low-income, racial, linguistic and gender minority students. One possible explanation for why existing research has failed to make a significant difference in addressing this problem is that it has failed to include the voices of those most impacted: educators, parents, community members and youth.

CPAR is a form of research that relies on both traditional and next-generation methodological approaches; but it is also a form of youth and adult development. The individuals involved in CPAR and YPAR projects typically benefit from feelings of connection, motivation, and empowerment as they work collaboratively to create positive change in their school or community contexts (e.g., Cammarota & Fine, 2010). Prior examples of CPAR projects in the U.S. context have included: efforts to halt discriminatory policing, explorations of implicit bias,



explorations of the effects of documentation status, and explorations of segregated schooling, among others. Prior examples of YPAR projects in the U.S. context have included: efforts to launch and evaluate an ethnic studies program, efforts to raise awareness about stereotypes of youth, efforts to address police-youth relationships, and school reform efforts.¹

There is a growing body of evidence that schools, community-based organizations, educators and adolescents themselves benefit from initiatives that authentically engage the perspectives of local stakeholders. Schools benefit when they fully integrate teachers', parents' and students' voices into their decision-making processes (e.g., Mitra, 2008). By collaborating with stakeholders at multiple levels, educators can better understand the ways in which teachers and students are make-meaning of the relationships, experiences, and contexts of school. Because meaning-making influences both the uptake of support services and the effect of these services on developmental outcomes (Aubery & Dahl, 2006; Buston, 2002; Davies & Wright, 2008; Masten & Wright, 2009; Mitchell & Sloper, 2001), understanding the experiences of teachers, parents and students who experience oppression and/or marginalization may be particularly important to address root causes of inequity within US school districts.

For all of these reasons, CPAR is a great fit for the *Portrait of a Graduate 2020 project*, which seeks to engage a community-driven process that will redefine success for Lowell students, including the values, knowledge, skills, and work habits they will need to thrive as learners, workers, and leaders in the 21st century. In particular, CPAR will empower teachers, parents, community members, and students in this district to help frame the types of questions and modes of analysis that get used in this investigation. At the same time, CPAR is an approach that ensures that those most effected by the current structures of schooling will have a say in helping to shift and reform these structures.

Therefore, this study has the potential to contribute to several critical fields of study in education including understandings of structural inequality in integrated school districts, community-driven school reform processes, authentic partnership between school districts and community-based partners, and the field of critical participatory action research. Most importantly, the findings from each research study have the potential to improve the everyday experiences of marginalized youth, parents and educators in schools.

5. STUDY PROCEDURES

5.1 Provide a complete overview of the study:

- Describe the procedures participants will be asked to complete or undergo.
- Explain step by step what participants will be asked to do
- Include how long the procedures will take.

If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.

The procedures below are for Part A of this study, which is the focus of this IRB. Part A of the study seeks to collect information about the CPAR process, which represents a partnership between the Lowell Public Schools, Dr. Brion-Meisels, and local community partners. **In this case, “participants” refer to those involved in the project, such as the community partners**



and representatives of the Lowell Public Schools.

At this time, there is a leadership team that guides the *Portrait of a Graduate* work. This is the team that chose to hire Dr. Brion-Meisels and invite her to conduct this research. This team will work in partnership with Dr. Brion-Meisels on all study-based decisions related to Part A. However, **the leadership team will not have access to identifiable data**. Dr. Brion-Meisels and her team will be responsible for collecting and analyzing all data.

Recruitment:

The leadership team already existed at the point when Dr. Brion-Meisels began this project.

Community partners will be recruited by this project leadership team, which will put out a call for proposals (Appendix A) and choose partner organizations from the applications received. Each community partner will determine their own research team, which will likely include both adults and youth, to engage with this project.

Community partners will attend a series of workshops with Dr. Brion-Meisels that will help them to learn about Critical Participatory Action Research (CPAR), study design, research methods, analytic methods, and the ethical questions that arise throughout the research process. During this time, community partners will be trained in basic research methods; they will create their study protocols, pilot these protocols, tweak these protocols, and collect data. Then, they will analyze the data and draft their findings. While all community partners will engage in this training and research process, individual participants will have the opportunity to “opt out” of the research at any point. In other words, participants may choose to engage in the *Portrait of a Graduate* project, but not participate in Dr. Brion-Meisels study of this process.

Dr. Brion-Meisels’ research team will collect information from the community partners at the start of the study, via a survey, and at the end of the study, via a survey and an exit interview or exit focus group. **(Drafted protocols for these are attached but may change as the leadership team weighs in on what they most want to know.)** In addition, Dr. Brion-Meisels will collect ethnographic data throughout the process. These data will be used to analyze the process itself, as well as cross-study and/or cross-district findings. Currently, only members of Dr. Brion-Meisels’ research team will be looking at the data; however, if members of the leadership team want to collaborate as co-researchers, they will be allowed to do so. In this case, Dr. Brion-Meisels will de-identify all process-related data before sharing it with others.

The specific research projects designed and implemented by each of the community partners (Part B) will be considered their own; the PI will not have permission to look at identifiable data or to use raw data as a part of her study, unless it has been de-identified and included in a research product created by the educator or youth researcher. The PI will have permission to look across the de-identified data, shared as a part of these study findings, in order to look for patterns across studies that the community partners conduct.

The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.

SURVEYS/ QUESTIONNAIRES/PSYCHOMETRIC TESTING

Skip this section if not applicable.

- 5.2 List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).

Community partners will be given a pre and post survey to explore their experience on the research team. A draft of this survey is attached as **Appendix B**, however the specific questions may change based on the desires of the leadership team. The survey will take approximately 30 minutes. Given the current requirement of social distancing, all surveys will be given via a Qualtrics link, online. Should we return to meeting in person, we will use Qualtrics regardless.

- 5.3 How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?

Participants will be asked to take the survey once at the start of the project and once at the end of the project. The survey will take approximately 30 minutes to complete.

- 5.4 Will you be using any survey software (such as Qualtrics)?

- Yes (see question below)
- No

If “Yes” which survey software will you be using? :

Qualtrics

INTERVIEWS/ORAL HISTORY/FOCUS GROUPS

Skip this section if not applicable.

- 5.5 Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)

Interviews and/or focus groups will take place at the end of the research process, in a semi-private space chosen by the community partners. (As of March 2020, social distancing regulations would require that we collect these online via Zoom, Google Hangouts, or FaceTime.) The drafted protocol for interviews and/or focus groups is attached as **Appendix C**, but again may change based on leadership team input.

- 5.6 Describe any steps you will take to protect the participant’s privacy during the interview/focus group.

By the time we do the focus group/interviews, participants will have worked with each other for over six months – in addition, participants will likely be interviewed individually or as a part of a focus group with members of their community-based team. In addition to setting group norms, we will be careful not to ask questions that will make folks feel vulnerable in the presence of their colleagues/peers.



As long as the COVID-19 social distancing restrictions persist, interviews or focus groups will be conducted via Zoom, Google Meets or FaceTime. They will be audio-recorded (via the Zoom cloud or a separate, digital device placed next to the computer) and only audio files will be sent out for transcription.

- 5.7 Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.

We anticipate conducting interview or focus group data from a subset of the community partners. Interviews/focus groups will take approximately 60-90 minutes. Our current drafted protocol is attached but may change based on leadership team feedback (Appendix C).

Interviews and focus groups will be conducted via Zoom, Google Meets or FaceTime. They will be audio-recorded (via the Zoom cloud or a separate, digital device placed next to the computer) and only audio files will be sent out for transcription.

OBSERVATIONAL/ETHNOGRAPHIC RESEARCH

Skip this section if not applicable.

- 5.8 If you will be actively participating in the field (as in participant-observation), describe what this will entail.

As the PI on this project, Dr. Brion-Meisels will be participating in all of the research training and planning. She will also be responsible for supporting the community partners with their study design and analysis. The ethnographic data for Study A will come from this participation in the project, and the learning that she does along the way. Community partners will be told that I am taking fieldnotes on my own experiences as a part of the project.

- 5.9 Describe what and who will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chatrooms and social media sites, etc.)

All parts of the training process will be observed. These will include research team meetings (large and small), meetings with district personnel during the project, public meetings held by the researchers, and other public meetings. All participants will have the option of having “off the record” meetings with Dr. Brion-Meisels, as requested, when I will refrain from taking notes about our dialogue.

- 5.10 Will any observational data be considered private, according to the standards of that community?

Yes (***see below***)

No

If “Yes” describe the information that would be private.

Because most of these discussions will happen within the context of a classroom, office, or virtual conference calls, they would be considered private. All data will be de-identified before being analyzed and before being written about. Although districts/organizations will be analyzed within- and across-cases, district and organization names will also be de-identified before any publication.

- 5.11 Will the data you collect contain any information that identifies specific individuals?



Yes

No

5.12 Do you plan to quote the remarks of participants in your study?

Yes

No

5.13 Will you notify participants that they are being observed?

Yes

No (*see below*)

If “No” explain the circumstances why you would not be able to let participants know they are being observed.

5.14 If permission to observe participants is obtained, how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation?

If community partners do not want to participate in the ethnographic portion of this study, they will be allowed to “opt out.” In this case, I would not use any of their individual data in my analysis. This is not difficult to do, given the small number of participants. Any notes taken about incidents that involve those folks will be marked as such, so that they are excluded from analysis.

AUDIO-RECORDING/VIDEO-RECORDING/PHOTOGRAPHS

Skip this section if not applicable.

5.15 What type of recording will take place? (check all that apply)

Audio-Recording

Video-Recording

Photography

Other (*see below*)

If “Other” describe:

Zoom may require us to use both audio and video recording, but we will delete the video recording immediately and only send the audio recording out for transcription. If we use a different online conference platform, we will plan to audio record with a separate device next to the computer.

5.16 Explain what types of data will be recorded or photographed.

Interviews will be audio-recorded or recorded to the Zoom cloud using the Zoom platform and only audio files will be sent out for transcription.

5.17 If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?

Data will be transcribed by a professional service that has signed an NDA. Audio-recordings will be transcribed on a rolling basis, so as to limit the amount of time that the audio record



itself exists. All recordings will be deleted after they are transcribed. All names will be removed from the transcriptions immediately.

5.18 Explain what will happen to the recordings/photographs at the end of the study.

All recordings will be deleted after transcription is complete and files have been cross-checked.

DECEPTION AND INCOMPLETE DISCLOSURE

Skip this section if not applicable.

Deception is the intentional misleading of a subject about the nature of the study. While withholding of full information is known as incomplete disclosure.

5.19 Describe what information will be withheld from participants or what misinformation will be provided to participants.

5.20 Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.

5.21 Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

Please be sure to attach a copy of the debriefing script (if applicable) to the “Local Sites Documents” section in the ESTR SmartForm.

USING PREVIOUSLY COLLECTED DATA

Please complete this section if you are receiving data that has already been collected. This section does not pertain to data that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.22 Indicate the identifiability of the data:

Will not contain any direct or indirect identifiers; will be anonymous.



- Will not be directly identifiable, but there will be a code held by the data source that links to the identities; will be coded.
- Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
- Will contain direct identifiers; will be identifiable.

5.23 Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.

5.24 Provide an overview of the types of variables that are contained in the dataset (for example, identifiable data such as names, dates of birth, addresses, or any data that are considered sensitive).

5.25 Was the data you plan to analyze collected in a previous research study?

- Yes (*see below*)
- No

If “Yes” provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

5.26 Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

- Yes (*see question below*)
- No

If “Yes” what websites will you access to obtain the data?

Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.

5.27 Is the data publicly available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?

- Yes
- No

5.28 Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?

- Yes
- No (***skip to question #5.31***)

5.29 Which organization will provide the HIPAA PHI to you?



5.30 How will permission to allow the use/disclosure of individual’s protected health information (PHI) be obtained?

HRP-330 WORKSHEET: HIPAA, which may be found in the ESTR library, provides an overview of items pertaining to HIPAA that may be helpful to the study team.

5.31 Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?

- Yes
- No

HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.

USING PREVIOUSLY COLLECTED BIOLOGICAL MATERIALS

Please complete this section if you are receiving biological material that has already been collected. This section does not pertain to biological material that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.32 Indicate the identifiability of the biological materials:

- Will not contain any direct or indirect identifiers; will be anonymous.
- Will not be identifiable, but there will be a code held by the data source that links to the identities; will be coded.
- Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
- Will contain direct identifiers; will be identifiable.

5.33 How will you obtain the material? (check all that apply)

- Residual clinical material
- Material obtained from a vendor
- Material that was collected as part of another research study (**please see below**)
- Other – (**see below**)

If you chose “another research study” provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

If “another research study” or “Other” please specify:



5.34 Will the material consist of any of the following? (check all that apply)

- Embryonic tissue
- Embryonic stem cells
- Stem cells
- Fresh human fetal tissue
- None of the above

5.35 Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).

DEVICES

Skip this section if not applicable.

5.36 List the device(s) that you plan to use in this study (add additional lines as necessary):

| Device Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|-------------------|---------------------|--------------|---------|--------------------|
| | | | | |

5.37 Is the device(s) that you plan to use FDA-approved/cleared?

- Yes
- No

5.38 If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.

Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the “Local Site Documents” section in the ESTR SmartForm.

DRUGS

Skip this section if not applicable.

5.39 List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):

| Drug/Biologic Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|--------------------------|---------------------|--------------|---------|--------------------|
| | | | | |



5.40 Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?

- Yes
 No

5.41 Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.

Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the “Local Site Documents” section in the ESTR SmartForm.

6. RISK AND BENEFIT ASSESSMENT

6.1 Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.

There is a slight risk associated with participating as a community partner.

The risks listed below are a part of daily life for most educators, parents, community members, and adolescents and are necessary since this project involves social interaction and dialogue. It is not anticipated that the level of psychological or social discomfort will exceed that experienced by most of the participants in their daily lives.

Risks for Community Partners:

There is a very small possibility that community partners will feel some risk to their psychological or social wellbeing by participating as researchers; although, the intention of the project is quite the opposite. Community partners may find it difficult to conduct research or may become frustrated with the district/organizational-based policies and practices that their research reveals. Community partners may also dislike other members of the group or feel frustrated with the university-researcher. Finally, community partners may worry that their supervisors or district/organizational leadership will become angry about their involvement in the project.

To address these risks, the community partners will meet with Dr. Brion-Meisels regularly to review and debrief the process. Also, individual community partners will be allowed to “opt out” of the research process when their academic or emotional needs make this necessary. Finally, we will be careful to make decisions as a group, such that we can protect those members of our team who feel most vulnerable.

Community partners will always have the option to use a self-identified pseudonym rather than their own name on research products.

Finally, community partners may experience some level of discomfort or risk from the surveys that they are asked to take, as a part of this project. To protect community partners against these risks, all surveys will be taken online and community partners will be allowed to use a numerical identifier if they do not want their names on the survey information.



- 6.2 Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)

In addition to meeting regularly and setting norms, we will be sure to check in with folks both individually and collectively about their experiences. We will work to buffer the community partners from any pushback that comes from district or school leadership, by placing our own names on the project as necessary/desired by them. In addition, community partners will be able to opt to include their names or self-identified pseudonyms, such that they can choose when and how to reveal their involvement in the project.

- 6.3 Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?

Yes

No

- 6.4 If applicable, what steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?

If the need arises for psychological support, we will work to connect the participant to a trusted resource. The leadership team will help with this connection.

- 6.5 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.

Community partners will be given a stipend to support their participation in the project, but this stipend will go to the organization not the individuals involved. In addition, experience suggests that participants may benefit from feeling a sense of efficacy about their engagement in this project, which often results in those with power listening more carefully to their life experiences and insights.

- 6.6 Describe any potential benefits to society.

This project has the potential to benefit society by helping to amplify the voices of marginalized educators and youth, such that integrated, urban school districts and organizations can more effectively serve the needs of *all* students by creating more equitable and inclusive systems.

7. CHARACTERISTICS OF THE STUDY POPULATION

- 7.1 Indicate the estimated number of participants, by subgroup if applicable. *If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.*

The participants will be community partners drawn from the Lowell community. It is unclear exactly how many participants will join from each community partner organization, but we



anticipate it will be between 5 and 50 individual partners. These partners will be the participants in Study A.

7.2 Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.

Community partners will apply in response to a call for proposals put out by the district and leadership team in May 2020 (Appendix A). Once community partners are chosen, all individuals involved in the *Portrait of a Graduate Project* (Part B) will be invited to participate in Part A, Dr. Brion-Meisels’ study.

7.3 Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)

- Children
- Wards of the State
- Prisoners/Detainees
- Pregnant Women
- Adults not Competent to Consent
- Non-English Speaking
- Employees of Harvard University (as a focus of the study)
- Undergraduate Students of Harvard University (as a focus of the study)
- Staff or students that are part of your lab or for whom you provide oversight
- Other – (*see below*):

If “Other” please specify:

[Empty text box for specifying other vulnerable populations]

CHILDREN

Skip this section if not applicable.

7.4 What is the age range of children participating in your study?

12-17

7.5 Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?

Although there may be some youth with learning disabilities who participate as members of the research teams (participants of Study A), we will not ask for that information. Given the content of this project and the existing scaffolding, we do not believe that there are any special considerations (other than translating the survey into relevant languages) that need to be considered.



PRISONERS

Skip this section if not applicable.

7.6 Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.

[Empty text box for response to 7.6]

7.7 Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

[Empty text box for response to 7.7]

EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY

Skip this section if not applicable.

7.8 Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.

[Empty text box for response to 7.8]

8. RECRUITMENT

8.1 Will potential participants be provided with information about the study?

- Yes (*see below*)
- No (*skip to next section*)

If “Yes” indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.

Community partner participants will be recruited for Study A after they have applied (Appendix A) and been chosen to participate in the larger *Portrait of a Graduate* Study. The RFP to participate in the larger study will be sent out through local channels, including the Lowell Public Schools, to potential partners. Recruitment for this study will take place in the context of the program; all community partners will be invited to participate in Study A.

8.2 Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?

- Yes (*see below*)



No

If yes, list the materials by document name here, and be sure to attach copies to the “Consent and Recruitment Materials” portion of the “Local Site Documents” section in the ESTR SmartForm.

HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.

9. SCREENING

9.1 Will you be screening participants for eligibility?

Yes

No (**skip to next section**)

9.2 Explain what your screening criteria will be and how you will conduct the screening process.

9.3 Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study as soon as the screening process is over?

Yes

No (**see below**)

If “No” explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.

10. INFORMED CONSENT PROCESS

If you plan on having more than one consent process (such as signed, written consent for one population and use of an online “click” consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.

ADULT PARTICIPANTS

If you will not include adults in your study, please skip this section.

10.1 Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?

Yes, I will be obtaining informed consent or an agreement to participate.

No, I will not be obtaining consent or an agreement to participate (**skip to next section after answering below**)

If you will not be obtaining consent or an agreement to participate, please explain:



- ***why this research involves no more than minimal risk to participants and***
- ***why it would be impracticable to carry out the research with consent or an agreement to participate***

All community partners who agree to participate in Study A will be asked to sign consent forms. Participants under 18 will be asked to have their guardian sign consent and will be asked to assent themselves.

As a result of social distancing requirements, community partners will be asked to consent orally via video conference (Appendix F). If they are 18 or over, participants will consent orally for themselves. If they are under 18, participants will be asked to have a parent/guardian come onto the screen for the consent process. They will then assent.

10.2 Will the consenting or an agreement to participate process involve obtaining a signature?

- Yes
 No (*see below*)

If a signature is not obtained, explain why:

10.3 Where will the consent or an agreement to participate process take place?

- In-person
 Online
 Over the telephone
 Other (*see below*)

If other, please describe::

10.4 Who will obtain consent or an agreement to participate from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?*

Consent will be obtained by either Dr. Brion-Meisels (the PI) or one of her research assistants.

10.5 Describe the process that will be used to obtain consent or an agreement to participate.

During our first meetings, Dr. Brion-Meisels will share the consent forms and orally describe the project and Study A. Dr. Brion-Meisels will then set up a time to speak with each individual participant to answer questions and obtain oral consent. Participants under 18 will be asked to have a parent on the video conference for this consent/assent conversation.

10.6 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

We will ask all adult participants whether they have questions or points of clarification that they would like us to make, both in the large group and in our one-on-one conversations.



CHILDREN PARTICIPANTS

If you will not include children in your study, please skip this section.

If you are including children in your research study, know that consenting or requesting an agreement to participate from a child is comprised of two parts: child assent and parent permission.

10.7 Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?

- Yes, I will be obtaining assent or an agreement to participate.
- No, I will not be obtaining assent or an agreement to participate (**skip to next section after answering below**)

If you will not be obtaining assent or an agreement to participate, please explain:

- Why this research involves no more than minimal risk to participants and
- Why it would be impracticable to carry out the research with assent or an agreement to participate:

10.8 Will the assenting or an agreement to participate process involve obtaining a signature?

- Yes
- No (**see below**)

If a signature is not obtained, explain why:

10.9 Where will the assent or an agreement to participate process take place?

- In-person
- Online
- Over the telephone
- Other (**see below**)

If other, please describe:

10.10 Who will obtain assent or an agreement to participate from child participants? Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?

The Principal Investigator or one of her research assistants will obtain consent from all community partners and, as required, parents/guardians.

10.11 Describe the process that will be used to obtain assent or an agreement to participate from children.

Youth researchers will be asked to assent to their participation in Study A, at the same time as their parent/guardian is asked to provide oral consent for their participation in the project. This will occur via video conferencing.



10.12 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

During this conversation, we will ask for clarification questions.

PARENT PERMISSION

If you will not be including children in your research, please skip this section.

10.13 Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?

- Yes, I will be obtaining parent permission or an agreement to participate.
 No, I will not be obtaining parent permission or an agreement to participate (**skip to next section after answering below**)

If you will not be obtaining parent permission or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with parent permission or an agreement to participate:***

We will obtain parent permission from the community partners (participants in Study A) under 18 years of age. Although students will be allowed to participate in the *Portrait of a Graduate* project without parental permission, their data will not be included in any analysis.

10.14 Will the parent permission or an agreement to participate process involve obtaining a signature?

- Yes
 No (see below)

If a signature is not obtained, explain why:

10.15 Where will the parent permission or an agreement to participate process take place?

- In-person
 Online
 Over the telephone
 Other (**see below**)

If other, please describe:

Parents or guardians will grant permission for youth to participate in Study A online, via a video conferencing platform.

10.16 Who will obtain parent permission or an agreement to participate from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?*

No consent forms will be collected. Dr. Brion-Meisels or a member of her research team will collect assent and consent.

10.17 Describe the process that will be used to obtain parent permission or an agreement to participate from parents.



Caregivers will be emailed or texted a copy of the consent form (Appendix I) explaining the project and asking for their permission to have their child participate. Then will then consent orally via a video conferencing platform.

- 10.18 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

Caregivers will be invited to call, text or email the PI if they have any questions or concerns.

OTHER TYPES OF PARTICIPANTS

If this section is not applicable, skip to next section.

- 10.19 If you will be including **Wards of the State**, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?

It is possible that some of the participants will be Wards of the State. In this case, we will use each child's **court appointed advocate**, who is different than their case worker, to provide permission for their participation. Advocates in Massachusetts are not employees of the Department of Children and Families; rather, they are lawyers or other adults who are instructed to act in the benefit of the youth and follow their guidance, as long as its legal.

- 10.20 If you will be obtaining consent from special populations such as **non-English speaking participants**, **illiterate participants**, or **adults not competent to consent**, please explain how you will obtain consent from those individuals.

All participants will speak English. If necessary, we will translate consent forms for parents.

- 10.21 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

In both cases, we will use standard procedures (e.g., offering to answer questions, provide additional information) as needed.

Please be sure to attach copies of all informed consent/parent permission/assent materials to the "Local Site Documents" section in the ESTR SmartForm.

11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

- 11.1 Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the [Harvard University Financial Policy on Human Subject Payments](#).*

Yes
 No (***skip to next section***)

- 11.2 What type of compensation will you provide to participants?

Cash
 Check
 Gift Card/Gift Certificate
 Course Credit
 Lottery/Raffle



Other (*see below*)

If you chose “Other” please specify:

11.3 What amount will the compensation be worth?

11.4 Describe which participants will receive compensation and when the compensation will be given.

11.5 Will you provide partial compensation for participants who do not complete all the study procedures?

Yes (*see below*)

No

If “Yes” please explain how partial compensation will be managed:

HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.

11.6 Will participants incur any financial costs by taking part in this study?

Yes (*see below*)

No

If “Yes” please explain.

12. DATA SECURITY AND MANAGEMENT

12.1 Describe the identifiability of the data when first obtained/collected:

Will not contain any direct or indirect identifiers (Anonymous) **(PART B)**

Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site* **(PART A)**

Will contain direct identifiers (Identifiable)

12.2 Describe the identifiability of the data when stored:

Will be directly labeled with personal identifying information (identifiable)

Will be labeled with a code that the research team can link to personal identifying information (Coded)

Will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (Anonymous or De-identified)

Other - explain here:

12.3 Which category of information best describes the data according to the [Harvard Research Data Security Policy](#)? ***Please know that it is the researcher’s responsibility to ensure compliance with the Harvard University Data Security Policy at all times.***



- LEVEL 1 - Data that is publicly available or not identifiable. Examples:
 - Research data that has been de-identified in accordance with applicable rules;
 - Published research data; published information about the University;
 - Course catalogs;
 - Directory information about students who have not requested a FERPA block;
 - Faculty and staff directory information.
- LEVEL 2 - Information the University has chosen to keep confidential but the disclosure of which would not cause material harm. Examples:
 - Research data that is identifiable but is not considered sensitive;
 - Patent applications and work papers, drafts of research papers;
 - Building plans and information about the University physical plant.
- LEVEL 3 - Information that could cause risk of material harm to individuals or the University if disclosed. Examples:
 - Information protected by the Family Educational Rights and Privacy Act (FERPA) to the extent it is not covered under Level 4 including non-directory student information and directory information about students who have requested a FERPA block;
 - HUIDs associated with names or any other information that could identify individuals;
 - Harvard personnel records (employees may discuss terms and conditions of employment with each other and third parties);
 - Institutional financial records;
 - Individual donor information;
 - Other personal information protected under state, federal and foreign privacy laws not classified as Level 4 or 5.
- LEVEL 4 - Information that would likely cause serious harm to individuals or the University if disclosed. Examples:
 - High Risk Confidential Information (HRCI) and research information classified as Level 4 by an IRB;
 - Personally identifiable financial or medical information;
 - Information commonly used to establish identity that is protected by state, federal, or foreign privacy laws and regulations;
 - Individually identifiable genetic information that is not Level 5;
 - National security information (subject to specific government requirements);
 - Passwords and Harvard PINs that can be used to access confidential information.
- LEVEL 5 - Information that would cause severe harm to individuals or the University if disclosed. Examples:
 - Research information classified as Level 5 by an IRB or otherwise required to be stored or processed in a high security environment and on a computer not connected to the Harvard data networks;
 - Certain individually identifiable medical records and genetic information, categorized as extremely sensitive.

12.4 In what format will the research data be **collected**?

- Paper
- Electronic
- Other – (*see below*)

If "Other" please specify:.

12.5 In what format will the research data be **stored**?

- Paper



- Electronic
- Other – (*see below*)

If "Other" please specify:

12.6 Explain **where** the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).

Data for Study A will be stored on Dr. Brion-Meisels' locked hard drive. Online data will be stored in a Qualtrics account associated with Harvard. Zoom recordings will be saved in the Zoom cloud temporarily, and then quickly deleted and used for transcription purposes.

12.7 Will the data be managed by Harvard researchers either remotely or housed at Harvard (e.g., physically or Harvard Cloud Storage)?

- Yes
- No

12.8 Do you anticipate that the research data will be transferred or transported from your possession to another at any time?

- Yes
- No (***skip to question #12.10***)

12.9 Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.

12.10 Will data be transferred from the EEA* to Harvard or another non-EEA location?

- Yes
- No

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.***

12.11 Will (or has) a Certificate of Confidentiality (CoC) be (been) obtained for this study? *If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.*

- Yes
- No

12.12 What will happen to the data at the conclusion of the study? (check all that apply)

- Direct identifiers* and/or the key to the codes will be destroyed upon completion of the research (all data will be stripped of identifying information and/or the key to codes destroyed, identifiable paper documents shredded, identifiable electronic files purged, identifiable electronic media securely erased).
- Retained for study record keeping purposes per institutional policy.
- Retained by the investigator for future research use.
- Retained for future research use (create repository/bank).
- Restricted use data will be destroyed or will be returned to the source.



- No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.
- This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.
- Other – (**see below**)

** **Direct identifiers.** These are variables that point explicitly to particular individuals or units. Examples include: names, addresses, including ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.*

***Indirect identifiers.** These are variables that can be problematic as they may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information (e.g., state, county, province, or census tract of residence), organizations to which the respondent belongs, educational institutions (from which the respondent graduated and year of graduation), detailed occupational titles, place where respondent grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by respondent.*

If "Other" please specify:.

13. SHARING DATA WITH OTHERS

13.1 Will the data be released to anyone who is not on the Harvard University Area research team?

- Yes
- No (**skip to question #13.4**)

13.2 Other than the Harvard University Area research team, who will have access to the data?

- Colleagues/Collaborators at other institutions
- Transcribers/coders hired by the research team
- Sponsor/Funding Agency
- Other (**see below**)

If "Other" please specify:.

13.3 How will the data be shared/disclosed beyond the Harvard University Area research team?

- Without any identifiers
- Coded
- With Identifiers

13.4 Will you be sharing research findings with study participants?

- Yes (**see below**)
- No

If "Yes" please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):



Findings from Study A will be shared with community partners and district partners at several key points, including during the analysis.

- 13.5 Does the study include establishing a repository for sharing data or specimens with other researchers?
- Yes (*If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created*)
 - No

GENOMIC DATA SHARING

- 13.6 Will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data?
- Yes
 - No (*skip to next section*)

- 13.7 Will you require a Genomic Data Sharing (GDS) Institutional Certification per NIH GDS policy?
- Yes
 - No

13.8 Include a description of all fields to be submitted to the repository:

[Empty text box for description of fields]

13.9 Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:

If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the [NIH guidance document](#).

If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the "Local Site Documents" section in the ESTR SmartForm.

[Empty text box for de-identification plan]