Study Title: Evaluating Contaminant Exposures from Local Fish and Shellfish Consumption in Communities Surrounding the Lower Passaic and Newark Bay

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Sponsor: Dept. of Environmental Medicine, NYU School of Medicine

1) Objectives

The overarching goals of the currently proposed exposure assessment pilot study, to get preliminary data for an NIH P42 application, are two-fold:

a) Implementation of a revised version of a previously IRB approved (and employed) prevalence survey of locally caught seafood consumption (S15-01157) completed by people living in the vicinity of the Passaic River, for residents and those visiting Newark, New Jersey and Lower Passaic River, New Jersey. Added to the end of that previously implemented survey is a request as to whether the subject would consider being asked to enroll in a follow up next study step (involving the collection of a blood draw)

b) From those who agree, during the consumption survey, to consider participating in an exposure assessment next study stage, we will then, at the same time, inform and consent this survey subset for a single follow-up blood draw by a certified phlebotomist at a local health testing center near their residence, to be scheduled for a later date. This will show protocol viability, and provide an initial assessment of the blood levels of key pollutants known to be elevated in locally caught seafood (e.g., mercury, PCB’s, and DDT) from ponds/streams used for sustenance fishing and in indoor drinking water; measure these same contaminants in the blood of recruited subjects.

This study will test the principal that individuals consuming locally caught seafood in vicinity of the Lower Passaic River and Newark Bay can be recruited and tested, and that at least some of them have measurable and elevated levels (compared to participants who do not consume locally-caught seafood) of the same contaminants previously found in the sediments and fish in that vicinity. These results will be useful in assessing the numbers needed to have sufficient power for the hypothesis test as to size and significance of differences in exposures between exposure groups, and vs. the previously reported nationwide National Health and Nutrition Examination Survey (NHANES) levels.

2) Background

The Newark Bay Complex includes Newark Bay, and the Lower Passaic River. It is a highly industrialized urban area, including a large racially-mixed and underserved population of more than 3 million people. The Hudson River Estuary, including its western Estuary (i.e., Newark Bay and its two tributaries; the Passaic River and Hackensack River) are defining natural features of the New
York City (NYC)/New Jersey (NJ) metropolitan area. They have played a key role in American history by serving as a major transportation route during the Industrial Revolution. However, trade activities during the Industrial Revolution and subsequent commercial activities and urbanization left their marks along these waterways leading to several being designated as U.S. federal Superfund sites because of high levels of pollution with a variety of chemical contaminants including PCBs, PCDDs (particularly, 2,3,7,8 -tetrachlorodibenzo-p-dioxin; TCDD) and mercury (Hg). Various companies manufactured pesticides and herbicides during the mid-20th Century, including those used to formulate the defoliant "Agent Orange," at facilities along the Passaic River in Newark, NJ, that are now part of the Diamond Alkali Superfund site, located in the Ironbound section of Newark (see Figure 1).

![Map of Newark, NJ's Ironbound District (tinted Red), vis-a-vis the Diamond Alkali Superfund site, Passaic River, Hackensack River, and Newark Bay](image)

The Superfund site is comprised of three parts: the former pesticides manufacturing plant and surrounding properties in Newark, the Lower Passaic River Restoration Project Study Area, and the Newark Bay Study Area. Assessing the potential health impacts of these polluted waterways and their various pollutants, and determining the most efficacious approach to remediate them, is an ongoing challenge. Today, the US EPA has classified the Hudson River and its estuaries as the largest Superfund site in the country.

While the form, solubility, and bioavailability of these contaminants will vary and affect the extent to which metals can be bioavailable to shellfish and the people who consume them, high
concentrations in sediment show the potential for exposure, should these contaminants mobilize into the river and estuary ecosystem.

In 1982, research conducted by the New Jersey Department of Environmental Protection (NJDEP) documented elevated levels of chemical contaminants in five species of fish and one species of crab in the Newark Bay Complex. Subsequently, the State of New Jersey adopted advisories to guide citizens on safe consumption practices for fishes and crabs. Since then, fish consumption advisories have been issued primarily through the Fish and Game Digest, a publication distributed by the state to licensed anglers. However, anglers in the Complex are not required to have a fishing license because the waters are marine in nature. Therefore, many anglers in this area do not receive advisory information. Thus, despite government warnings against consumption of crabs and fishes caught by anglers in the Passaic River, Hackensack River and Newark Bay, many individuals continue to both crab and fish, and eat their catch.

As reported by Burger (2002), 8-25% of the people surveyed who fish and/or crab in the Newark Bay Complex consume more than 1,500 g of their self-caught catch per month. While 30% or more of the people surveyed reported that they do not eat their self-caught fish or crabs, in reality, some people angling in the Newark Bay Complex were found to eat crabs at a rate well over 1,500 g/month, and about 70% ate crabs even though there is a total ban on both their harvest and consumption due to potential health risks. These consumption patterns were negatively correlated with mean income, indicating that this reflects subsistence fishing and crabbing by underserved populations. Indeed, in an early study of Newark Bay anglers, Pflugh et al. (1999) found that, while 60% of people had heard about advisories, most either did not believe, or were unconcerned about health effects from eating contaminated species. Although previous surveys demonstrate that ingestion of self-caught fishes/crabs from the Newark Bay Complex is a relevant issue, data from these studies are more than a decade old and thus may not reflect current practices. The current survey being proposed is to evaluate the prevalence of eating locally-caught fishes and crabs in the Newark Ironbound District of Newark, which is a lower income neighborhood located adjacent to the Passaic River, just upstream of Newark Bay (See Figure 1).

Based on past studies of sediments in the Passaic River and Newark Bay, Hg, PCB’s and dioxins (particularly TCDD) are among the most highly concentrated contaminants found, with all being repeatedly found to be many times above their respective ERL’s (Effects Range Low) in the river sediment (Long, et al., 1995; US COE, 2009). An effect range level is the median sediment contaminant concentration from a set of data where adverse biological effects have been observed. These values are not regulatory guidelines and they indicate only a correlation, rather than a causal relationship, but they are among the only guidance numbers available to examine the potential effects of sediment contamination (NY/NJHEP, 2002). For example, in the Passaic River Sediment Sampling Program conducted in 1999 (U.S. EPA, 2016), the ratios of the measured sediment concentration to their ERL in a typical sample was: PCB ratio = 125; TCDD ratio = 171; Hg ratio = 76, indicating contamination levels for all of these contaminants orders of magnitude above those considered acceptable. While the form, solubility, and bioavailability of these contaminants will vary based on environmental conditions and affect the extent to which they can become present in aquatic species, such elevated concentrations in sediment show the potential for high exposures upon mobilization into the river and estuary ecosystem, including local fish and shellfish.
Recent studies in the Newark Bay – Hudson River Complex indicate that Superfund-related contaminants, including TCDD, PCBs and Hg, are indeed found in local fish and shellfish in high concentrations. Measurements of their body/tissue burdens have been made from fish/shellfish recovered from different locations in the Lower Passaic River, as displayed in Figure 2. Measured levels of Hg were on the order of 100’s of µg/kg in White Perch and Blue Crabs caught up and down the river, with some White Perch being measured at over 500 µg/kg Hg, greatly exceeding the EPA 300 µg/kg Hg action level, among the fish caught in the lower part of the Passaic. Measured levels of PCBs in fish and shellfish were even higher, being on the order of 1000 µg/kg in White Perch and Blue Crabs caught in various locations and years. (LBGI, 2014)

The proposed pilot study builds upon our previous IRB approved study (S15-01157) of Newark, NJ locals residing along the lower Passaic River to determine the extent of the practice of obtaining and consuming locally caught fish and shellfish.

In collaboration with our Community Based Organization (CBO) partner, the Ironbound Community Corporation (ICC) (http://ironboundcc.org), we previously conducted an IRB-approved study consisting of a survey of Ironbound residents regarding their consumption of locally caught fish and/or shellfish (e.g., crabs) in order to provide substantiation of the practice, and to provide input into our study recruitment and sampling aims. Using a fish and shellfish consumption questionnaire, developed in collaboration with our NYU NIEHS Center’s Community Outreach and Engagement Core and our ICC community partner, participants were queried at local community meetings (e.g., knitting clubs and other community meetings) in 2015 and 2016. Overall population demographics of those surveyed were predominantly minority in race (only 10.2% identified themselves as White/non-Hispanic, vs. 63.7% White/non-Hispanic in the entire U.S. in 2010 (U.S. Census, 2011). More than half of respondents (53.5%) were women. Educational attainment in the surveyed population was quite low, with 51% of respondents having never completed a high school education vs. only 15.1% in the US overall population (U.S. Census, 2012). As shown in Figure 3, in this underserved minority population, we found that the practice of catching locally caught fish is
surprisingly common (n=16 of 56 had fished in the Passaic River, or 28.6% of respondents), and even a higher percentage had consumed fish caught by themselves or others in the Passaic River (n=19, or 33.9%). These results strongly support our contention that we will be able to identify and recruit the numbers of participants proposed.

Figure 3. Results of 2015 Fish Consumption Survey of Residents in the Ironbound District of Newark, NJ

3) **Study Design**
This is a cohort study of individuals who live on or near previously EPA determined contaminated waterways in the Lower Passaic River and Newark Bay, NJ, involving two components: a survey of up to 150 subjects, followed by a blood draw on a subset of those who completed the survey.

4) **Research Population**

a) **Number of Subjects**

For this feasibility study, we expect to enroll up a total of 150 subjects for the food consumption survey component. Of the 150 subjects, 15 will participate in the blood collection component of the study.

b) **Gender of Subjects**: Both men and women will be recruited for participation in the study.

c) **Age of Subjects**: Subjects must be over the age of 18 years old and not older than 80 years old.

d) **Inclusion Criteria**: 1) 18 years of age at the time of enrollment living in the vicinity of the Lower Passaic River and Newark Bay, especially in and around the Ironbound section of Newark.

e) **Racial and Ethnic Origin**: This study aims to recruit participants from the vicinity of the Ironbound neighborhood of Newark, NJ, which is a community rich in diversity (35% Hispanic
and Latino), in order to ensure that the benefits of research participation are distributed towards the intended community.

f) **Exclusion Criteria**: Individuals who do not live in the vicinity of the Passaic River or Newark Bay will be excluded from the study. Pregnant women, breastfeeding women, and subjects under 18 years old will not be enrolled.

g) **Vulnerable Populations**: The study will not recruit nor enroll any vulnerable populations.

5) **Methods and Procedures**

a. **Subject Identification and Recruitment**

NYU study personnel will recruit participants for the study during local community meetings and events. NYU study personnel will identify potential subjects at ICC or NY/NJ Baykeeper meetings and events, implement an informed consent for those interested in participating, and then give them the fish consumption survey. Survey gathering will target members of the community along the Lower Passaic River and Newark Bay who might catch and/or consume locally caught seafood, as well as locals who do not do so (as controls).

After the seafood consumption survey is completed, the subjects who indicate an interest in participating in the second component of the study (exposure evaluation by blood collections) will then be recruited for that (optional) participation, and later contacted in order to schedule an appointment to complete the blood draw by a certified phlebotomist at a local health testing center.

b. **Consenting (Process and Documentation)**

During the consent process, study personnel will go over the consent form in detail with the potential participant, including the nature of the study, inclusion and exclusion criteria, a description of study procedures, and risks and benefits. The contact numbers of the PI (George D. Thurston, ScD) are listed in the consent form. This will be pointed out explicitly to the participants, and they will be told that they may contact him at any time prior to signing the consent or during the study if they have specific questions. We will also provide the PI’s business card at the time of the meeting, which will also have the contact information.

Potential participants will be specifically told that participation in the study is voluntary. If they agree to participate, they will be asked to sign the informed consent form. The original consent form will be placed in the research file, and a copy will be given to the participant.

Participants with diminished capacity will not be enrolled in this study. Therefore subjects vulnerable to coercion will not be included.

Written consent will be obtained and stored in a locked office of the PI, George D. Thurston, ScD.
c. Study Procedures: Survey and Blood Collection

The study will consist of first conducting up to 150 fish consumption surveys in the Newark, NJ Ironbound Community and vicinity (using the instrument implemented previously), but with one additional optional question requesting contact information from those interested in participating in the blood draw exposure assessment. The survey will be administered by approved NYU study personnel, and will evaluate fishing and/or crabbing habits and consumption of fish and/or crab from the Passaic River by residents and those visiting Newark, New Jersey and the Lower Passaic River and Newark Bay, New Jersey (see Appendices B and C). The survey component of the study will be hosted by our collaborating neighborhood groups, the ICC and the NY/NJ Baykeeper, at community events and fairs in the summer and fall of 2017, or spring, summer, or fall of 2018, at which an approved NYU study personnel will be present to administer the survey instrument.

Those who expressed willingness at the end of their survey to participate in the second (optional) component of the study will then be scheduled for the subsequent blood collection procedure, to be conducted by a certified phlebotomist at a local health testing center near the subject’s residence. Based upon the survey participants’ responses, we will select (and schedule subsequent blood collection meetings with) a total 20 subjects who indicated on their surveys that they consume locally caught seafood, and 20 subjects who indicated that they did not (as local controls). Transportation expenses will be reimbursed by NYUMC, if needed, to travel to a local health testing center that will work as a fee-for-service vendor with a certified phlebotomist (who is not study personnel), in order to collect a blood draw from that subject. The total time for the visit will be approximately one hour, including travel time.

The certified phlebotomist will draw two Vacutainer tubes (6-ml each) will be collected from each individual; one tube (without an anti-coagulant) will be used to measure serum metal concentrations (e.g., Hg) by ICP-MS, and the other organics (e.g., PCB’s and dioxin). Given the time-constraints of this study, biomarker measurements will only be performed at a single time point during the study. Whole blood (0.75 ml) and serum (0.75 ml) will be combined with 1.5 ml concentrated nitric acid, 2 ml concentrated hydrogen peroxide and 8 ml MilliQ water and the solution digested using a microwave digester. The digestate will be analyzed using the same Departmental ICP-MS used for the environmental water samples; empty blood tubes will serve as a background control.

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<tr>
<th>Study Procedures</th>
<th>Number of Visits</th>
<th>To be performed by</th>
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<tbody>
<tr>
<td>Survey</td>
<td>1 visit, at the same time as participant recruitment and consent</td>
<td>NYU Study Personnel</td>
</tr>
<tr>
<td>Blood draw</td>
<td>1 Visit</td>
<td>Certified Phlebotomist at a local health testing center near participant’s residence</td>
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6) **Data Management**

**Data Analysis:** The aim of this study is to show proof of our ability to collect such surveys and biological samples in this community, and obtain preliminary results, not test a hypothesis (which is the goal of the full study that we will propose to NIH next year). However, while we do not yet have biological samples collected from our proposed participants, a previously published study of anglers in the Newark Bay-Hudson River Estuary Complex provides inputs needed to estimate the numbers of participants required to detect significant differences associated with Hg exposure. As discussed above, Gobeille et al. (2006) conducted a cross-sectional study of 191 anglers recruited from Hudson River piers and fishing clubs. Participants who reported eating locally caught fish had significantly higher levels of Hg (mean (M)=2.4 ng/mL, standard error (SE)=1.2) than anglers who never ate locally caught fish (M=1.3 ng/mL, SE=1.1). A positive dose-response pattern was also observed, where participants who reported eating locally caught fish more than once a week had higher Hg levels (M=2.6 ng/mL, SE=1.1) than anglers eating fish less frequently (M=2.0 ng/mL, SE=1.2) or never at all (M=1.3 ng/mL, SE=1.1). The differences found among anglers in the Hudson River are likely less than we would find along the Passaic and Newark Bay, as a major source of Hg was present along Berry’s Creek, feeding into the Newark Bay and Passaic River, leading in turn to higher sediment concentrations, where most participants will have obtained their fish for consumption. Thus, these published results clearly indicate that, although we will not be able to do a statistical hypothesis test, we should be able to collect and measure levels of contaminants in volunteers who consume locally caught fish or shellfish, confirming the fact that such a hypothesis test could be done, and providing information useful in doing a Power Analysis in the formal application to NIH in one year.

**Data storage and Confidentiality:** Research data will be stored on an NYU MCIT-managed secure departmental network server in a password-protected system in a key and password locked room. The links between these codes and PHI will be stored on the server. Participants will be informed the specimens will only be used for this current study and not for future research purposes. No genetic testing will be performed on bio-specimens. **Confidentiality Risk** – Participants will be informed that the information gathered in the study will be confidential, and will not adversely affect any treatment that they may receive at the participating hospitals or their community health clinic.

Data to be collected will also include participant demographics and dietary habits. All demographic and clinical variables will be compiled in a secure database on the NYULMC server and all biomarker data will similarly be compiled in secure databases with de-identified numerical identifiers. Access to this information will only be available to principal investigator co-investigators and to study personnel. We will use an electronic sample tracking system for sample inventory. All raw data gathered for the study will be kept in a locked cabinet in the PI, George D Thurston’s office at NYU. All computerized data will be on an MCIT-managed network drive, and only be accessible to trained study personnel. All participants will be assigned a unique identifier (code number) that will be used in all computerized files containing study data. A file containing links between participant identity and code number will be maintained in a separate file with a separate password and will only be accessible to trained study personnel who must know the participants’ identities to contact participants for enrollment, and/or manage the data. All study personnel will receive training...
in human subjects’ protection prior to any involvement with participants or study data and will be continuously supervised by George D. Thurston, Sc.D.

Access to Samples and Donor Information: The principal investigator, co-investigators, and study personnel in charge of the specimens will have access to the samples.

7) Risk/Benefit Assessment

a. Risks to Subjects

There are no risks to those participating in the survey component anonymously (i.e., those who do not provide contact information). For those who indicate their contact information, and that they are willing to be contacted for possible participation in the blood draw recruitment, there are breach of confidentiality and privacy risks for the survey. However, as noted above, data confidentiality and security measures will be applied to minimize that risk.

For those who participate in the second study component, the blood draw may be slightly painful and can cause bruising at the site of the needle stick. There is a very small chance that infection may occur at the blood draw site. Our trained personnel will reduce this risk.

b. Protection Against Risk

Provisions for Research Related Injury (1) a certified phlebotomist will be present during all blood draws and available for consultations around any significant clinical issue that may arise. Additionally, weekly research team meetings will be held during which any research concerns that may have arisen during the week will be discussed and any appropriate actions will be taken.

There is always a small risk that data may be obtained by highly motivated individuals with sophisticated methods to access the secure/encrypted databases locked and housed on the NYULMC campus. NYULMC protects its networks and servers with sophisticated encryptions and locked storage facilities.

c. Potential Benefits to Subjects

There are no direct benefits to participants. The benefit to society is potentially great, as the study will promote an increased understanding of the effects of environmental exposure from local fish consumption. Such knowledge may inform efforts to design programs to prevent the development of many chronic diseases. Furthermore, it is hoped that this study will contribute to an understanding of avoidable risk factors for the development of chronic diseases. Such findings would potentially have powerful influences on future research initiatives and public policy directed at minimizing the morbidity associated with environmental exposures.

8) Costs to the Subject

Participants will not incur any cost to participate in this study.
9) **Payment for Participant**
Participants will receive a $10 gift card for completing the survey part of the study. Participants will receive $100 for their participation in the optional blood-draw part of the study. This is needed because of the inconvenience of the travel involved to NYUMC and back, taking up to 3 hours total, including the blood collection process.

10) **Withdrawal of Subjects**
Study participants may withdraw from the study at any time with no consequence. Participants may also refuse to participate in any part of the study.

11) **Sharing of Results with Subjects* Community Presentations**
The research team including the PI (George D. Thurston, Sc.D) will coordinate the presentation results with the Ironbound Community Corporation (ICC) and NY/NJ Baykeeper Board members to ensure the results are presented in an accessible and meaningful way to their community members. Summary research results will be presented at community meetings set up by the research staff and the advisory board in the local church, public areas such as the town library and town community hall.

12) **External Collaboration/Collaborator(s)**
The research will be conducted in collaboration with the Ironbound Community Corporation (ICC) and the NY/NJ Baykeeper (see Letters of Support), who will host community events and/or meetings, where NYU study personnel will be able to attend and recruit participants for the study.

13) **Bibliography**


Appendices: The following appendices must be attached to the protocol if used for the research

Appendix A: Study Consent Form
Appendix B: Fish Consumption Survey Questionnaire
Appendix C: Fish species