

PROCEDURES FOR PROPOSALS FOR USE OF NYC HANES SPECIMENS

All investigators (including NYC DOHMH investigators) must submit a proposal for use of NYC HANES specimens.

Proposals are limited to a maximum of 2-3 single-spaced typed pages, excluding figures and tables, using ten cpi type density. The cover of the proposal should include the name, address, and phone number and E-mail address of the principal investigator (PI) and the name of the institution where the laboratory analysis will be done. All proposals should be E-mailed to nychanes@health.nyc.gov.

The following information should be used to develop the proposal content.

- 1. Specific Aims** - List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested. NYC HANES is designed to provide prevalence estimates of diseases or conditions that are expected to affect at least 5-10 percent of the population. Research proposals that expect much lower prevalence estimates need to provide more detail on why specimens from NYC HANES are needed for the project and provide details on how these data will be analyzed. Research proposals that involve genetic testing on specimens will not be considered.
- 2. Background and Public Health Significance** - Briefly describe the background of the proposal, identifying gaps in knowledge that the project is intended to fill. State concisely the importance of the research in terms of the broad, long-term objectives and public health relevance including a discussion of how the results will affect public health policy or further scientific knowledge. The proposal should justify the need for subsets of specimens that are representative of the NYC population.
- 3. Research Design and Methods** - Describe the research design and the procedures to be used. A description of laboratory methods must be included (with references) as well as the quantity of serum or urine being requested. Investigators should expect that up to 100 microliters would be available for any given proposal and should provide justification for requesting more than this amount. Laboratory performance characteristic (e.g., test sensitivity/specificity and gold standard to be used) and quality control procedures should be described. Include a justification for determination of sample size or a power calculation. If the researcher is requesting a sub-sample of specimens, a justification, must be given. The researcher must describe how this sub-sample will be re-weighted to provide citywide estimates. The program will evaluate the study design and analysis plan in the proposal to determine whether the project is consistent with the design of the NYC HANES survey.
- 4. Qualification of Investigators** - A brief description of the Principal Investigator's expertise in the proposed area should be provided.
- 5. Funding** - The source and status of the funding to perform the requested laboratory analysis should be included. Investigators will be responsible for the cost of processing and shipping the samples.

6. Timeline for laboratory tests –Investigators must have substantial progress (defined by the start of laboratory testing) in the first year after the specimens have been shipped, and all testing should be completed in the second year. The investigator should address his/her ability to comply with this timeline or request and justify additional time for the project. Return of the specimens will be requested if progress is not made in the project at the end of the second year. Refund of payment for the specimens will not be returned in this situation.

Approvals

All research proposals must receive approval from the Technical Panel, a multi-disciplinary team of DOHMH scientists. This team will consist of content experts from programs that are most closely associated with the content area of the specific proposal. Every year a call for proposals will be disseminated to local research institutions in December. **All Proposals received prior to April 1st will be reviewed during the month of April. Proposals can be submitted at any time during the year, however they will only be reviewed in April unless compelling justifications are presented and approved by the Commissioner of Health.** Proposals received prior to April 1st will receive an initial response by May 30th. The initial response will be an acceptance, rejection or request for clarification. If clarification is requested, the investigators will need to submit a response within 2 weeks. Final decisions on proposals needing clarification will be made within 4 weeks of receipt of the response.

All proposals that receive approval from the Technical Panel require approval from the NYC DOHMH IRB. Once approval has been obtained from the Technical Panel, an IRB application packet will be provided to the investigators which will include an IRB Application form and a calendar of the NYC DOHMH IRB meetings and submission deadlines. Final approval of the research proposal will be subject to the decision of the NYC DOHMH IRB as well as the IRB from the investigators institution.

AGENCY AGREEMENT

A formal signed agreement with investigators for approved projects will be completed before the release of the samples. This agreement will contain the conditions for use of the samples as stated in this document and as agreed upon by the investigators and NYC DOHMH.

PROGRESS REPORTS

Brief progress report will be submitted annually to the NYC HANES unit. The investigator is required to submit NYC DOHMH IRB continuation reports annually.

DISPOSITION OF RESULTS AND SAMPLES

No samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Technical Panel and the NYC DOHMH IRB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be returned to the Repository or disposed of upon completion of the approved project. All laboratory results will be returned to NYC DOHMH and will be part of the public domain. The data will not be released until approximately 1 year after reporting the results to NYC DOHMH, to allow the investigator time to publish results, unless otherwise required by State or City law.