FAQs for HBCD Phase II FOAs

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GENERAL QUESTIONS

1. Are only current Phase I Healthy Brain and Child Development R34 grantees eligible to apply, or is this an open competition?

   Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) may apply.

2. How many awards does NIH plan to make?

   NIH intends to fund approximately 20-25 research sites, 1 HBCD Data Coordinating Center (HDCC) and 1 HBCD Consortium Administrative Core (HCAC).

3. Can a PI be a PI on more than one component?

   Investigators are permitted to apply for only one component of the overall HBCD Consortium (HDCC, HCAC or research site) as the PD/PI but may serve as co-investigator on more than one component.

4. How should our team decide whether to apply as three linked research sites, or as one award with subcontracts?

   The RFA outlines the expectations for an application as well as the review criteria by which the applications will be evaluated. Each applicant needs to determine how best to develop their application.

5. May the HBCD Data Coordinating Center (HDCC) and HBCD Consortium Administrative Core (HCAC) applications reference each other?

   Applications for the HDCC and the HCAC must be stand-alone (meaning one should not need to read one to understand the other), but they can reference each other. The content of each

application is at the discretion of the applicant. Applicants should not assume that a reviewer will see any application other than the one he/she submits.

6. Should applicants discuss how they will work with the HCAC and HDCC?

   Applicants should explain how their work will integrate with the HCAC and HDCC. Applicants are encouraged to review Section I of the FOA. The section of the FOA notes that this initiative seeks to fund three highly integrated components.

7. Can applicants add a SOP as an appendix?

   No, per NOT-OD-17-098, the only appendix material allowed are:
   - *Blank data collection forms, blank survey forms and blank questionnaire forms -- or screenshots thereof.*
   - *Simple lists of interview questions.*
     - *For clarification, these blank forms and lists are not and do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.*
   - *Blank informed consent/assent forms*
   - *Other items only if they are specified in the FOA as allowable Appendix materials*

8. Can applicants include links in the application?

   No. Hyperlinks and URLs are only allowed when specifically noted in funding opportunity announcement (FOA) and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. It is highly unusual for a FOA to allow links in Specific Aims, Research Strategy and other page-limited attachments.

9. Should applicants get letters of support?

   Please refer to https://nexus.od.nih.gov/all/tag/letters-of-support/

10. Do applicants need to demonstrate that they have recruited these populations before?

    Demonstration of experience and success conducting brain-imaging research among infants and children in the age range proposed in the application (e.g., sampling, recruitment and retention of high-risk participants, comprehensive phenotypic assessments, neuroimaging in infants and young children, biospecimen collection) is highly desirable.

11. Will all linked application receive the same score?

    No. Each application will receive its own overall score based on the scientific and technical merit of the submitted application.

12. How will NIH make decisions about funding?

The following will be considered when making funding decisions: 1) scientific and technical merit of the proposed project as determined by scientific peer review, 2) availability of funds, and 3) relevance of the proposed project to program priorities.

RESEARCH PLAN

1. Do all sites in a group of linked applications need to include identical research plans in their applications?

   For linked applications, all but two pages of the application must be identical. The application from each site must contain a Research Strategy that clearly describes those aspects of the project that are common to all sites of the collaboration. Variations in the Research Strategy between sites, no matter how minor, should be highlighted in a subsection of the Research Strategy with the heading "Elements Unique to This Site." The Specific Aims must include an Overview section that should be identical for all applications that are linked for the collaborative U01. The Overview should provide an overall rationale for applying as a linked collaborative study; the role of each site; the approach to project management; and elements unique to any of the sites.

2. Our team plans to apply as an unlinked research site. Does our application need to address all the issues outlined in the Research Strategy section of the RFA?

   The FOA outlines the expectations for an application as well as the review criteria by which the applications will be evaluated. Each applicant needs to determine how best to develop their application. If an applicant addresses only a subset of measures, the applicant might consider including a justification for this decision.

3. Should our team write our aims to address the objectives in the FOA, or propose innovative aims?

   Aims should be written to address the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. The application should cover all the elements identified in the RFA.

4. There are many assessments outlined in the RFA. May our team propose an approach whereby the entire team uses a focused protocol of core measurements and a subgroup of sites conducts additional assessments?

   The FOA outlines the expectations for an application as well as the review criteria by which the applications will be evaluated. Each applicant needs to determine how best to develop their application. If an applicant addresses only a subset of measures, the applicant may consider including a justification for this decision.

5. Are we required to conduct all imaging assessments at every time point? How should applicants prioritize?

Applicants should propose a plan for evaluation (imaging and other assessments) at intervals sufficient to provide a detailed measure of early neurodevelopment that will not overburden study participants. Longer intervals between scans can be considered as the child matures. Applicants should propose implementation of an imaging protocol that is developmentally sensitive; can be reliably administered at multiple sites and is feasible for infants and children over the course of the study.

SAMPLING APPROACH

1. Should applicants assume that the entire sample will have 7,500 children by the end of year 5?

   Per the RFA, the research plan of the application should describe a sufficient sample size to achieve the dual study goals of assessing normative brain development and analyzing the effect of substance exposures and environmental adversity on brain development. Preliminary estimates suggest a total HBCD Study consortium sample size of approximately 7,500 participants at the end of the 5-year funding cycle would be needed. Applicants should include plans for handling attrition, so that this goal can be attained. A smaller sample size can be proposed if it will meet the research objective in RFAs and is justified by feasibility and statistical-power analyses.

2. Since there will be about 20-25 sites, and the target is 7,500 participants, should applicants plan on 300 participants per site?

   Applicants should propose what is feasible for their site given budgetary and other constraints. Depending on many factors, participants may not be evenly distributed across sites.

3. Is this a longitudinal study for 5 years, or 10 years?

   The desired duration of data collection is 10 years, but we are only providing funding for the first five years currently.

4. What proportion of our sample should include the normative pregnant women, pregnant women who used opioids and other substances during pregnancy, and the comparison group of pregnant women from similar backgrounds/environments as the cohort of pregnant women who used substances?

   Applicants should propose what makes the most sense to address the research objectives posed in the RFA.

5. Will all sites be expected to have an equal distribution of these three groups?

   Applicants must provide a scientifically justified rationale for the sampling strategy proposed.

6. There is extensive polysubstance use in our community. Thus, the women we survey are unlikely to only be using opioids. Will this be a problem for the HBCD study?

It is expected that the study will include women that have used multiple substances. The research strategy should include a comprehensive assessment of substance use history to permit accurate estimates of pre-/perinatal exposure of substance use (e.g., opioids, marijuana, tobacco/nicotine, alcohol, psychostimulants, hallucinogens, etc.) using multi-modal approaches such as interviews and other self-report methods, biospecimen collection from mother and infant and/or drug metabolite and toxicology screening, and/or survey of medical records.

7. Our sites do not include many Hispanic residents. Is it a problem if our area doesn't have many people from this ethnic group?

   It is not a problem if the cohort recruited is representative of the area where the applicant's study is taking place. The entire study consortium, however, should include a normative sample that represents the diversity of pregnant women in the U.S. population.

8. Do all pregnant women participating in the study need to be recruited during pregnancy, or can applicants also recruit women after birth?

   Per the FOA, recruitment should occur beginning during the 2nd trimester and continuing through birth.

9. Should applicants plan to assess study participants on an annual basis?

   Applicants should propose a plan for evaluation (imaging and other assessments) at intervals sufficient to provide a detailed measure of early neurodevelopment that will not overburden study participants. Longer intervals between scans can be considered as the child matures.

NEUROIMAGING

1. Our team does not have the capacity to conduct all the neuroimaging assessments listed in the FOA. May we collaborate with another partner, so we can cover all these measurements?

   Yes, a research project site can be a single institution if all functions (e.g.,neuroimaging, biospecimen collection, non-imaging assessments) can be accomplished at that site; or a central hub institution with other institutions as spokes for the hub, such that all the required data collection can be accomplished by the contributing institutions.

2. Our set of linked applications includes 4 sites. Does the applicant need to have at least 2 sites with each type of scanner (e.g. 2 Philips and 2 Siemens) – or at least 2 sites with the same type of scanner (e.g. 1 Philips and 3 Siemens would be okay)?

   For linked applications proposing to use scanners from different vendors across linked research sites, there must be at least two research sites with scanners from the same vendor in order to disentangle potential site vs. scanner effects. If a single vendor is represented in a consortium, a justification should be included.

3. Will grantees be expected to image newborns/infants?

Applicants should plan to image infants and additional subsequent timepoints.

4. The RFA appears to require EEG measurements. Is this mandatory?

   EEG measurements are expected.

BIOSPECIMENS

1. What costs do applicants need to cover related to biospecimens? Should applicants include shipping fees in their budgets?

   Grantees will be expected to cover collection of biospecimens and shipping fees to the biorepository. Detailed plans and procedures to collect, process, analyze (where appropriate, e.g., SARS-CoV-2 testing), and ship biospecimens (e.g., urine, blood, saliva, hair) indicative of substance exposure and other environmental contaminants (lead, heavy metals, etc.) should be described; plans must include a prioritized list and details about chain of custody of samples from collection to analysis (i.e., barcode system). Biospecimens will be sent to the NIDA Neurodevelopmental Studies Repository for analysis and subsequent distribution to qualified researchers.

2. What about collecting genetic and COVID-19 data? Do applicants need to propose assays? Will this all be done centrally?

   Applicants should justify which biospecimens they propose to collect. Assays will be conducted centrally. One exception may be that SARS-CoV-2 testing of participants which may be required as protection for the research staff and participants. Applicants are expected to use the NIDA Neurodevelopmental Studies repository (to be named) for biospecimen storage and subsequent processing for genetic, epigenetic and other assays.

3. There are several biospecimens mentioned in the FOA. What is the plan for analyzing this data?

   Grantees will cover the costs for collection and shipping of the samples, but the repository will do the assays.

BUDGET

1. Will the budgets be the same for each site? How will NIH handle sites with different F&A rates? Is it a total of $1M per site regardless of F&A?

   Each site will have different costs and each site is not capped at $1 million. Applicants should propose budget costs appropriate for their respective site and the research proposed. As noted in the FOA, application budgets are not limited but need to reflect the actual needs of the proposed project.

2. Should applicants plan to budget for all 7,500 children? Our sites do not have the capacity to collect data from all 7,500 children.

   Applicants should budget for the costs associated with the number of children that they plan to survey/scan at their site.

3. The RFA defines the budget for Year 1. What can applicants expect for the out years? Should applicants assume that that the budget is flat for the rest of the project?

   NIH has no additional information aside from what is stated in the RFA. The budget for subsequent years should be consistent with the proposed research. Future year amounts are contingent upon annual appropriations.

4. The RFA states: "NIH intends to fund 1 HBCD Data Coordinating Center, corresponding to a total of up to $4,000,000 for fiscal year 2021." Is this $4,000,000 for the total budget (direct and indirect costs) of the HEALthy Brain and Child Development Consortium or just the coordinating center?

   This is for the HBCD data coordinating center for FY2021 only. Funds available are total costs.

5. Can this grant be used to fund substance use treatment for women participating in the study?

   This grant cannot fund treatment. However, applicants should include plans for referral to available services.