

INPHAASE Informational Meeting April 21, 2008

Dr. Gloria Heppner welcomed the group. She stated that INPHAASE is a joint program between WSU and HFHS. The aim is to develop research programs between the two institutions. Each grant that is awarded must have representation from both institutions. The 2008 INPHAASE funding will prepare our institutions will prepare us for the National Children's Study (NCS).

Dr. Christine Johnson provided information regarding the NCS. She stated that this is a contract that involves a national sample from 105 counties across the country. Five counties were chosen in Michigan to be part of this national study of children from birth to age 21. In Michigan, Michigan State University leads the effort with Nigel Paneth as PI. Other collaborators are WSU, UM, the Michigan Department of Community Health, and Henry Ford Health Systems. This consortium (MANCS – Michigan Alliance for the National Children's Study) has been funded for Wayne County, and currently the group is getting ready to apply for the four other Michigan counties (Genesee, Lenawee, Grand Traverse and Macomb).

A contract is not as hypothesis-driven as an R01, but is interested in developing infrastructure in which to collect data and samples. NCS wants a total of 100,000 families throughout the U.S., with each county providing 1000 families. There will be eight cores proposed in Michigan for developing infrastructure, which are cross-institutional and interdisciplinary. The Wayne County technical proposal lists "three population cores: community engagement (CE), sampling, enrollment and maintenance (SEM), and vital data collection (VDC); three clinical cores: obstetric (OB), pediatric (PE) and developmental assessment (DA); and two specimen cores: biological (BIO) and environmental (ES). Environmental sampling (soil, air, water, dust) and biological samples will be obtained from the mother – and also cord blood, merconium, etc., from the babies. Home visits will be made by a combination of the environmental and biological samples, plus developmental assessment, and pediatric core."

A patient advocate will shepherd the mom through clinic appointments and will be there at birth, to make sure that the samples are taken.

The success of NCS depends on people making use of the data, so they will be releasing data (through Westat, the coordinating center) fairly quickly after being collected.

The first wave of data/sample collection will probably be January 2010. We are hoping to develop some studies in advance (via INPHAASE) so that we will be ready to propose adjunct studies. For example, It may not be hard to add an instrument to the study; however, invasive samples will be harder to get, although an extra tube of blood might be doable from the mothers. Also siblings might be something that might be of interest. On the NCS website (www.nationalchildrensstudy.gov) you can see other areas that have been funded – which will

give you an idea of the competition. There is also an emphasis on rural areas, so Lenawee, northern Macomb and Grand Travers will probably come in – think of studies in these areas.

Five main hypotheses have been chosen – it is suggested that you do NOT use the exact same hypotheses for your INPHAASE proposal, but rather develop something similar in: **obesity, neurodevelopment, asthma, birth defects, and physical injuries.**

Samples will be collected, but stored initially (not distributed or analyzed) in order to save money. Eventually, investigators should apply to use these samples. Note that babies' blood samples will be limited; maternal blood will be more readily available. Additional questions will also be looked upon favorably, so long as they do not contribute too much of a time burden to the existing survey questions. Nigel Paneth and the others are asking to be allowed to collect duplicate samples that are stored locally, so these samples might become available in the future.

Dr. Heppner emphasized that the purpose of INPHAASE is to develop feasibility-type studies that will make you competitive for other grants, which will provide data that will give you a strong proposal to propose adjunct studies with the NCS.

Look at the NCS website (www.nationalchildrensstudy.gov) to view the application procedure for the adjunct studies.

Questions:

1. Will there be some opportunity to do an actual intervention with the children? Yes.
2. CUS is interested in putting together a neurodevelopmental database to address lead poisoning in children, tied to a particular house or geographic area. This would then be linked to and used by others, such as the courts and public health systems. Would NCS be interested in tracking what is being done to reduce the lead in the houses or areas?
Response: The NCS likes the idea of linking databases – health, community health, health department, hospitals.
3. What kinds of analyses will be done on the blood samples? Ultimately, it will need to be decided which tests will be performed. We do know that childhood cancer will not be measured because of the relatively small sample size. NCS will be asking for a neurodevelopmental assessment; they'll look at asthma, so possibly pulmonary function will be assessed; anthropometric measures will be taken due to the incidence of diabetes; there will be samples available to look at DNA. (Note: The SEER data base – geographically based – might be interesting to look at to track for cancer type – particularly for mothers or father. Early markers for cancer – such as markers for inflammation – might be studied.)

4. Is there a central analytic chemistry testing site? There are two RFPs that were issued earlier this year but were pulled (for monetary reasons) and will be issued again next year: biological specimens/samples storage, and biochemical analysis.
5. As a bench scientist, what framework /structure should I set up to develop something that might be implemented clinically in the future? This summer, the vanguard centers will have the actual questions. So we'll know exactly what questions will be asked. They're forming committees for adjunct studies approval. They will develop methods to connect environmental samples with health outcome.
6. What is the sequence? Use INPHAASE to write a grant proposal, as you would for submitting something to NCS. This Letter of Intent that you write for INPHAASE, can be used to submit something to NCS. They want a variety of experts to come together to propose something.

So the sequence is:

INPHAASE Proposal for feasibility study



External funding, which will provide preliminary data



Proposal of NCS Adjunct Studies

7. When will funding for the INPHAASE awards start? Hopefully by September 1, 2008. Half of the money \$400,000 is coming from HFHS, half from WSU. In previous awards, we said we were looking for a certain level of award. We did not limit the size of any one grant this year – but encourage you to ask for what you need.
8. If we have questions before the LOI is due, whom should we contact? Chris Johnson cjohnso1@hfhs.org, if you have questions regarding ties to the NCS.
9. Is there room for a health campaign or social science project? An opportunity to improve community engagement or a social science project will be welcome, as well as retention of subjects, to see if some things work better. NCS wants to collect a lot of information on the home and family structure – once de-identified, the data will be quite usable.
10. What actions are we going to take if we see high levels of lead in the home? Charles Barone, the pediatrician involved with ensuring follow-up by pediatricians of the subjects –wants to report child abuse and other ethical issues. A mechanism is set up to report to Dr. Barone. At this time, we are unsure of what to do with reports of high lead levels. Contact Dr. Barone (cbarone1@hfhs.org) for further information.

11. Can we propose to change health behaviors? In terms of physical safety, a lot of bioengineers might be interested in exploring this (for example, Ann Snowden, King Yang, Al King) – the use of car safety devices, as well as what is available in the home. You might characterize families by their overall level of safety and how that might impact other areas like car safety.
12. UM's developmental assessment – will they be adding additional data beyond the NCS assessment? The developmental assessment includes neurological assessment and a newborn exam. There are opportunities to add to this.
13. Where will they take environmental samples? They'll want environmental samples from areas where the child spends 30 hours or more.
14. Will they interview teachers? That is not currently part of the protocol. However, interviewing teachers would be a good study because you don't further burden the time of the mother or child.
15. How do you decide where in Wayne County to recruit? The UM's Institute for Social Research has been looking at school districts, political boundaries, sources of pollutants, and other areas in which to recruit, and will map all this. Mike Elliot has divided up 'like clusters', and other areas where we want to obtain samples. They'll pick it randomly out of these clusters. When is that selection going to be made? Pretty soon.
16. Would letters of support from community partners be important for the NCS LOI? In the past, this has been helpful. It would be a good idea to call Chris Joseph (cjoseph1@hfhs.org) – to make sure nothing in the Community Engagement core conflicts with what you're suggesting.
17. Do you have any measurement for physical activity? That might be something that is measured because of obesity being an aim/outcome. That would be a great topic for a proposal, along with the external environment.

Next steps:

We will make the Wayne County proposal (technical proposal) available (please contact Shay Izzard at ski@wayne.edu) if you are interested.

We will make the e-mail addresses of attendees available to all:

John Reiners (john.reiners.jr@wayne.edu) – Institute for Environmental Health Sciences, WSU

Cathy Jen (cjen@wayne.edu) – Nutrition and Food Sciences, WSU

Sharon Milberger (smilber1@hfhs.org) – CHEDP, HFHS

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