

NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER:

LOI #: LOI - - - -

Title of Formative Research: Placenta Studies: Cell Collection, Banking, and Morphology Assessment

Participating Institutions: **Brown University, CHOP, Mount Sinai, Northwestern, South Dakota, UNC, University of California-Davis, University of California-Irvine, Iowa, Utah, Wisconsin**

Recruitment Study Arms: **Enhanced Household; Two-Tier High-Low**

SME:

COTR: **Various**

Purpose of the Study: To evaluate the parameters that will yield useful and reproducible data from placentas and cord blood being collected as part of the Vanguard Study. Of critical importance is to know how the quality of the collected placental tissue will affect recovery of stem cells from cord blood, placenta, and umbilical cord samples, RNA and DNA, assessment of placental morphology, and the detection of metals and other contaminants in these biospecimens.

Benefit to NCS Vanguard or Main Study: There has been considerable variation in the time that placentas were shipped from Initial Vanguard collection sites to the Placental Processing Site, ranging from 1-6 days. Additionally, there was variability in the ways in which the tissue is handled and processed at Initial Vanguard Center hospitals prior to shipment. Variability in processing has raised questions regarding how the different methods of specimen processing might affect the results of specimen analysis. This formative research study is important for establishing the gold standard as well as "minimal acceptable conditions" appropriate for sample collection and preservation for future use of these tissue resources for stem cell banking, genetics, environmental analyses, and morphology/pathology.

Study Design: Study Centers will pilot test the collection protocol by collecting 42 placentas, umbilical cord samples, and cord blood samples from mothers not geographically eligible for the NCS Vanguard Study. For the subsequent stage of this formative research study, Vanguard Centers will collect an additional 240 placentas, umbilical cord segments, and cord blood samples from NCS Vanguard Study participants. Following collection, samples will be shipped to a central processing site, where the samples will be examined for an assessment of morphology/pathology. For the morphology portion of the study, an additional 335 NCS placentas will be examined.

Target Respondents: This project would recruit NCS Vanguard Study pregnant women and pregnant women not geographically eligible for the NCS Vanguard Study.

Method of Recruiting: We will collect samples during birth visits and within the context of the NCS Vanguard Study.

***Confidentiality:** Study Centers must abide by the terms of their Data Use Agreement, which should reference all formative research efforts involving the collection or management of NCS restricted-use data. All participating Study Centers will have approved Data Use Agreements and Security Plans prior to launch.

***IRB Approval:** Local IRB clearance for this activity has been requested by all participating Study Centers; Local IRB clearance will be obtained prior to contact with participants, including legal guardian consent per local jurisdiction requirements.

Remuneration: Consistent with the approved NCS Vanguard Study Phase 2 incentive structure, we propose to offer a \$25 monetary incentive for each participant contact of this formative research project.

* To be completed before project proposal is submitted for OIRA clearance.

Send completed forms to ncs@mail.nih.gov

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up to 1 hour of information collection activity. These amounts would be in addition to other monetary incentives approved for participants in the NCS Vanguard Phase 2.

Sensitive Questions: We will not ask sensitive questions as a component of this study.

Proposed Project Schedule: We will begin this project upon receipt of all regulatory approvals.

Data Collection Burden:

	Contact #1	Total
Informed Consent and Biospecimen Collection	.25	.25
Total Burden Hours	.25	.25
# of Respondents	617	--
Total Respondent Burden Hours	154	154
Proposed Monetary Incentive	\$25	\$15,425

Please check here after ensuring that all calculations have been verified

Estimated Costs: Staff Hours: 308 hours.
Supervisor Hours: 77 hours.

Attachments: Informed Consent Exemplar (for Non-NCS Vanguard Study Participants), Birth Visit Information Sheet (only for NCS Vanguard Study Participants joining LO12-BIO-18). Note: The consent will be customized for each participating study center and target population, as appropriate, and approved by the local IRB prior to use.

Please check here after ensuring that the OMB #: 0925-0590 and Expiration Date: June 30, 2011 date have been inserted as first-page headers on each proposed instrument.

Please check here after ensuring that the following OMB burden statement has been inserted as a first-page footer on each proposed instrument.

Public reporting burden for this collection of information is estimated to average [SC insert estimated response time] minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0590*). Do not return the completed form to this address.

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Appendix 1. NCS Incentives, by Study Activity and Impact on Participants, Stage 1 (*Approved by OMB 7/23/10*)

Data Collection Activity Characteristics	Initial NCS Vanguard Study	NCS Recruitment Substudy
Time for encounter	3 hours	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions
Physical measures	Yes	No
Environmental specimens	Yes	No
Biospecimens	Yes	No
Participant observation	Yes	No
Monetary incentive, per visit	\$100*	\$25
Non-monetary incentives (tote bags, post its, key chains, etc.)	<u>In addition to the monetary incentive</u> , non-monetary incentives valued at \$25 or less may be offered to participants	<u>As an alternative to the monetary incentive</u> , NCS logo gifts valued at \$25 or less may be offered to the participants in lieu of cash or local incentives not exceeding \$25 in value and deemed non-coercive by local IRBs