**CDNM | BWH / Harvard Cohorts Biorepository**

**Labcode Verification Form [E]**

**LIFECYCLE OF A PROJECT utilizing samples from NHS | NHSII | HPFS | PHS | GUTS**

**![C:\Users\n2xek\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\PNYE1VJW\MC900432530[1].png]()GETTING READY**

All investigators and collaborators must read and agree to comply with the [GUIDELINES FOR ACCESSING SAMPLES](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/GuideA_Guidelines%20for%20Accessing%20Samples.docx?attredirects=0) prior to beginning a project.

**![C:\Users\n2xek\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\PNYE1VJW\MC900432530[1].png]()**

**CREATE A PROJECT BUDGET**

The [BLOB Proposal Form [A]](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_A_BLOB_Proposal.docx?attredirects=0&d=1) calculates an estimated BLOB charge for your grant proposal.

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**COMPLETE PILOT STUDIES**

The [Pilot Study Form [B]](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_B_Pilot_Request.docx?attredirects=0&d=1) plans any **REQUIRED** Pilot Studies for a project that utilizes an assay that has not been previous tested on the archival samples of the Biorepository.

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**GET INTO THE PROJECT QUEUE**

After your grant is funded, the [Get-in-Queue Request Form [C]](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_C_Get_In_Queue.docx?attredirects=0&d=1) updates the costs estimates of a project and places a proposed project in our queue.

**![C:\Users\n2xek\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\PNYE1VJW\MC900432530[1].png]()**

**SELECTING SAMPLES**

The Selections Forms [[D1](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_D1_Nested_Case_Control_Study.docx?attredirects=0&d=1) and [D2](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_D2_Cohort_CrossSectional_Case_Only%20Study.docx?attredirects=0&d=1)] help to select participant samples based on your projects specific criteria. The Data Management team will help you with identifying the correct form for your project.

**VERIFY PROJECT – ASSIGN LABCODE**

The [Labcode Verification Form [E](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/Form_E_Labcode_Verification.docx?attredirects=0&d=1)] finalizes the specifications and updates costs estimates of your project so that the biorepository can work on your project.

**PAYMENT & PREPARATION OF SAMPLES**

Once you have approved the final cost estimate, your project will be added to our lab worksheet, the samples will then be prepared by the BHCB and FINAL INVOICE will be sent to PI for payment.

**RESULT DATA AND ANALYSIS**

Project results are sent to PI after payment is received.

General Information about LABCODE VERIFICATIONS

This form is required to finalize specifications so that the BWH/Harvard Cohorts Biorepository (BHCB) can work on your project. One of the BHCB staff will request this form **AFTER** data management confirms that the selection is complete. The data manager for each cohort (Chris Murphy [nhcdm@channing.harvard.edu] for NHS and NHSII and Robert Sheahan [hpres@channing.harvard.edu] for HFPS) will provide the case/control numbers.

After initial submission, we will provide estimated charges. Please review the charges, check **√** the approval box below, AND provide the Peoplesoft account number(s) to be charged for your project. If multiple accounts will be charged, please specify which projects should be charged to each account. Once work in the Biorepository work is completed, you will be sent an official invoice.

**If you are using more than one cohort, please fill out a separate form for each cohort**.

If changes in research plans are requested **AFTER** the lab starts working on the project (e.g. decide not to send some samples for assay or add an assay), you will be responsible to pay for all the work completed up to the time the change was requested. Therefore, if there is a chance that the research plans may change, contact Janine Neville-Golden, as soon as possible, at: (617) 732-5781 or via email at BLOBforms@channing.harvard.edu.

CONTACT

Send completed forms to us via: BLOBforms@channing.harvard.edu

Questions: Janine Neville-Golden, Senior Laboratory Manager

 BLOBforms@channing.harvard.edu

 617-732-5781

# POLICY AGREEMENT

 I,       , have read and understand the [[Guidelines for Accessing Samples](https://sites.google.com/a/channing.harvard.edu/bwh-harvard-cohorts-biorepository2/docs/GuideA_Guidelines%20for%20Accessing%20Samples.docx?attredirects=0)](https://sites.google.com/a/channing.harvard.edu/nci-bp-website/biomarker-lab-and-repository/document-with-policies), and I understand that by checking this box [ ] , I signify that I agreed to all of the policies.

**Today’s Date:**

# GRANT INFORMATION

**Do you have a BWH or Partners account?**

 [ ]  **Yes** [ ]  **No**

|  |  |  |
| --- | --- | --- |
| **If “YES”, you MUST complete the section below and provide a Peoplesoft number.** We will confirm with your Grants Portfolio Manager that there are sufficient and available funds in the account(s) to cover the estimated BLOB costs. This money will be encumbered.**Your projects WILL NOT proceed without this “pre-bill approval”.** |  | **If “NO” you MUST complete the section below.** Please note that if you do not have a prime or subcontract account at PHS/BWH external rates will apply. For more information contact Janine Neville-Golden at 617 732-5781 to discuss how payment will work.  |
| **Peoplesoft number(s):**      (Please specify how each Peoplesoft number applies for each project.)**End date of funding:**      **Did the PI of the grant approve these charges?** [ ]  **Yes** [ ]  **No** **Other comments regarding funding:**       |  | **Grant Name / Funding Source:**      **Institution where funding is Primed:**      **End date of funding:**       **Grant Finance Manager***Name:*      *E-mail:*      *Telephone:*      **Other comments regarding funding:**       |

# PI/CONTACT INFORMATION

**Principal Investigator**

*Name:*

*E-mail:*

*Telephone:*

***Primary contact for proposal*** *(if other than PI)*

*Name:*

*E-mail:*

*Telephone:*

# ENDPOINT/COHORT INFORMATION

**Endpoint:**

**Cohort**:

**Will this project include multiple cohorts?**

 [ ]  **No**  [ ] **Yes**

If **YES**, remember to submit separate forms for multiple cohorts.

 ***What other cohort(s) will be used?***

 ***Are any of these cohorts external to the Core* (e.g. WHI, WHS)*?***

 [ ]  **No** [ ]  **Yes 🡪** Please explain

***Do you want related projects from multiple cohorts sent to the lab at the same time?*** [ ]  **No** [ ]  **Yes 🡪** Please explain

**IRB Approval #:**

**Which Sample collection you would like to use?**

(E.g. first or second collections in NHS, NHSII, HPFS or MLVS; WLVS):

A complete list of collections within each cohort is available online at:

<https://sites.google.com/a/channing.harvard.edu/using-the-biorepository/using-samples/collection-list>

NOTE:

If you plan to utilize multiple sample collections from within a cohort, please contact Janine Neville-Golden for further clarification.

***For example:***

You would like to utilize samples from both NHS first AND second collection or NHSII follicular and luteal samples.

**Has a SELECTION been conducted previously for this project?**

[ ]  **Yes** [ ]  **No**  [ ] **Don’t know**

If **YES**, when:

 Name of Project:

 PI, if known:

# PROJECT INFORMATION

**Are any laboratories you are using located outside the United States or Canada?**

[ ]  **Yes** [ ]  **No**

If **YES**, which assay lab is international?

**NOTE:** Additional International Shipping Costs will apply (See Section I).

**Study type**:       (nested case-control study, sub-cohort, other)

 Expected number of samples in the project:

 Number of cases, if applicable:
 Number of controls, if applicable:

**Quality control (QC) samples are used to assess assay variability in the project** Percent QC samples:       (default is 10%)Specific QC requirements:       (e.g., fasting, postmenopausal)

**NOTE:** The biorepository does not charge for the 10% QC samples; however, it is the responsibility of the PI to pay the assay costs associated with QCs.

|  |  |
| --- | --- |
| About **PARTICIPANT DRIFT SAMPLES**Drift samples (for plasma, urine, or saliva assays) are used to assess and correct for laboratory drift between projects conducted over time.Participant Drift: 12-18 controls sent in a prior labcode with more plasma volume than their matched case that will be sent in current project. The contact person will provide the biorepository with an ID list selecting prior samples with low, medium and high levels of the biomarker from prior project. | **Will your projects need to include PARTICIPANT DRIFT SAMPLES for any plasma, urine, or saliva assays?**[ ]  Yes [ ]  No Provide details:     **If YES, please note the (specific assays if more than one) in the “Comment” Section of the table.** |

|  |  |
| --- | --- |
| About **DRIFT POOLS**Drift Pools are composed of plasma (and urine) from donors who were chosen to be similar to cohort participants and were purchased from an outside company. You should include drift pools if you plan to do an assay in the future with this endpoint. The biorepository does not charge to include drift samples; however, it is the responsibility of the PI to pay the assay costs associated with them. | **Will your projects need to include DRIFT POOL SAMPLES for any plasma or urine assays?**[ ]  **Yes** [ ]  **No** Please provide preference:      |

# PLANNED ASSAYS

* **Make sure to include ALL planned assays.**
* **The Investigator is responsible for calculating estimated number of participants.**
* **Use a separate row for each Assay Lab. Several assays can be measured in one aliquot sent to the same lab.**
* **Each sample type MUST be listed SEPARATELY.**
* **Use a SEPARATE ROW for aliquots from different collections (1.1, 1.2, 1.4 etc.) and/or for INCIDENT and PREVALENT disease.**

 **Please explain your research plans by completing the** table below:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Plan #** | **Sample Type, Collection**  | **Lab** | **Assay(s)** | **FU cycles** | **Volume** (ml) If known | **Ca: Co ratio**(Prevalent or incident) | **Sample Size** | **Special Instruction** |
| ***EXAMPLES*** | **Plasma, NHS 1st collection** | **Pollak** | **Insulin, IGF** | **02-04** | **0.20** | **1:2, incident** | **440** | ***Integrate with samples from example 2 below*** |
| **Plasma, NHS 2nd collection** | **Pollak** | ***Insulin, IGF*** | ***02-04*** | ***0.20*** | ***1:2, incident*** | ***220*** | ***Integrate with samples from example 1 above*** |
| **WBC** | **DeVivo** | ***DNA Extraction***  | ***76-04*** | ***0.10*** | ***1:1*** | ***1020*** | ***WBC will be used for GWAS*** |
| **1** |       |       |       |       |       |       |       |       |
| **2** |       |       |       |       |       |       |       |       |
| **3** |       |       |       |       |       |       |       |       |
| **4** |       |       |       |       |       |       |       |       |
| **5** |       |       |       |       |       |       |       |       |
| **6** |       |       |       |       |       |       |       |       |
| **7** |       |       |       |       |       |       |       |       |
| **8** |       |       |       |       |       |       |       |       |
| **9** |       |       |       |       |       |       |       |       |
| **10** |       |       |       |       |       |       |       |       |

# NEXT STEPS

* **Submit to:** **BLOBforms@channing.harvard.edu**

 We will utilize this information to create a final estimated BLOB charge in the table below (Section J).

# BLOB CHARGES

**BLOB Charge User Fees**

Pricing for FY18 begins on **OCTOBER 1, 2017 - SEPTEMBER 30, 2018**.

*(BWH/Partners Health System Fiscal Year)*

|  |  |  |
| --- | --- | --- |
| **USER TYPE** | **YEAR OF GRANT START** | **FY18** |
| **Internal** | 1st Internal Aliquot | $46  |
| 2nd Internal Aliquot | $26  |
| Integration Fee (Per sample)\* | $7 |
| **External to Partners:****Academic** | 1st External Aliquot | $66 |
| 2nd External; Aliquot | $37 |
| Integration Fee (Per sample)\* | $9  |
| **External to Partners:****Industry** | 1st Industry Aliquot | $105  |
| 2nd Industry Aliquot | $59  |
| Integration Fee (Per sample)\* | $14  |

\*Charge per vial to place samples from the same participant who have samples in different collections (or in NHSII, gave a follicular and luteal sample) next to each other in the same box.

External to Partners/Academic Users are charged: the internal Subsidized rate PLUS an academic BWH Overhead rate of 44%.

External to Partners/Industry Users are charged: the internal NON-subsidized rate plus 20% with an additional 59% to cover the BWH Industry Overhead rate.

International Shipping with be invoiced as: Internal= invoice amount; External/Academic= the invoice plus 44% BWH OH Rate; and Industry Users= the external invoice amount plus the Industry OH of 59% for BWH.

**NOTE: Industry rates may be negotiated but MUST include the internal Partner fee (non-subsidized) PLUS 59% OH for BWH.**

1. **ADDITIONAL FEES**

**The estimated BLOB charge does NOT cover all project related costs.**

**10 % QCs:**

Although the Core does not charge for the 10% QC samples included in each project, it is the responsibility of the investigator to pay the assay costs associated with QCs. IN addition, any larger than normal QCs requests may carry and additional per vial charge.

**International Shipping Costs:**

The Core will cover the cost of all domestic shipping and deliveries via Federal Express, taxicab, or alternate courier service. However, if you elect to use an international lab, you will be billed for the shipping costs. Quick International is the only trusted international shipping service used. If the PI is an external user, overhead will be calculated and added to the international shipping invoice.

**Change in plans:** If you change your plans (addition, deletion, integration, new assay lab etc.) after the project has been started in the lab, you will be responsible for the charges until the date of notification. There will be additional charges for time of the Manager, Project Manager and/or RA time to accommodate the changes requested.

**GWAS, Metabolomics and other projects that require additional Data Management time:** A charge (consultation fee) will be assessed based on the additional time and/or efforts by Data Management and others for more complicated projects.

|  |
| --- |
| ESTIMATE (To be completed by the Biorepository Staff): |
| Plan # | Sample Type | Laboratory | Aliquot #1st  2nd or 3rd | BLOB fee*Per aliquot*  | # Of aliquots | BLOB fee *subtotal*  | *Comments* |
| 1 |       |       |       |  |  | **$ 0.00** |       |
| 2 |       |       |       |  |  | **$ 0.00** |       |
| 3 |       |       |       |  |  | **$ 0.00** |       |
| 4 |       |       |       |  |  | **$ 0.00** |       |
| 5 |       |       |       |  |  | **$ 0.00** |       |
| 6 |       |       |       |  |  | **$ 0.00** |       |
| 7 |       |       |       |  |  | **$ 0.00** |       |
| 8 |       |       |       |  |  | **$ 0.00** |       |
| 9 |       |       |       |  |  | **$ 0.00** |       |
| 10 |       |       |       |  |  | **$ 0.00** |       |
|  **Estimated BLOB CHARGE TOTAL:** | **$ 0.00** |  |

**Date PI Notified/Notes:**

**IMPORTANT Details about your BLOB Estimate**

* Work cannot begin on the project until your portfolio manager approves a “financial verification”.
* **You are responsible for the charges once the project has commenced.** Therefore, any changes, issues or concerns must be addressed now at: BLOBforms@channing.harvard.edu.
* If changes in research plans are requested AFTER the lab starts working on the project (e.g. decide not to send some samples for assay), you WILL be responsible to pay for the work completed up to the time the change order was requested. **If there is a chance that the research plans may change, contact Janine Neville-Golden, as soon as possible.**
* **An official invoice for each labcode will be issued to you as soon as the pull is complete.**
* If applicable, international shipping costs (Quick International) will be billed separately, once the invoice from the shipping company is received.