**Multicenter AIDS Cohort Study**

**Concept Submission Form & Guidelines**

**A. GENERAL INFORMATION**[[1]](#footnote-1)**,** [[2]](#footnote-2)**,** [[3]](#footnote-3)

1. Date of submission: Click here to enter a date.

2. Lead Investigator(s): Click here to enter text.

3. Study Title: Click here to enter text.

4. Contact Person (*if different from lead investigator*): Click here to enter text.

5. Submission type:  Initial  Revised [*Double click box to add check.*]

Addendum/Expansion of previously approved Concept4

(Readme#): Click here to enter text.)

6. Summary of Changes (For Revisions/Addendums only; highlight or track changes):

Click here to enter text.

7. Guidelines (pages 8-11) have been reviewed:  Yes  No

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Continue on next page ➔ | | | | | | |
| **INTERNAL USE ONLY**  **DO NOT MOVE OR REMOVE** | | | | | | |
| Received by CAMACS: | | | WG(s) to review: | | | |
| MACS EC Review Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | MACS Readme#: r\_\_\_\_\_\_\_\_ |
| \_\_\_\_ Approved |  | | | | | \_\_\_\_ Revision Requested |
| \_\_\_\_ Approved w/comment | | | |  | | \_\_\_\_ Rejected |
| \_\_\_\_ Approved for grant submission | | | | | | \_\_\_\_ Deferred |
| EC Specimen restrictions: **Do Not Use:**  SC  LTNP  Last specimen at person-visit  Other (specify): | | | | | | |
| Site-assigned investigators  to Writing Committee: | | BALT:  CHIC:  CAMACS: | | | PITT:  UCLA: | |

**B. CONTACT INFORMATION**

1. Institution: Click here to enter text.

2. Address: Click here to enter text.

3. Telephone Number: Click here to enter text.

4. FAX Number: Click here to enter text.

5. Email: Click here to enter text.

**C CONCEPT INFORMATION**

1. Proposal includes:  MACS-wide

MACS local study only. Please indicate which center(s):

Baltimore/District of Columbia  Chicago

Los Angeles  Pittsburgh/Columbus

Involves cohorts (*check all that apply*):

NA-ACCORD  WIHS

Other, specify: Click here to enter text.

2. Topic (*check all that apply*):

Aging  Behavior  Biomarkers  Cardiovascular disease  Clinical/Epidemiology

Co-infection  Disease progression  Drug abuse  Genetics  Hepatitis/Liver

Immunology/Virology  Lab  Malignancy/Pathology  Metabolic  Methodology

Mental Health/Neuropsychology/Neurology  Pulmonary  Renal  Treatment response

Other (please specify): Click here to enter text.

3. Indicate the level of NIH HIV/AIDS research priority and provide a ≤100 word explanation of how the concept addresses this priority (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>)

High Priority, specify:

Click here to enter text.

Medium Priority, specify:

Click here to enter text.

Low Priority, specify:

Click here to enter text.

4. Funding Source (*Please complete part a, b and c*):

a. Proposed study is related to an existing grant?

Yes, MACS parent grant

Yes, other than MACS Parent grant (*Please indicate the sponsor and grant number*)

Sponsor: Click here to enter text.

If NIH, Grant Number: Click here to enter text.

No

b. Proposed study is related to a future grant submission?  Yes (*If yes, complete 1 - 4 below*)  No

1) NIH (Please specify solicitation number below)

NIH Solicitation Number: Click here to enter text.

2) Other sponsor (*please specify*): Click here to enter text.

3) Your grant submission deadline: Click here to enter text.

4) Is a letter of support from the MACS needed?  Yes  No

5) Grant submission title: Click here to enter text.

Please inform Jeremy LaMaster ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)) and Robin Huebner ([rhuebner@niaid.nih.gov](file:///C:UsersjkonigDocuments1wpdocsacsformsadministrativeacs-wihsrhu)) about the outcome of your grant submission within 1 year following approval of Concept.

c. If you answered “No” to both 4.a & 4.b please indicate the source of funding for this proposed study:

Click here to enter text.

5. IRB & Human Subjects Issues:

a. Does this project have local IRB approval?  Yes  No

If no, please explain: Click here to enter text.

b. Time period of IRB approval: Click here to enter text.

c. Local IRB reference #: Click here to enter text.

6. Will this project require the withdrawal of specimens

from the DAIDS MACS Central Repository?  Yes  No

a. If “Yes,” the deadline date you will require specimens (mm/dd/yy)[[4]](#footnote-4) Click here to enter a date.

**7.** Regardless of whether or not a subcontract is arranged, will this collaboration involve an institution or company that is not located in the United States?[[5]](#footnote-5)  Yes  No

Name of non-US institution and lead investigator: Click here to enter text.

**D. STUDY DESIGN** (*PLEASE LIMIT EACH SECTION TO NO MORE THAN 1000 WORDS.12 point font only.*)

**1. Abstract** (*Maximum 150 words in lay language; include impact on participants.*)

Click here to enter text.

a. Does this project involve additional participant burden?

Yes (*Check below all that apply*)  No

Additional specimen collection needed

New questionnaire

New procedure (e.g., MRI)

New or added consent needed

Additional visit required

**2. Background** (*Maximum 400 words, not including references.*)

Click here to enter text.

**3. Specific Aims and Hypotheses** (*Maximum 200 words, not including references.*)

Click here to enter text.

**4. Study Design**  (*Maximum 400 words; summarize the study, inclusion criteria, and sample size.*)

Click here to enter text.

**5. Laboratory Methods**  (*Maximum 400 words.*)

Click here to enter text.

**6. Test Results:**

a. Will test results be returned to participants?  Yes  No  NA

b. If yes, when and how? Click here to enter text.

c. If no, why not? Click here to enter text.

**7. QA/QC Procedures** (*Maximum 100 words; summarize laboratory QA/QC procedures and participation in recognized proficiency program.*)

Click here to enter text.

**8. Data Analysis and Sample Size Calculations**[[6]](#footnote-6)(*Maximum 400 words.)*

Will statistical/programming support be required from CAMACS?  Yes  No

Click here to enter text.

**9. Manuscript will be completed by** (anticipated month and year of submission to the EC before submission for publication):

Click here to enter a date.

**E. SAMPLE SPECIFICATIONS**

1. Epidemiologic Specifications:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| a. | Subgroup | HIV (+) | HIV (-) | High Risk HIV (-) | Seroconverter |
|  | No./Subgroup | \_\_\_ | \_\_\_ | \_\_\_ | \_\_\_ |
| b. | HIV Disease Progression |  | Rapid | Intermediate | Slow |
|  | Immunologically defined |  | \_\_\_ | \_\_\_ | \_\_\_ |
|  | Clinically defined |  | \_\_\_ | \_\_\_ | \_\_\_ |
|  | Specify: Click here to enter text. | | | | |
| c. | Number of specimens per participant and timing of specimens: | | | |  |
| d. | Other (*specify*): Click here to enter text. | | | | |

2. Sample Type:  Serum  Heparinized Plasma  EDTA Plasma

PBMCs (viable)  PBMC pellet (not viable)  B cells

Other (*specify*): Click here to enter text.

3. Sample Quantity: Minimum: Click here to enter text.

Optimum: Click here to enter text.

4. Expected number of Person-Visits to be studied: Click here to enter text.

5. Expected number of unique participants to be studied: Click here to enter text.

6. Specimen Shipping Information:

1. Investigator in charge of Lab (to whom MTA will be sent):

Name: Click here to enter text.

Email address: Click here to enter text.

Phone Number: Click here to enter text.

1. Other contact person (if different from above):

Name: Click here to enter text.

Email address: Click here to enter text.

Phone Number: Click here to enter text.

c. Lab name & shipping address:

Click here to enter text.

**F. ADDITIONAL SPECIMEN REQUIREMENTS**

1. Specimens obtained may not be used for anything other than the approved project without prior consultation and permission from the MACS EC.
2. Storage of plasma collected with EDTA started April 1, 2006. Specimens previously thawed for other initiatives will most likely be shipped. If unacceptable, give a reason above for requiring specimens not previously thawed. Leftover material cannot be returned to the National Repository without prior approval from EC.
3. Use of MACS specimens requires submission of a signed MACS Materials Transfer Agreement (MTA).
4. If specimens are being shipped to multiple locations, please copy and complete the information above (*E.6.a-c. above*) for all locations. An MTA will need to be completed for all locations receiving specimens.
5. If you are requesting lymphoblastic cell lines, the NIH AIDS Research and Reference Reagent Program requires all investigators to be registered prior to receiving samples. Registration materials and instructions can be found on the Reagent Program web site located at [*www.aidsreagent.org*](http://www.aidsreagent.org.)
6. A data file containing lab results and a codebook of specimens received must be submitted to CAMACS prior to the release of visit data for analysis. There are absolutely NO EXCEPTIONS to this requirement.

**G. STATEMENT OF AGREEMENT**

I hereby acknowledge and agree that:

1. All information that I provide in this Concept is complete and correct as submitted.
2. Use of specimens and/or data is restricted to the aims outlined in Section D3.
3. IRB approval has been, or will be, obtained before any data and/or specimens are received.
4. I will complete a MACS Data Use Agreement (DUA) if this proposal receives approval.
5. I will submit a MACS Material Transfer Agreement (MTA) if this proposal receives approval.
6. Under no circumstances will I make any MACS study subject 5 digit ID number public whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.
7. My signature below indicates a complete review and acceptance of the Guidelines for collaborations, publication, and acknowledgment as outlined in the attached “Guidelines.”

Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NOTE:** After your Concept has been submitted electronically, please sign and FAX (410-955-7587) or email (jlamaster@jhu.edu) this signature page and page one of the Concept to Jeremy LaMaster.

**H. MACS INFORMATION**

1. MACS Liaison: Click here to enter text.

2. Institution: Click here to enter text.

3. FAX Number: Click here to enter text.

4. E-mail Address: Click here to enter text.

5. Mailing Address: Click here to enter text.

6. CAMACS Point Person: Click here to enter text.

Telephone Number: (410) 955-4320

FAX Number: (410) 955-7587

Mailing Address: Johns Hopkins University

Bloomberg School of Public Health

Department of Epidemiology

615 North Wolfe Street, Room E7644

Baltimore, MD 21205-1999

**NOTE:** Email completed Concept file to Robin Huebner at NIH ([rhuebner@niaid.nih.gov](file:///C:UsersjkonigDocuments1wpdocsacsformsadministrativeacs-wihsrhu)) and Jeremy LaMaster at CAMACS ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)).

**Please read the following Guidelines: ➔**

**Guidelines**

**A. General Instructions**

The MACS Concept Submission Form (Concept) is intended for use for all collaborations, whether the initiative is for the MACS or to combine data from multiple studies.

**B. Research:**

**Concept Submission:**

1. Investigators wishing to access MACS data or biologic samples are encouraged to review their proposed research with the MACS. If you do not have a MACS liaison, contact the NIH Project Officer Robin Huebner (240-627-3216 or [rhuebner@niaid.nih.gov](file:///C:UsersjkonigDocuments1wpdocsacsformsadministrativeacs-wihsrhu)) for possible recommendations. It is recommended that the Lead Investigator review the MACS Publication Policy (<https://statepi.jhsph.edu/macs/MACSpubpolicy.pdf>) prior to Concept submission.
2. Internal MACS investigators: review Concept with site PI. External non-MACS investigators: review Concept with MACS liaison and enter liaison’s contact information under Section H.
3. Submit completed Concept to Robin Huebner at NIAID [via email ([rhuebner@niaid.nih.gov](file:///C:UsersjkonigDocuments1wpdocsacsformsadministrativeacs-wihsrhu)) or FAX (301-402-3211)] and Jeremy LaMaster at CAMACS [via email ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)) or Fax (410-955-7587)].
4. Concepts are assigned to appropriate MACS Working Group(s) for review. The Working Group(s) may contact investigator for further clarification or suggestions. The Working Group Chair posts their approval and/or comments to the Submitted Concept Forum for the Executive Committee’s (EC) review, or sends them to Jeremy LaMaster at CAMACS to post.
5. The MACS EC reviews Working Group-reviewed Concepts on their monthly conference calls (usually the 1st Wednesday of the month), after which time the investigator may be asked to participate in a conference call for further clarification.
6. The investigator will be contacted by the EC Chair with information that the concept was approved, approved with comments, tabled for further clarification, needs to be revised and reviewed again, or was rejected.
7. CAMACS will send investigators needing MACS data the Data Use Agreement (DUA) for signature, after the Concept has been approved.
8. After your Concept has been approved, please review the MACS publication policy in depth located at <https://statepi.jhsph.edu/macs/MACSpubpolicy.pdf>**.**

**Policy on Approved Use of Data and Specimens**

1. Specimens or data provided by the MACS are intended for the express purpose of performing EC-approved research. These specimens and data must **not** be provided to other investigators or used for additional projects without the written consent of the MACS EC.
2. Unauthorized use of data and/or specimens for work not specifically described in the aims of the Concept will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data and specimens.
3. **Joint Co-Authorship**
4. For joint MACS/WIHS publications, with the first author being a co-investigator of either study, the number of co-authors should be: 1 to 3 from the 1st author's center and the analytical (CAMACS/WDMAC) center combined; and a total of 2 to 3 from specific study sites combined (e.g., Cole SR [CAMACS/WDMAC], Li R [CAMACS], Anastos K [WIHS], Detels R [MACS], Young M [WIHS], Chmiel JS [MACS], Muñoz A [CAMACS/WDMAC]. Stat Med 2003).

**Manuscripts**

1. Manuscripts resulting from collaborative studies must be reviewed by MACS investigators who are co-authors. Sufficient time for revision should be allowed before submission to a journal. Final revisions also must be available to co-authors for review before resubmission. Manuscripts need to be posted on the MACS Forum at least 2 weeks prior to submission to the journal.
2. If data analysis for the manuscript has not been carried out at CAMACS, the lead author of the manuscript is responsible for sending the computer programs, final data sets and codebooks that directly relate to tables and figures in the manuscript to CAMACS. The programs and data should be labeled table1.dat, table1.sas (if SAS was used), etc. and should be sent along with reprints to Eithne Keelaghan ([ekeelag1@jhu.edu](mailto:ekeelag1@jhu.edu)) at CAMACS.
3. Lead authors should notify CAMACS ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)) of any and all manuscripts submitted, accepted or published, as well as abstracts presented at conferences.
4. Lead authors are responsible for complying with the NIH Public Access Policy that peer-reviewed manuscripts arising from NIH funding and accepted for publication on or after April 7, 2008 are deposited in PubMed Central (PMC). The PMCID or NIHMSID should be sent to Jeremy LaMaster ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)) at CAMACS, along with notification of accepted for publication or actual publication of a manuscript.
5. **An electronic copy of all published manuscripts should be sent to Jeremy LaMaster (**[**jlamaster@jhu.edu**](mailto:jlamaster@jhu.edu)**) and Joana Roe (**[jroe@niaid.nih.gov](mailto:jroe@niaid.nih.gov)**) at NIAID for the MACS.**

**Acknowledgment:**

All publications and presentations of studies utilizing samples and/or data supplied by the MACS should acknowledge the contribution of samples and/or data, as well as the MACS consortia. The suggested language for acknowledgment may be found at: <http://www.statepi.jhsph.edu/macs/manuscript.html>

**Progress Beyond Concept Approval by EC**

1. Externally funded investigators utilizing MACS data are requested to send a copy of their annual Progress Report (minus budget information) to Jeremy LaMaster at CAMACS ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)).
2. Investigators who use MACS specimens or data in grant-related projects are requested to send a copy of their annual progress report (identifying the lead investigator and title of the original Concept) to Jeremy LaMaster at CAMACS ([jlamaster@jhu.edu](mailto:jlamaster@jhu.edu)).

. **Internal MACS Investigators Only**:

1. Upon approval of a Concept, authors are expected to uphold the following time frame:
2. Assembly of analytical data set should follow 0.5 to 1 month after receipt of request. A writing group will be assembled during this time and the lead investigator will be notified of the membership. One of the co-authors will be designated to receive copies of all drafts and analytic data sets. That author should be prepared to stand in if you are unable to complete the work in a timely fashion.
3. Preliminary statistics, data visualization, descriptions, and exploration should be completed within 2 to 3 months after Concept approval.
4. A focused statistical analysis aimed at addressing research questions, including draft of figures and tables to be included in the paper, would follow within two months. At this point, co-authors should be solicited for input.
5. Two to 3 months after Concept approval, reworking of analyses and writing should be in process. The analyst will be responsible for helping to draft “Methods and Results” sections of manuscript. The lead author and co-authors are responsible for drafting other components. By the end of month 3, a fairly complete draft of manuscript should be circulating.
6. Four to 6 months after Concept approval the draft should be revised with input from co-authors in preparation of the final draft.

* By end of month 6 there should be a manuscript ready to submit for MACS EC approval and publication.
* This time frame is dependent on many variables but it is a reasonable target. The clearer the Concept, the faster the process. Investigators should be willing to be continually engaged with the analyst. Lead investigators are expected to keep the CAMACS Point Person apprised of any delays in testing, analysis, writing, and manuscript submission.
* Your submission indicates that you agree with all the information on the previous pages (Internal Investigators only) and that you have received local IRB approval for testing to be performed at the time samples are requested from the repository. The MACS EC will review your Concept for MACS collaborative studies. You will be notified of the status of your Concept via email after your Concept has been approved, approved with comment, revision requested or rejected. Additionally, approved Concepts will be assigned a project number: rYY## (MACS), where YY = year. You should use this project # in all correspondence up to and including publication.

1. **BEFORE SUBMISSION:**

   1. Internal investigators should have the completed Concept form reviewed by the site PI.
   2. External investigators should have the completed Concept form reviewed by their co-investigator liaison (as indicated in Section H: MACS INFORMATION) from the studies to determine that this Concept is appropriate.

   [↑](#footnote-ref-1)
2. By submitting this Concept, you agree to abide by the MACS Publication Policy ([http://www.statepi.jhsph.edu/macs/MACSpubpolicy.pdf](file:///C:\Users\jkonig\Documents\1wpdocs\macs\1-Forms\administrative\macs-wihs\(http:\www.statepi.jhsph.edu\macs\MACSpubpolicy.pdf)). The policy includes submitting manuscripts accepted for publications to NIHMS for PMCID number, if not using a NIH-approved PMC journal. [↑](#footnote-ref-2)
3. Productivity (e.g., preliminary data analysis, presentation, and/or publication) of approved Concepts is required within 2 years of approval; otherwise the topic may be reassigned.

   4 To be considered for an addendum, the proposal changes should be either the addition of person-visits or new variables to the original Concept. New analytical plans along the same scientific area should be submitted as a new Concept and reference the approved original. [↑](#footnote-ref-3)
4. *Following approval of the concept, you will need to complete the MACS Materials Transfer Agreement (MTA) that will be sent to you.* [↑](#footnote-ref-4)
5. *NOTE: If yes, please keep in mind that collaborations with non-US investigators proposing to use specimens and/or data from NIH-funded awards cannot be initiated without prior NIH approval. Should this Concept receive Executive Committee approval, the lead investigator at each primary awardee institution involved with the collaboration should immediately contact the NIAID Program Official (Ms. Robin Huebner, rhuebner@niaid.nih.gov) in order to receive further details for obtaining such approval.* [↑](#footnote-ref-5)
6. *Provide details about the planned statistical data analyses. Where appropriate, indicate which variables are needed from MACS database [MACS questionnaires with variables are available on line at* [*http://www.statepi.jhsph.edu/macs/forms.html*](http://www.statepi.jhsph.edu/macs/forms.html)*].* [↑](#footnote-ref-6)