

# MULTICENTER AIDS COHORT STUDY PUBLICATION/PUBLICITY POLICY

## Key Elements of Publication Policy/Procedures

1. Discuss idea with site PI and working group.
2. Complete concept sheet according to guidelines.
3. Concept sheet gets reviewed by working group.
4. Working group chair notifies EC.
5. Following review by EC, chair notifies investigator of approval or need for further clarification.
6. Writing committee is formed; communicate analytical plan, results and writing assignments.
7. Include MACS acknowledgment. Shortened version with augmentation may be used with discretion of lead author.
8. Submit abstracts and papers to CAMACS for distribution and posting.
9. Provide a lay language summary (one paragraph summary of the study and its impact on participants) when manuscripts are accepted for publication
10. Submit final manuscripts to CAMACS for incorporation into Archive. Send a PowerPoint slide with primary results for Dossier.
11. **MACSIDs should not be used in any public presentations or publications.**

Details on the Publication Policy follows

**Exceptions May Occur with EC Approval**

## I. PUBLICATION POLICY

A publication policy assists investigators and allows the study to keep track of scientific concepts as they undergo their various stages in preparation for publication. This system helps to ensure the main goal of the study is met, which is to provide the public with information on men with HIV and AIDS mainly through publication in scientific journals; therefore, all investigators who wish to use and publish data from the MACS **MUST** follow the publication policy below. Doing so will ensure proper acknowledgment of authors' research.

### A. DEFINITIONS

The publication policy is designed to address all investigations that may use data collected in this study as outlined in the MACS research agenda. Several categories of investigations are identified below.

#### 1. JOINT INVESTIGATIONS (Primary)

Joint investigations are collaborations involving the MACS cohort and one or more additional cohorts designed to accomplish core MACS-specific aims. Joint investigations are highly encouraged. Investigators are responsible for researching other HIV/AIDS cohorts to determine if collaborations are appropriate. Joint investigations require EC approval and so must undergo the MACS approval process outlined below.

#### 2. CORE INVESTIGATIONS (Primary)

Core investigations are designed to achieve designated MACS aims. Core investigations involve all MACS sites, and only MACS sites; therefore, the publications generated from using MACS core data **should** include a representative from every MACS site because each site was involved in collecting the data responsible for the analyses. Core investigations may require the formation of additional substudies, the addition of questions and/or clinical measures, or data analysis alone. Co-authors are required to dedicate significant efforts to the paper. Core investigations require EC approval and so must undergo the MACS approval process outlined below.

#### 3. SITE-SPECIFIC INVESTIGATIONS (Secondary)

Site-specific investigations involve only one site. These investigations sometimes require the collection of new data at the site. Strictly methodologic work may be considered a CAMACS' site-specific investigation. Publications using data from site-specific investigations need only include authors from the site involved. If support outside of that site is provided, the supporting investigator should be included as a co-author. For site-specific concept sheets, as long as the site's Principal Investigator approves the investigation, it does not require EC approval. Publication of site-specific investigations should not supercede core investigations.

#### 4. MULTI-SITE INVESTIGATIONS (Primary and/or Secondary)

Multi-site investigations involve at least two, but not all MACS sites. These investigations may require the collection of new data at the sites. These investigations require EC approval and therefore must undergo the MACS approval process. Publications generated from multi-site investigations should include a representative from all involved sites.

## B. MACS APPROVAL PROCESS

MACS EC review is required for all joint, core and multi-site investigations, to ensure that the science and rationale behind the proposals are practical, necessary and sound. The approval process is aided by the MACS Forum, where all MACS concepts, abstracts and manuscripts are posted for review. MACS personnel can access these postings at all times, and may post comments directly to the forum for others to view. The EC Chair will notify investigators, both internal and external, of approved concept sheets by email.

It should be noted that the most recent version of all investigator-related forms can be found on the MACS Website at <http://www.statepi.jhsph.edu/macs/forms.html>. Investigators should carefully read and follow the guidelines found on the Collaboration Concept Sheet.

## 1. CONCEPT SHEETS

The MACS/WIHS Collaboration Concept Sheet (CS) is intended for use for all collaborations, whether the initiative is to combine data from both studies or for just one of the studies. Concept proposals for all investigations involving data analyses from existing data sets or the collection of new data (questionnaires, clinical and physical measures) and/or specimens must be submitted in concept sheet form to Joana Roe ([jroe@niaid.nih.gov](mailto:jroe@niaid.nih.gov)) who will post on the forum. The **most recent** version of the concept sheet submission form must be filled out in full. Incomplete forms or CS submitted on the wrong version will be returned to the author for correction. Please go to <http://www.statepi.jhsph.edu/macs/concept.doc> to view this form.

Investigators wishing to access MACS data or biologic samples are encouraged to review their proposed research with the MACS. If there is no MACS liaison, contact NIH Project Officer, Robin Huebner, at 301-402-4239 or [rhuebner@niaid.nih.gov](mailto:rhuebner@niaid.nih.gov) for possible recommendations. Before submission, internal investigators (those within the MACS) should review concepts with their site's Principal Investigator (PI). External investigators should review their CS with a MACS liaison and enter the liaison's contact information on page 2 of the CS.

Joana Roe assigns each concept sheet to a MACS Working Group for review within 2 weeks. The Working Group may contact the investigator for further clarification or suggestions. If approved by the Working Group, the investigator should submit the CS to Joana Roe from NIH for posting to the web and review by the MACS Executive Committee (EC). The Working Group Chair will notify the EC that the CS has received preliminary approval. The MACS EC will then review the concept within 2 weeks of posting on an EC conference call. The EC Chair will contact the investigator that the concept was approved, approved with comments, tabled for further clarification, needs to be revised and reviewed again, or rejected.

If a revision is requested, the investigator is responsible for sending CAMACS an updated version within two weeks. After the revisions take place, the concept will be posted and re-reviewed by the EC.

After a concept is approved, a Writing Committee will be formed. Specimens may also be requested at this time. Only specimens included in the concept sheet can be requested.

## 2. FORMATION OF A WRITING COMMITTEE

Writing committees are formed for EC-approved research: 1) at the time of EC approval; 2) by a Working Group for a specific project; or 3) when the first author requests site coauthors from the PIs.

After a CS is approved, PIs should carefully select their sites' representatives and notify the lead author within 2 weeks of CS approval.

The chair (first or senior author) of the designated writing committee should convene a meeting or conference call periodically to review the progress of the project. If the analysis is performed at CAMACS, investigators may be brought to CAMACS to discuss the theory and analysis at different stages. Conference calls are encouraged to review drafts of the manuscript. The chair or MACS point person is responsible for reporting the progress to the EC.

To maintain co-authorship, co-authors must be fully involved in the writing process. The writing chair is responsible for completion of the analyses and preparation of the publication. Lead authors are expected to communicate the progress of a manuscript with all co-authors and their PIs.

The writing chair will be responsible for requesting and facilitating a conference call early in the planning of the analysis. During this time, writing assignments should be given to interested committee members, and a proposed order of authorship should be considered. Co-authorship order should be based on the percent of effort each co-author plans to commit to the project.

Writing chair tasks include:

- a. Determining order of authorship.
- b. Obtaining consensus on the authorship order from the writing committee.
- c. Notifying CAMACS and the EC Chair within one month of appointment of:
  - I. the list and proposed order of the writing committee membership;
  - ii. proposed analysis target dates for abstract and first draft of paper; and
  - iii. proposed target date for paper submission.
- d. Coordinating with CAMACS to ensure that data analyses are distributed to the writing committee members in a timely fashion.
- e. Notifying the EC (or designated committee) of significant problems or delays in completion of analyses or writing of drafts, or the need for changes in authorship.
- f. Notifying the writing group of manuscript submission to the EC.
- g. Notifying CAMACS and the EC Chair of outcomes of journal submission.

### **FOR JOINT MACS/WIHS PUBLICATIONS**

For joint MACS/WIHS publications, with the first author being a co-investigator of either study, the number of additional coauthors should be: 1 to 3 from the first author's center and the analytical (CAMACS/WDMAC) center combined; and up to 3 (preferably 2) additional co-authors from each of the MACS and WIHS studies (e.g., Cole SR, Li R, Anastos K, Detels R, Young M, Chmiel JS, Muñoz A. Stat Med 2003).

### **3. DATA SPECIMENS AND ANALYSIS REQUESTS**

Once a project is approved, the lead investigator or project contact, as identified on the CS, should communicate with CAMACS to start collaboration in study design, creation of analytical datasets, selection of repository specimens, and data analysis. During the analysis phase, CAMACS will work intensively with the contact. The contact will be responsible for updating working groups and other members of the writing committee.

All data requests should be submitted to the CAMACS Senior Coordinator (Janet Schollenberger) via e-mail ([jscholle@jhsph.edu](mailto:jscholle@jhsph.edu)). The request should list the standard MACS variable names for the data needed as noted in the codebooks. Codebooks are distributed to each site and are also located on the MACS Administrative Website, <http://www.statepi.jhsph.edu/macs/codebooks/>, by visit. Variable names may also be found on copies of study forms starting with visit 39.

Analytical projects are assigned a CAMACS programmer as well as a readme number. The programmer works closely with the investigator in the compilation and analysis of the data. This may entail weekly meetings with a local investigator, or with a CAMACS' epidemiologist and/or statistician involved with the project, or by telephone if the investigator is not local. The investigator may be brought to CAMACS to discuss crucial points in the analysis. The project should be reviewed at a scheduled statistical meeting or internally by the PIs. CAMACS requires a two-week time period for the production of an analytic database. If the data request is complex, an extension may be granted.

All specimen requests should also be submitted to CAMACS via email. If the investigator has already determined ID-visits, requests should include the MACSIDs (or PUBIDs), visits and visit dates. If the investigator has not yet determined ID-visits, a CAMACS programmer will determine appropriate ID-visits. After approval by the lead investigator or project contact, CAMACS will process the request in the repository database (BSI), and investigators will be notified of missing specimens and/or discrepant dates. If discrepancies are found, alternate ID-visits may be requested.

**NOTE:** Requests for specimens will not be processed until verification of local IRB approval has been provided.

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.

Given a backlog in responding to specimen requests, the EC sets a priority. Requests that involve aliquotting may take at least 1 month (if highest priority) to at least 6 months or longer (if low priority).

To obtain MACS data corresponding to the person-visits of tested specimens, the investigator should send to CAMACS, the results (a data file containing lab results) together with the variables that are needed.

#### 4. MANUSCRIPTS AND ABSTRACTS

##### a. CREATION OF A MANUSCRIPT

After the data analysis is complete and the specimens are tested (if applicable), a manuscript **must** be developed. The analyst will be responsible for helping to draft methods and results sections. The lead author and other co-authors are responsible for drafting other components and doing final edits. The following is an appropriate timeline for manuscript development:

- End of Month 1 – Assembly of analytical data set and/or request of specimens. A writing committee will be assembled during this time and the investigator(s) will be notified of the membership.
- End of Month 2 – Preliminary statistics, data visualization, descriptions, exploration should be complete.
- End of Month 3 – A focused statistical analysis aimed at addressing research questions, including a draft of figures and tables to be included in the paper, should be completed. A first draft should be revised with input from co-authors in preparation of the final draft.
- End of Month 4 – A manuscript should be ready for MACS EC review and submission.

This time frame is dependent on many variables but is a reasonable target. The clearer the concept sheet is the faster the process. Investigators should be willing to be continually engaged with the analyst. Lead authors are expected to keep the CAMACS Point Person apprised of any delays in testing, analysis, writing, and manuscript submission.

##### b. REVIEW OF MANUSCRIPTS

All manuscripts and abstracts should be submitted to the PI or Co-PI for review prior to journal submission. 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 submission.

All manuscripts should be sent to co-authors for methodological and statistical review prior to posting for EC review. Co-author(s) must participate in the writing and/or review process in a timely manner. If a co-author does not participate, he or she may be removed from the manuscript. Once the manuscript has been approved by ALL co-authors, it should be submitted electronically to CAMACS for posting and EC review. Manuscripts will be posted to the "Manuscripts" bulletin board on the MACS Forum. CAMACS will email EC members to inform them of new manuscript postings along with the date of review periods.

If a co-author disagrees with a manuscript, or finds the data misleading, he or she must resolve these issues with the writing group/co-authors before the manuscript is submitted to the EC. If a co-author still finds fault with the version submitted to the EC, he or she should address these concerns with the lead author and/or writing group chair. They may also indicate their concerns by posting to the manuscript thread in the MACS Forum. If the lead author and one or more of the co-authors still disagree with

analyses in the paper, he or she may wish to be removed as a co-author. This must be done BEFORE submission to journals.

While CAMACS is usually responsible for developing the analyses for MACS publications, in some cases data analyses are done elsewhere. In these cases, the first author of the manuscript should send CAMACS the final data sets that relate to the tables and figures in the manuscript. The data sets should come in the form of statistical programs and data and should be labeled: table1.dat, table1.sas (whereby running table1.sas will produce the statistics presented in table 1 of the paper). CAMACS will maintain the confidentiality of data.

c. ACKNOWLEDGMENT WHEN MACS DATA / SPECIMENS WERE USED

All publications and presentations of studies utilizing samples and/or data supplied by the MACS should acknowledge both the contributions of samples and the MACS collaboration itself. Where possible, the full acknowledgment boilerplate should be used. It is located on the web at <http://www.statepi.jhsph.edu/macs/manuscript.html>.

For papers external to the MACS or to journals that require signatures of all in the acknowledgment, a shortened version, augmented with other investigator names (according to co-authorship) may be used:

Data in this manuscript were collected by the Multicenter AIDS Cohort Study Collaborative Study Group with centers (Principal Investigators) located at:

The Johns Hopkins Bloomberg School of Public Health (Joseph Margolick); Howard Brown Health Center and Northwestern University Medical School (John Phair); University of California, Los Angeles (Roger Detels); University of Pittsburgh (Charles Rinaldo); and Data Analysis Center (Lisa Jacobson). The MACS is funded by the National Institute of Allergy and Infectious Diseases, with additional supplemental funding from the National Cancer Institute; and the National Heart, Lung, and Blood Institute: UO1-AI-35042, 5-M01-RR-00052 (GCRC), UO1-AI-35043, UO1-AI-37984, UO1-AI-35039, UO1-AI-35040, UO1-AI-37613, and UO1-AI-35041.

d. REVIEW OF ABSTRACTS AND PRESENTATIONS

Final abstracts must be reviewed and approved by the EC prior to submission to scientific meetings. These abstracts will be posted by CAMACS to the Forum.

Investigators must e-mail their abstract information to CAMACS. The following information must be included:

- Name and dates of conference
- Conference deadline
- Type of study (core, site-specific, etc.)
- Title of abstract
- All authors names
- Brief description of abstract

The abstracts will be posted to the MACS Forum. MACS EC members will be notified of the posting via e-mail, and will have one week to comment on the abstract, recommend acceptance, rejection or acceptance with revisions. The site PI must review and approve the final abstract.

## 5. SENDING THE MANUSCRIPT TO A JOURNAL

When a manuscript is sent to a journal, the lead author is responsible for informing CAMACS so that the collaborations table may be updated. If a manuscript is accepted for publication, lead authors are also responsible for sending a PDF (Portable Document Format) version of the published article to CAMACS. A

copy of all published manuscripts should be sent to Judy Konig to provide an archival record of work resulting from the study. An additional copy should be sent to Joana Roe for inclusion in the annual MACS Publications Compendium.

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**You must provide a lay language summary** (provide a one paragraph summary of the study and its impact on participants) **when manuscripts are accepted for publication. Materials may be photocopied and faxed for review to Judy Konig. Please submit electronic copies only, in MS WORD or WordPerfect format to Judy Konig. For an example of lay language summary, see attached citation:**

**Rappocciolo G, Piazza P, Fuller CL, Reinhart TA, Watkins SC, et al. (2006) DC-SIGN on B lymphocytes is required for transmission of HIV-1 to T lymphocytes. PLoS Pathog 2(7): e70. DOI: 10.1371/journal.ppat.0020070**

**Additional initiatives should be submitted to the EC via completion of a new Collaboration Concept Sheet Submission Form.**

Please remember that presentations or manuscript submissions that do not have prior EC approval and NIH notification are inconsistent with the spirit of collaborative research. Disregard of this policy may result in a denial of access to data and a cessation of collaborative support.

## 6. SECONDARY AND ANCILLARY PUBLICATIONS

Secondary publications refer to investigations using data collected as part of the core MACS protocol, but that are not directly related to the main hypotheses of the MACS research (see MACS Proposal, Part A). While the primary MACS hypotheses have priority in terms of data analysis, proposals to study other scientific questions using MACS data are encouraged. MACS members and Institute staff may propose these studies on their own behalf or on behalf of other qualified investigators from their own or other institutions. These studies fall into three categories: a) secondary studies among investigators from each of the sites utilizing pooled MACS data, b) ancillary studies that use study data in conjunction with data from individuals who are not participants in MACS, and c) site-specific data that does not involve the pooled MACS data.

- a. Secondary studies require MACS EC approval. The proposing investigator will follow the guidelines outlined in the approval process. The EC review of such plans should assure that the study will not interfere with the conduct of the core studies and that publications arising from the study will not compete with or conflict with similar reports from MACS primary investigators.
- b. Ancillary investigations that use study data in conjunction with data from individuals who are not participants in the MACS require MACS EC approval. The proposing investigator will follow the guidelines outlined in the above approval process. The EC review of such plans should assure that the ancillary study will not interfere with the conduct of the primary or secondary studies and that publications arising from the ancillary study will not compete or conflict with the reporting of the core or secondary findings of the MACS data.

- c. Site-specific concepts must have the approval of the site's Principal Investigator. Site-specific proposals that use central laboratory specimens must undergo the central review process. Proposals requiring analyses at CAMACS must be approved by the CAMACS PI.
- d. Final abstracts, presentations, and publications of secondary and ancillary studies must also be approved by the site's PI and NIH before any presentation to a formal scientific meeting or prior to submission for publication. These requests will follow the same approval process as outlined in Section B.4.c.

## E. CREDIT AND AUTHORSHIP

### Core Investigations

- 1st author's site
- CAMACS - One or two
- Other MACS sites - One or two from each site

### Joint Investigations

- 1st author's site
- CAMACS - One or two, if analyses were performed at CAMACS
- Other MACS sites - one or two total
- Other non-MACS sites - one or two total

### Outside Collaborations/Investigations

- 1st author's site
- CAMACS - One (if CAMACS provided datasets)
- MACS sites - one or two total
- Other non-MACS sites - one or two total

Each author must contribute sufficiently to the work involved in the development of a manuscript. It is important that all authors take public responsibility for the content in their manuscripts.

Criteria for authorship should be based on contribution to the work as represented by the manuscript. All authors and co-authors should be involved in the manuscript editing process, making comments and corrections to the document. Each site must sign off on their level of contribution before order of co-authors is determined on the manuscript. Disagreements or problems with individual author participation should be addressed with the lead author's site's PI. If this fails, formal grievances regarding credit or authorship must be directed to the MACS EC.

All MACS manuscripts must acknowledge that the data were collected through the Multicenter AIDS Cohort Study. They must also credit participating institutions (MACS representatives plus CAMACS and the supporting NIH agencies). <http://www.statepi.jhsph.edu/macs/manuscript.html> contains short and long format MACS acknowledgments. Investigators must use one of these acknowledgments when crediting MACS participating institutions. In addition, NIH support and all federal agencies' contract numbers should appear on the front page of the manuscript.

### 1. CORE INVESTIGATIONS

All sites, including the data center (CAMACS), should be represented in MACS core publications because every site was involved in collecting and processing the data involved in the analyses. The number of co-authors should not exceed seven.

In most cases, papers based on core investigations should include the following co-authors:

- Key involved investigators from 1<sup>st</sup> author's site (typically no more than 3).
- One or two from CAMACS.
- One or two from all other MACS sites.

### 2. JOINT INVESTIGATIONS

Proposed studies that involve pooled data from MACS and other cohorts should include authors from each of the partner organizations involved. The writing chair will be chosen based on: development of the concept for

the paper; analysis and interpretation of data; drafting of the article and revising it for critically important content; approving of the final version of the manuscript; and whether the investigator's site contributed substantively to the collection of the data to be analyzed in the paper. As in all cases, the writing chair must choose the order of co-authorship. Co-authorship should be based on the relative contributions of the writing group members.

- Key involved investigators from 1<sup>st</sup> author's site (typically no more than 3).
- One or two from CAMACS.
- One or two total MACS authors combined from other MACS sites.
- One or two total authors from non-MACS sites.

### 3. OUTSIDE COLLABORATIONS/INVESTIGATIONS

In some instances, collaborators who are not members of MACS EC or partner organizations will be involved in data and/or laboratory analyses. These collaborators will be required to acknowledge that MACS specimens and laboratory data are the property of MACS. Collaborating scientists will be encouraged to raise relevant scientific questions beyond the data analysis as contracted by the MACS; however, these requests for approval for data analysis, presentation, or publication must follow the principles outlined in this Publication Policy. Outside investigators should name a MACS contact person whose responsibility is to ensure the lead investigator has had the opportunity to share his/her ideas with the working groups. Assignment of the writing chair and authorship will follow similar guidelines. For reports resulting from work that exclusively utilizes laboratory data, the collaborating laboratory scientist will have significant input into the assignment of the writing committee and of authorship. However, reports which utilize clinical and laboratory data will likely include authorship of investigators based in MACS. Analysis of laboratory data from MACS participants limited to an individual site shall not be published or presented prior to the submission for publication of studies of the core research questions using pooled data.

The expectations and responsibilities of outside investigators are:

- Review and sign response indicating agreement to follow the MACS Publication Policy.
- Disseminate results to MACS collaborators in a timely manner. Even though not all studies will result in publication or presentation, all studies from outside investigators should be summarized and presented to the MACS in a written form.
- Before receiving MACS samples or data, sign a document indicating that the samples and data will only be used as agreed upon in the collaboration. This will be documented at completion of the study. When a study is complete, remaining samples should NOT be returned to the MACS.
- Outside investigators will forward agreed upon data to CAMACS as described below. These data will then be entered into the MACS database where they can be used as part of other analyses after the initial collaborative analyses are completed.
- MACS investigators have the option to publish results of the analyses if the outside investigator does not wish to write up the study, but agrees that a publication is worthwhile.

Papers based on outside investigations should include the following co-authors:

- Key involved investigators from 1<sup>st</sup> author's site.
- One from CAMACS – if CAMACS provided the datasets.
- One or two total MACS authors from other MACS sites.
- One or two total authors from non-MACS sites.

#### 4. CITING THE MACS IN PUBLICATIONS

There are instances where an investigator wishes to cite data from an already existing MACS publication. In these cases, the MACS article must be properly cited in the journal.

#### 5. DEPARTING INVESTIGATORS

Departing investigators or staff from the MACS sites including CAMACS or Institute Program Offices shall submit a proposal for authorship role on abstracts and/or papers to the MACS for approval, based on the following guidelines:

- The investigator must submit the abstract or paper within two years of departure from the institution.
- The departing investigator may petition for authorship on abstracts and/or papers in process before departure.
- The departing individual must meet all criteria for authorship as outlined in the requirements of the journal and the MACS EC.
- A current individual and a departing individual from the same institution may co-author a single abstract or paper.

## II. PUBLICITY POLICY

### A. LOCAL PUBLICITY

Local publicity refers to media distributed to each site's city, metropolitan area, or state. This includes: local TV stations, radio stations, and newspapers; city, county, or state health department newsletters; hospital publications; and local university publications, not available by general public subscription.

1. Each site may release general information about their site and about the MACS to local media.
2. In process study data or analyses should never be disclosed without prior clearance by the EC.

### B. REGIONAL/NATIONAL PUBLICITY

National publicity refers to media distributed widely outside each site's city, metropolitan area, or state. This includes network television, network radio, major newspapers, national newsletters and widely disseminated university publications.

Because national publicity may impact the overall reputation of the MACS, all questions by national media should be directed to the site's Principal Investigator, who should then notify cooperating federal agencies.

MACS data analyses should never be discussed without prior clearance by the MACS EC. Media questions about the MACS should always be directed to MACS Principal Investigators and/or cooperating federal agencies.

### C. GENERAL GUIDELINES

1. If significant questions arise about other sites or funding agencies ("How much is XIX agency spending overall on the MACS study?"), refer the reporter to the appropriate agency (i.e., investigators at those sites or agencies).
2. When answering questions, make clear distinctions between personal opinions and positions which have been arrived at jointly by the MACS collaborators.