

Consortium Agreement
between the Centre for International Health at the University of Bergen
(CIH), Norway and Partners in the
Centre for Intervention Science in Maternal and Child Health
(CISMAC)
funded by the Research Council of Norway (RCN)

*Based on RCN's template for Consortium agreements as of 6 February 2009
pursuant to the Research Council of Norway's General Terms of Contract.*

1 Consortium Agreement – scope, purpose and relationship to the Contract

This Consortium Agreement is between the Centre for International Health at the University of Bergen (CIH), Norway and Partners in CISMAC, RCN Project No 223269. It defines roles and responsibilities, regulates the organisation and implementation of CISMAC studies as well as rights and obligations of the Partners. For a description of CISMAC Management: Please see clause 4 in this Consortium Agreement and Annex 2.

- 1.1** The Project Owner, The University of Bergen (UiB), receives funding from the RCN on behalf of the consortium. Release of RCN funds is incumbent upon this Consortium Agreement being signed by UiB and the CISMAC Partners. The CISMAC Management based at CIH is, on behalf of UiB, responsible for implementation of CISMAC (clause 2).
- 1.2** The framework for CISMAC, including the terms for funding from the RCN, the extent of such funding, CISMAC objectives and description, funding plan and reporting requirements and definitions of terms, are set out in the Contract between RCN and UiB Annex 1, including the Revised CISMAC Description (Annex 3) and Budget (Annex 1) submitted 02.04.2013 and approved by the RCN.
- 1.3** In the case of addition of new Partners or withdrawal of existing Partners, this Consortium Agreement may be amended following advice from the CISMAC Executive Committee and approval by the CISMAC Board (Annex 2).
- 1.4** In the event that there is a conflict between the Contract and this Consortium Agreement or amendments thereof, the Contract shall take precedence.
- 1.5** The following 8 annexes are part of this Consortium Agreement.

Annex 1: The Contract between RCN and UiB

Annex 2: Description of CISMAC Management Structure

Annex 3: Revised CISMAC Application/Description submitted to RCN 02.04.2013 and approved

Annex 4: CISMAC Protocol Development and Review Procedures

Annex 5: CISMAC Guidelines for Authorship, Publication and Dissemination

Annex 6: CISMAC Guidelines for Data Ownership, Sharing, Storage and Distribution

Annex 7: CISMAC Guidelines for Travel and per diem

Annex 8: Definitions

2 CISMAC Project Owner and Partners

Project Owner

University of Bergen represented by the CIH, Norway.

Low and Middle Income Country (LMIC) Partners

Society for Applied Studies	India
Tribhuvan University	Nepal
University of Zambia	Zambia
Makerere University	Uganda
University of Fort Hare	South Africa
Addis Ababa University	Ethiopia
Hawassa University	Ethiopia*
Translational Health Science and Technology Institute	India

*School of Public and Environmental Health, College of Medicine and Health Sciences, Hawassa University, Ethiopia accessed the Consortium after the Contract with the RCN was signed.

Scientific and Technical Support (STS) Partners

World Health Organization Headquarters	Switzerland
Chr. Michelsen Institute	Norway
Norwegian Institute of Public Health	Norway

The CISMAC Management comprises the CISMAC Executive Committee, the Technical Advisory Group and the CISMAC Administration Team. The CISMAC Management is based at CIH.

The CISMAC Management supported by the Faculty of Medicine and Dentistry is, on behalf of UiB, responsible for implementation of CISMAC.

The LMIC Partners are responsible for administration and implementation of CISMAC Studies.

The STS Partners have advisory, supporting and/or monitoring roles or provide technical inputs for implementation of CISMAC studies and in the inclusion of innovative and cross-cutting aspects in the studies.

UiB as Project Owner signs the Contract with RCN (clause 1.1).

The CISMAC Director and the Director of the Division of Research Administration at UiB sign this Consortium Agreement with all Partners.

The CISMAC Director and the Director of the Division of Research Administration at UiB sign Base Project Fund Agreements and Study Implementation Agreements with individual LMIC Partners (clause 6) and Scientific and Technical Support Agreements with individual STS Partners.

2.1 LMIC Partners

Each of the LMIC Partners undertakes to contribute to implementation of CISMAL in accordance with the tasks and obligations set out in the CISMAL Base Project Fund and Study Implementation Agreements. These Agreements will be developed and signed prior to initiating the Study or Study component for which the Partner is responsible. The Base Project Fund and Study Implementation Agreements shall be supplemented with a Detailed Study Protocol for each CISMAL Study.

2.2 STS Partners

Each of the STS Partners undertakes to advise, support and/or monitor or provide technical inputs to LMIC Partners in implementation of CISMAL studies and in the inclusion of innovative aspects and cross-cutting themes in the design of the studies in accordance with the tasks set out in the Scientific and Technical Support Agreements. These Agreements will be signed by STS Partners and CISMAL Management after this Consortium Agreement is in place.

2.3 New Partners

New Partners may be added to CISMAL. Following a proposal from the CISMAL Executive Committee, the CISMAL Board will consider the participation by new Partners. Following a positive decision, the new Partner will be entitled to be represented on CISMAL advisory, management and/or governing structures. It is a precondition that the inclusion of a new Partner be reflected in an amendment to this Consortium Agreement. The new Partners accede to the amended Consortium Agreement by signing a declaration of accession describing the new Partner's roles and responsibilities, organisation and contribution to the implementation of CISMAL Studies.

2.4 Withdrawal of a Partner

2.4.1 A Partner may request permission from the CISMAL Board to discontinue its participation in the Consortium, thereby waiving all its rights and being released from its obligations pursuant to this Consortium Agreement. The request must be submitted with minimum six months' notice.

2.4.2 If a LMIC Partner is unable to carry out or contribute to the undertaking of an agreed Study according to CISMAL plans and standards, the Board may decide to transfer the Study or Study component in whole or in part to another existing or a new Partner, or terminate all or part of the Study or Study component. In such a situation, both the CISMAL Management and the Partner shall do their utmost to increase the likelihood for successful implementation of the Study or Study component. A Board decision to terminate the Study or transfer the required activities to another Partner shall follow a process that includes i) the written communication with the Partner informing it of identified problems in implementation and ii) the review of the Partner's response to the Board's concerns. Should the Board decide, after considering the Partner's response, on the need to transfer or terminate the Study or Study component, the decision should be communicated in writing to the Partner with a minimum of 3 calendar months prior to the transfer or termination of the Study.

2.4.3 Discontinuation or transfer (described in clause 2.4.1. and 2.4.2) does not release the Partner in question from its other obligations pursuant to this Consortium Agreement,

the Base Project Fund Agreement and the Study Implementation Agreement (LMIC partners) or the Scientific and Technical Support Agreement (STS Partners).

3 Collateral Funders

- 3.1** A separate Agreement, developed by the CISMAC Executive Committee and approved by the Board, will state the general conditions for any potential Funding Organisations which provide collateral funds to support specific CISMAC studies or CISMAC activities in general.
- 3.2** Representation of Funding Organisations in CISMAC advisory, management and governing structures is contingent on a proposal by CISMAC Executive Committee to the CISMAC Board and the approval of the proposal by the CISMAC Board.

4 CISMAC Management

- 4.1** The Consortium shall have a Board, a Strategic and Scientific Advisory Committee (SSAC), the Executive Committee (EC), the Technical Advisory Group (TAG); Project Management Teams (PMTs) and an Administration Team (AT) (Annex 2). Each PMT is led by a PMT Leader pair¹ comprising one senior scientist at UiB and one senior scientist at the LMIC institution. One of these senior scientists will be the Study's Principal Investigator (PI).
- 4.2** The Board shall contribute to facilitate effective cooperation between UiB and CISMAC Partners.
- 4.3** The Board shall support CISMAC to achieve the objectives and goals of Studies within the adopted timeframe. The Board in liaison with the Executive Committee shall make recommendations of amendments to the CISMAC description (Annex 3) and budget (Annex 1), taking into account local opportunities for, and impediments to Study implementation.
- 4.4** CISMAC's Director supported by the Executive Committee has day-to-day responsibility for CISMAC and reports to the Board. In addition, the Director nominates Board members in consultation with the Faculty of Medicine and Dentistry, UiB.
- 4.5** The research coordinator of Department of Maternal, Newborn, Child and Adolescent Health, WHO, shall represent a reference group of the LMIC Partners in the Board.
- 4.6** The Director and the Leader of CISMAC Administration Team shall convene annual Board meetings. An agenda and relevant documents shall accompany the notice of the meeting.

¹ For any multi-site study, each site will be represented by a PMT Leader.

- 4.7** A quorum of at least 5 Board members is required to reach decisions. The Chair of the Board has a double vote if simple majority is not reached. Participation may be in-person (preferred) or via electronic communication channels.
- 4.8** The Board makes decisions concerning the addition of a new Partner or withdrawal of a Partner pursuant to clause 2.3.
- 4.9** The Leader of the CISMAC Administration Team or a person seconded by the Director shall write down all decisions and action points in minutes that are distributed to all Board members and, following its approval, to the CISMAC Management and, when relevant, to CISMAC Study PIs for distribution within the PMTs.

5 Resource Allocations and Budgetary Flexibility

- 5.1** UiB is responsible for funds disbursed by the RCN being managed in accordance with the Contract and guidelines adopted by the Board. The same applies to the disbursement of funds to the Partners.
- 5.2** Maximum financial allocations to each CISMAC Study will be outlined in budgets attached to the Base Project Funds Agreement² and Study Implementation Agreement² for LMIC Partners and in Scientific and Technical Support Agreement² for STS Partners. For LMIC Partners, that are to execute the CISMAC Studies, the maximum financial allocation comprises
- Base Project Funds (BPF) designated for employment of scientific staff and for development of the Detailed Study Protocol, and related activities therein (clause 6.1). The duration of allocation of BPF will extend from six months prior to initiation of the Study through the duration of Study implementation and continue to six months after completion of the Study.
 - Project Running Costs (PRC) that will cover the expenditures of implementing the Study (clause 6.2). The duration of allocation of PRC will cover the Study implementation period.

The initiation of a Study is signalled either by start of field activities for formative research or recruitment of the first Study participant.

- 5.3** The total transaction costs on funds transferred by CISMAC to Partners must not exceed 1% and are to be borne by the Partner.
- 5.4** Provided the sum total of the costs stays within the budget, the Study PI can approve shifts of resources between-budget lines up to 10% of the line total in response to project needs. Modifications exceeding this limit will require written (including by email) approval by the CISMAC Executive Committee.
- 5.5** Between-year transfer of funds and no-cost extensions require written requests with justification to be submitted to the CISMAC Executive Committee and the approval by the Committee.

²Template 1 for Base Project Funds Agreement, Template 2 for Study Implementation Agreement and Template 3 for Scientific and Technical Support Agreement are available for development of these bilateral institutional agreements.

- 5.6** In cases where expansion of the Study size or complexity requires funding beyond the agreed financial allocation, PIs are encouraged to lead applications for collateral funding.
- 5.7** The CISMAC Executive Committee may in consultation with the Board modify resource allocations in response to strategic opportunities or the level of scientific achievement and efficiency of the particular PMT.
- 5.8** Activities such as workshops, investigator meetings, consultant and monitoring visits, external reviews will be carried out in support of Study excellence. Funding for these activities is allocated as part of the BPF or PRC, supplemented by CISMAC funds held by UiB.

6 Agreements between UiB (Project Owner), represented by CIH, and Partners

The Base Project Fund Agreements, Study Implementation Agreements and Scientific and Technical Support Agreements will be developed subsequent to signing of this Consortium Agreement. In case of discrepancy between this Consortium Agreement and the Base Project Fund Agreements, Study Implementation Agreements and Scientific and Technical Support Agreements, reasonable efforts will be made to comply with all four Agreements. If this is not possible, this Consortium Agreement prevails.

6.1 Base Project Fund Agreement

The Base Project Fund Agreement is designed to regulate institutional support, including enabling the initiation of activities for development of the Detailed Study Protocol, standard operating procedures, including laboratory procedures and formative research activities. Annex 4 outlines the procedures for protocol development.

BPF are also intended for the hiring of scientific staff responsible for processes and procedures linked to development of the Detailed Study Protocol and for implementation of the Study or Study component for which the LMIC Partner is responsible. CISMAC funds will be used to finance staff according to rules and regulations of the Partner Institutions and only up to 100% of the position.

The PI of the Study shall include costs related to review, monitoring, support, travel and equipment in the BPF, preferably assigning different accounts to each of these activities.

BPF shall be provided by CISMAC to the LMIC Partner within 60 days following receipt of a signed BPF Agreement. BPF will be paid out in 6 month instalments, unless otherwise specified in the Agreement; continuation of BPF payments is contingent on satisfactory progress.

The amount of the instalment shall be decided by the CISMAC Executive Committee in consultation with the Partner.

6.2 Study Implementation Agreement

The Study Implementation Agreement defines the research obligations of the LMIC Partner(s) and describes a plan and timeline of milestones and deliverables that are conditional for disbursement of PRC. The Study Implementation Agreement is to be signed after approval by the CISMAC Executive Committee of the Detailed Study Protocol and detailed budget. Both

institutional and ethical approvals before the Study must be available for the disbursement of PRC.

Unless otherwise agreed in writing, the LMIC Partners shall invoice CISMAC in advance every six months, unless otherwise specified in the Agreement. Payment shall be made within sixty (60) calendar days of the invoice date.

The disbursement of PRC for Study implementation is contingent on

- a) Detailed Study Protocol approved by the CISMAC Executive Committee and a budget for the first 6 months (for payment of first instalment) and for instalments thereafter (delivered at the start of each period)
- b) Financial reports that show the use of funds provided by CISMAC compared with the original budget expenditure plan agreed between the LMIC Partner and CISMAC. The financial reports should reflect and correspond to the budget items, and should include personnel costs, operating costs, travel costs, consumables and equipment expenditures and other study costs as specified in budget and financial report templates provided by CISMAC.
- c) Technical Reports of Study performance that describe data quality and completeness of follow-up ($\geq 90\%$)
- d) Attainment of milestones and deliverables as stated in the Study Implementation Agreement

6.3 Scientific and Technical Support Agreement

The Scientific and Technical Support Agreement defines advisory, support, monitoring or technical inputs obligations of the STS Partners. It also describes a plan, timeline and deliverables for support to CISMAC and CISMAC Studies. The Scientific and Technical Support Agreement is to be signed following the signing of the Consortium Agreement.

STS Partners shall invoice CISMAC in advance annually. The invoice shall detail use of funds for personnel, operating and travel costs. Payment shall be made within sixty (60) calendar days of the invoice date and is subject to

- a) Annual financial reports that show the use of funds provided by CISMAC compared with the original budget expenditure plan must be submitted. Budget and financial report templates will be provided by CISMAC Management
- b) Submission of satisfactory Technical reports with attainment of milestones and deliverables as stated in the Scientific and Technical Support Agreement

7 LMIC Partners' R&D work

7.1 Compliance with safety and security in research: Each Partner is responsible for ensuring appropriate routines and requirements for safety and security for its activities. It is the responsibility of the Partner to establish and implement policies and practices to assure and provide for the safety of its employees, the public and the environment during the conduct of the supported research. If the supported research involves the use of dangerous biological agents, the Partner shall establish and implement an appropriate safety plan.

7.2 Prior to recruitment of Study participants, the PI of each Study shall ensure that all required ethical approvals related to study implementation are obtained and that the

Study (when a trial) has been registered in <http://clinicaltrials.gov> or other appropriate database(s) approved by the CISMAC Executive Committee. For a Study that is not a trial, the PI should interact with the Executive Committee to ensure that any relevant pre-enrolment registration has been made.

- 7.3** All CISMAC trials shall be registered, and one or several Sponsors should be defined before the start of the trial. A Sponsor is defined as the organisation, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Sponsor is responsible for ensuring the trial is properly registered. A Sponsor of a clinical trial on therapeutic products must compensate a trial subject for any damage that he or she may suffer within the framework of the clinical trial. To meet this obligation the Sponsor may take out insurance.
- 7.4** Research is to be performed according to the standards of research integrity, as defined in “Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide” (www.oecd.org/sti/gsf) and other appropriate documents, including any relevant national codes of conduct and disciplinary or national ethical guidelines that apply. Each Partner agrees to inform the CISMAC Executive Committee of any such suspected deviation from these standards. Each Partner also agrees that any such incidence must be investigated according to local rules applicable in the country of the Partner Institution. All Partners further agree to cooperate in and support any such investigations; and to accept (subject to any appeal process) the conclusions of any such investigation and to take appropriate actions.
- 7.5** Subcontracting: With prior written approval of the CISMAC Executive Committee, a Partner may entrust part of the R&D work for which it is responsible to a qualified subcontractor. This does not release the Partner from its obligations in relation to CISMAC and the other Partners. Expenses incurred by the subcontracted activities must be covered by the PRC.

8 Reporting

- 8.1** The CISMAC Director and Leader of the CISMAC Administration Team are responsible for coordinating the financial and technical reporting to the RCN. The CISMAC Executive Committee with support from the Technical Advisory Group and the Administration Team will compile the reports and plans into an annual CISMAC report and Work Plan.

For LMIC Partners

- 8.2** The PI of each Study shall submit to the Executive Committee annual financial and scientific and technical reports and a work plan for the continued implementation of the Study. The Study Implementation Agreement will define appropriate timelines for development and submission of such reports and plans.
- 8.3** All financial and technical reports may be subject to audit by CISMAC Management (or an entity tasked by the CISMAC Management), including examination of supporting documentation and relevant accounting entries in the Institutions’ books. In order to facilitate such reporting and audit, the Partner shall ensure that accurate and systematic accounts and records are kept in respect of the project. If not agreed otherwise with the

CISMAC Management, the final financial and technical reports must be submitted within 120 days after the termination of each Study. Annual accounts as well as the final accounts for each Study may be subject to external audit in each Partner country according to that country's legal and financial regulations.

For STS Partners

8.4 STS partners shall submit to the Executive Committee annual financial and technical reports and a work plan for the support to be provided to CISMAC studies. The Scientific and Technical Support Agreement will define appropriate timelines for development and submission of such reports and plans. All financial and technical reports may be subject to audit by CISMAC Management (or an entity tasked by the CISMAC Management), including examination of supporting documentation and relevant accounting entries. Annual accounts as well as the final accounts may be subject to external audit according to the STS Partner's legal and financial regulations.

9 Data Protection and Project results

9.1 Data Protection and Privacy

Data protection should conform to European standards and guidelines (http://ec.europa.eu/justice/data-protection/individuals/rights/index_en.htm) and be in compliance with each Partner's respective national regulations.

9.2 Data ownership

The ownership of the Study's data will rest with the LMIC Partner. Although the Partner owns the Study data, the PIs, The University of Bergen and STS Partners will have rights to access and use the data. The PIs will have stewardship over the Study data; they will control the implementation, publication, and copyright of any research, subject to institutional agreement. The PIs will hold custody of the data on behalf of the Partner. The University of Bergen on behalf of RCN, will have specific stipulations for how data shall be retained and shared. Guidelines on Data Ownership, Sharing, Storage and Distribution are presented in Annex 6.

9.3 Partners that leave the Consortium

A Partner that voluntarily leaves the consortium and any Partner that is found in breach of contract and therefore must leave CISMAC shall transfer all available data, including unpublished reports and drafts to UiB.

10 Publication and Dissemination of Study results

The CISMAC Partners agree to present Study results at national and international research and policy meetings, publish Study results in peer-reviewed scientific journals and to use public dissemination channels. All CISMAC Partners will adhere to Authorship, Publication and Dissemination Guidelines specified in Annex 5. The Publication Committee shall review and approve all dissemination and publication plans.

11 The Agreement's entry into force, winding up of the Consortium, interpretation etc.

11.1 The Agreement enters into force on the CISMAC start date 01.09.2013, and it applies in its entirety until the Consortium has been wound up pursuant to the Contract between RCN and UiB. Thereafter, the provisions in clauses 6-10 remain in force until all relevant internal reports have been appropriately submitted and approved, and scientific communications (articles and conference presentations) have been published.

11.2 Should an extraordinary situation outside the control of CISMAC Management and Partners/PMTs arise that makes it impossible to perform duties under this Agreement, and which under Norwegian law shall be classified as *force majeure*, the other Partners which are affected by the situation shall be notified of this as soon as possible. The obligations of the affected Partner(s) shall be suspended for as long as the extraordinary situation prevails. The CISMAC Management and Partners shall, in connection with *force majeure* situations, have a mutual disclosure obligation to each other concerning all matters that must be deemed to be of relevance to CISMAC. Such information shall be disclosed as soon as possible.

11.3 This Agreement shall be construed in accordance with the laws of Norway. Any dispute relating to the interpretation or execution of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Partner(s) and UiB or in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The Partner and UiB shall accept the arbitral award as final.

12 Liability of the Consortium Partners for any damages inflicted on a third party

Each Partner is liable for all losses, material damages and personal injury inflicted on a third party resulting from the Partner's exercise of its obligations under this Consortium Agreement or from the Partner's use of the Study results.

13 Signature of the Agreement

The CIH (on behalf of the UiB) and Partners accede to this Consortium Agreement by signing the 'Declaration of Accession'. The CIH and Partners accede to the Agreement individually. All Partners will receive a copy of the Agreement and Declarations of Accession.

Declaration of Accession for the CISMAC Consortium Agreement (RCN Project No 223269)

The undersigned hereby confirms that

[legal name of Signing Institution]

enters into the above-mentioned Agreement as a Partner, and will have the rights and obligations that follow from the provisions of this Consortium Agreement.

<u>Accepted on behalf of</u>	
_____ Signature	_____ Signature
_____ Name, Authorizing Official from Signing Institution	_____ Name, Authorizing Official from Signing Institution
Place: _____	Place: _____
Date: _____	Date: _____

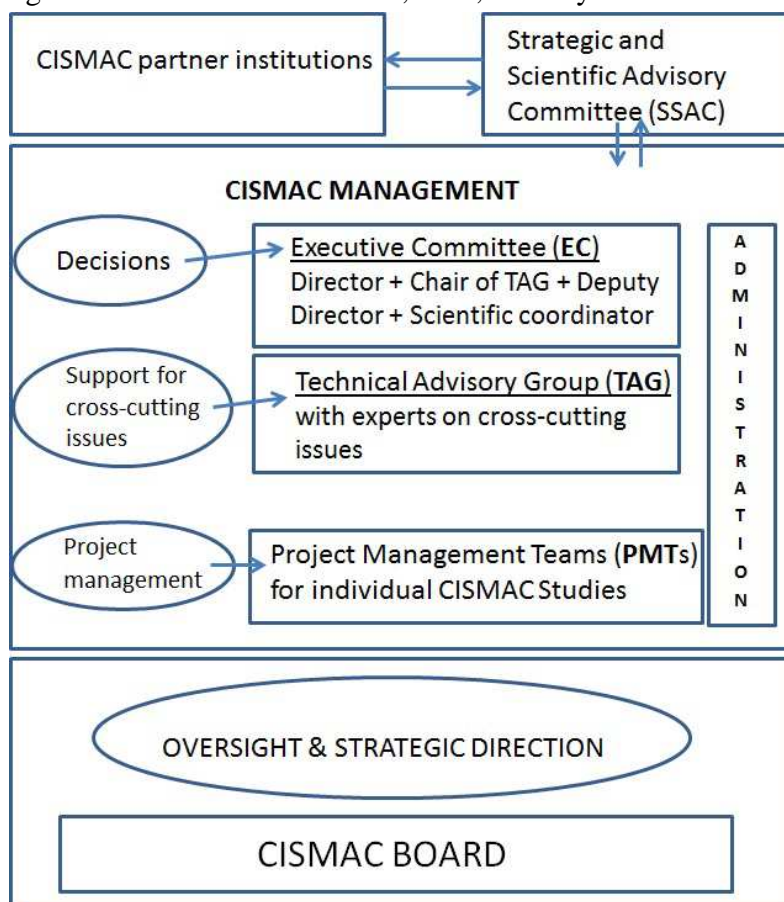
optional second signatory

<u>Accepted on behalf of CIH and University of Bergen:</u>	
_____ Halvor Sommerfelt, Director of CISMAC	_____ Director of Division of Research Administration, UiB
Bergen: _____	Bergen: _____
Date: _____	Date: _____

Annex 2 – CISMAL Advisory, Management and Governing Structures

CISMAL is a consortium of research institutions with its central management (named CISMAL Management) anchored at the Centre for International Health (CIH) at the University of Bergen (UiB), Norway and consists of research teams at the following partner institutions:

- i. Centre for Health Research and Development (CHRD), Society for Applied Studies (SAS), India
- ii. Dept. of Child Health, Institute of Medicine, Tribhuvan University, Nepal
- iii. School of Medicine, University of Zambia
- iv. College of Health Sciences, Makerere University, Uganda
- v. Effective Care Research Unit, University of Fort Hare, South Africa
- vi. Dept. of Epidemiology and Biostatistics, Addis Ababa University, Ethiopia
- vii. School of Public and Environmental Health, College of Medicine and Health Sciences, Hawassa University, Ethiopia (accessed Consortium after signing of the Contract)
- viii. Pediatric Biology Centre, Translational Health Science and Technology Institute, Haryana, India
- ix. Dept. of Maternal, Newborn, Child and Adolescent Health, WHO Headquarters, Switzerland
- x. Chr. Michelsen Institute, Bergen, Norway
- xi. Norwegian Institute of Public Health, Oslo, Norway



CISMAC's Strategic and Scientific Advisory Committee (SSAC):

The **SSAC** will consist of scientists representing cutting-edge Maternal and Child Health (MNCH) intervention science and cross-cutting epidemiological research as well as international MNCH programs. Dr. Mickey Chopra, Head of UNICEF Health and Associate Director of Programs; Kåre Mølbak, Chief Epidemiologist, Statens Serum Institute, Copenhagen and Ellen Piwoz, Interim Deputy Director, Nutrition Lead for the nutrition team in the Family Health division of Global Health Program of the Bill & Melinda Gates Foundation have agreed to be SSAC members; one or two additional members will be named. The SSAC will advise CISMAC on relevant strategic, program and research methods developments, and may be asked to comment on what CISMAC Management considers to be finalized study proposals and protocols. SSAC meetings are scheduled to be held twice or thrice yearly via electronic means of communication (Skype or telephone), while face-to-face meetings will be held every other year (starting from 2014), and as a response to specific needs and opportunities.

CISMAC MANAGEMENT

comprises the **CISMAC Executive Committee (EC)**, the **Technical Advisory Group (TAG)** **Project Management Teams (PMT)** and the **CISMAC Administration Team (AT)**.

The CISMAC Management supported by the Faculty of Medicine and Dentistry is, on behalf of UiB, responsible for management and implementation of CISMAC.

CISMAC LMIC Partners are responsible for administration and implementation of CISMAC Studies at their LMIC sites.

The **Chair of the TAG**, M.K. Bhan (or his successor) will promote strategic thinking and consistency of the work plan with the vision of CISMAC. He will support innovation, delivery of high quality research and relevance of CISMAC work to LMIC health programs.

Executive Committee (EC)

The **Executive Committee** will be the major decision-making body and will be in charge of the day-to-day implementation of CISMAC. It consists of four members: the Director, Deputy Director, Chair of the TAG and Scientific Coordinator.

EC decisions will primarily be made by consensus. In cases where voting is needed to reach a conclusion, it will require a simple majority. In cases where the votes are equally divided, the CISMAC Director will cast the decisive vote. A quorum of at least 3 members is required to reach a decision.

Terms of reference for CISMAC Executive Committee (EC):

1. Propose to the Board amendments to the CISMAC Consortium Agreement, e.g. in relation to addition of new Partners.
2. Appoint members of CISMAC TAG
3. Assessment of Detailed Study Protocols – with assistance from external reviewers
4. Approve Detailed Study Protocols for allocations of CISMAC funds
5. Assessment and ranking of applications for CISMAC PhD and postdoctoral fellowships - with the support from institutional and/or external reviewers
6. Designation of experts for monitoring of study implementation and performance, e.g. data quality and completeness of follow-up ($\geq 90\%$)
7. Approve subcontractors and subcontracting activities
8. Approve modifications to annual study budgets and no-cost extensions in response to strategic opportunities or the level of scientific achievement and efficiency of the particular PMT – in consultation with CISMAC Board
9. Lead investigations of research misconduct according to national policies and procedures
10. Set timelines for development and submissions of annual work plan
11. Develop agreements between CISMAC and collateral funders
12. Assist in the development of applications for collateral funding and define the size of any financial contribution from CISMAC
13. Propose to the Board representation of collateral funders to appropriate CISMAC advisory, management and governing structures

Director

The **CISMAC Director**, Halvor Sommerfelt (or his successor), will serve as project manager pursuant to the contract between the Research Council of Norway (RCN) and UiB. He will represent CISMAC internally within UiB and externally. The Director, and the Director of the Division of Research Administration at UiB, sign Agreements with Partners. The Director will have considerable independence in relation to scientific matters as well as substantial influence on the recruitment of staff to CISMAC.

The **Deputy Director**, Ingvild F. Sandøy (or her successor) will undertake some of the Director's responsibilities, as delegated by the Director, and act for the Director when required.

Terms of reference for CISMAC Director:

1. Day-to-day responsibility for CISMAC
2. Allocation of study funds in response to the quality and relevance of CISMAC Studies, availability of external funds, strategic opportunities and/or as a response to PMT achievements and efficiency – in consultation with CISMAC EC
3. Nomination of Board and SSAC members in consultation with the Faculty of Medicine and Dentistry, UiB
4. Organization of annual Board meetings – assisted by Leader of CISMAC AT in writing meeting minutes and action points from Board meetings for circulation to members and to other parts of CISMAC Management.

5. Coordination of annual technical and financial Work Plan and reports to RCN – assisted by the CISMAC TAG and AT
6. Approval of any data analyses that has to take place outside of the Partner institution owning the data

Scientific Coordinator

The **Scientific Coordinator**, José Martines (or his successor), in a 60% position, will develop and maintain mechanisms to promote and support the implementation of high quality research.

Terms of reference for CISMAC Scientific Coordinator:

1. Liaison with Unit for Maternal, Newborn, Child and Adolescent Health, World Health Organization (MCA-WHO), Geneva.
2. Coordination and harmonization of data collection, including developing core variable lists for multi-site studies.
3. Coordination of technical review of proposals for collateral funding and Study protocols by:
 - a. Conducting pre-reviews and provide technical, administrative and budgetary inputs;
 - b. Organizing external reviews: identifying and engaging with reviewers, consolidating feedback, assisting in incorporating recommendations
 - c. Conducting final reviews of revised proposals to ensure adequacy of response to reviewers' comments and readiness for Study implementation
4. Coordination of the oversight of implemented Studies by CISMAC's Board and Data Safety Monitoring Boards (DSMBs):
 - a. Coordination of the SSAC meetings
 - b. Identification and recruitment of DSMB members and organization of DSMB meetings
5. Coordination, together with MCA-WHO, of LMIC site and CISMAC Study support and monitoring.
6. Development of reporting mechanisms for Studies and assessment criteria for Study implementation (e.g. adherence to protocols, implementation quality)
7. Review of periodic Study reports
8. Organization of technical response to Study needs – identification of needs and recommendations for consultant visits or other type of technical support
9. Development of guidelines for authorship, publication and dissemination.
10. Appointment of Publication Committee (s), comprising TAG members and if required other scientists
11. Coordination and chairing of Publication Committee(s), in particular to ensure adherence to guidelines for authorship, publication and dissemination
12. Assist site team in preparation of manuscripts for publication
13. By virtue of heading the Publication Committee, approve and keep a record of publication and dissemination activities of Studies.
14. Development of guidelines for data ownership, sharing, storage (safety and location) and distribution.

15. Development of administrative guidelines and mechanisms for monitoring of adherence to regulations in relation to travel expenses and per-diem allowances.

Technical Advisory Group (TAG)

The **Technical Advisory Group** is composed of experts in cross-cutting issues. It will support the PMTs and EC in the conception, planning and management of projects; individual TAG members, may in this respect, be involved in the development of specific Detailed Study Protocols and/or in the monitoring of specific studies assigned to them. TAG will also be involved in recruitment of PhD students and post-doctoral fellows.

The following members, in addition to taking part in the implementation of specific projects, will oversee the following areas: Capacity Development (Victoria Nankabirwa); Long-term effects of interventions (Jan Van den Broeck); Integration of Maternal, Newborn, Child and Adolescent Health (Justus Hofmeyr); Social sciences/anthropology (Karen M. Moland); Equity and ethics (Ole F. Norheim), Health economy (Bjarne Robberstad); Harmonization of data management (Frederik Frøen). The TAG will be chaired by Maharaj K. Bhan.

The membership period of the TAG is up to 4 years, and may be renewed. The TAG may be expanded when need arises. Appointments and reappointments will be made by the EC.

Project Management Teams (PMT) & Principal Investigator (PI)

Each CISMAC Study will be coordinated by a **Project Management Team**. Each PMT is led by a PMT leader pair comprising one senior scientist at UiB and one senior scientist at the LMIC institution. The PMTs are responsible for development of the Detailed Study Protocol. In addition, they will execute, analyze and report on their CISMAC study and manage the study data.

Principal Investigator

One of the two (three or more for multi-site studies) senior scientists constituting the leader pair/group will be identified as the **Principal Investigator** for the Study, according to criteria that take into account his/her roles in the conception and implementation of the Study.

Terms of reference for Principal Investigator:

1. Lead (i) PICO development and justification and (ii) Protocol development and submission through review and feedback process in liaison with EC, WHO, TAG members and external experts
2. Develop Base Project Fund and Study Implementation Agreements
3. Responsible for obtaining all required institutional, governmental and ethics approvals related to Study implementation prior to recruitment of study participants.
4. Responsible for implementation of the Study.

5. The PI can approve shifts of resources between-budget lines up to 10% of the line total, when deemed necessary because of protocol modifications, changes in expenditures, and unforeseen alterations in Study implementation.
6. Preparation of annual work plan for - technical and financial implementation of Study and for reporting to RCN.
7. Ensure that all reports that are to be published and/or disseminated are communicated to the Publication Committee for consideration.
8. Lead applications for collateral funding for expansion of Study, Study size or complexity
9. For CISMAC group II studies in addition to the above mentioned functions, PIs will also play lead roles in proposal development for procurement of funding.

Administration Team

The **Administration Team** is located at the CIH, UiB. Responsibilities include facilitating interaction between CISMAC advisory, management and governing structures, securing appropriate affiliations and appointments to CIH and CISMAC, support for the development of proposals for (collateral) funding, supporting the study coordination and quality control activities, disbursement of funds, safeguarding fiscal accountability and high-quality postgraduate training. The administration will consist of the following functions and individuals who will need to overlap considerably with respect to task performance:

- Leader of CISMAC Administration Team (Sumathi Subramaniam)
- Advisor (Ingvild Hope) 20%¹: Personnel management and communication between administrative staff at CISMAC, Department of Global Public Health and Primary Care, the Faculty of Medicine and Dentistry and UiB's central administration.
- Consultant (Øyvind Mørkedal) – 50%¹ position dedicated to CISMAC budgeting and accounting.
- Higher Executive Officer (Therese Marianne Istad) – 30%¹ position in communications: internal (with PMTs and between EC, TAG, Board and SSAC) and external (with relevant research groups, funders, policy makers, press etc., aided by Marion Solheim). Responsible for developing and maintaining appropriate Content Management Software (CMS) for internal and external use. Will also provide support to the Scientific Coordinator in his communication with the WHO, UNICEF, PMTs and LMIC institutions.
- Executive Officer in a 50%¹ position will support the Director and, to the extent time allows, other core CISMAC staff with respect to critical administrative tasks.

CISMAC BOARD

The CISMAC Board will consist of 7 members. The composition of the Board for the first 4 year-term is as follows:

1. Nina Langeland, Dean, Faculty of Medicine and Dentistry, UiB.
2. Rolf Terje Lie, Head of Department of Global Public Health and Primary Care (IGS) or Bente E. Moen, Director, CIH on a 2-year rotatory basis

¹ As CISMAC's needs will change with time, these proportions will be adjusted accordingly.

3. Anne Christine Johannessen, Vice-Rector for international relations, UiB.
4. Camilla Stoltenberg (Director-General, Norwegian Institute of Public Health) for 2 years or Ottar Mæstad (Director, Chr. Michelsen Institute) on a 2-year rotatory basis, each Director representing the interest of both Norwegian Institutions when on the Board.
5. Rajiv Bahl, Department of Maternal Newborn Child and Adolescent Health, World Health Organization.
6. LMIC representative 1
7. LMIC representative 2

LMIC representatives 1 and 2 are selected amongst the Partners by the EC using a random process. Each LMIC representative will serve on a 2- year rotary basis, with only one representation on the Board during the 10-year duration of CISMAC.

The agenda for Board meetings will be presented to the LMIC Partners, in advance, for discussion. Communication amongst LMIC Partners will be facilitated by CISMAC Management providing teleconferencing EC, if so desired.

The CISMAC EC has proposed that the Board is chaired by Prof. Nina Langeland.

The Board members will serve 4 year terms. Thereafter, the EC will review the composition and propose new Board members (and Chair) or reappointment of existing members (and Chair). [A decision on which entity will consider the EC's suggestions for new Board members will be made shortly, the most likely entity is the Faculty of Medicine and Dentistry at the UiB or the UiB Board, or a combination of the two, possibly supplemented by a representative from MCA-WHO (which will also represent LMIC partner institutions).

Observers include:

1. Director of the Faculty of Medicine and Dentistry, UiB
2. Chair of TAG – Dr. M.K. Bhan
3. Representative from the Norwegian Institute of Public Health or Chr. Michelsen Institute, depending on rotation on the Board
4. Representative from the IGS or the CIH, depending on rotation on the Board
5. CISMAC Director or person seconded by Director
6. Leader of CISMAC Administration Team

Annual Board meetings will be scheduled. Participation and voting may be done via electronic real-time communication (i. e. not only by email), such as via Adobe connect, Skype, telephone etc. A quorum of at least 5 members is required to reach a decision. The Board Chair has a double vote if required to obtain a majority.

Terms of reference for the CISMAC Board:

1. The Board shall contribute to facilitate effective cooperation between UiB and other CISMAC Partners.
2. Approve additions of new Partners and other amendments to the CISMAC Consortium Agreement.

3. Withdrawal of Partners – Board decides to take appropriate actions that could include transfer of R&D work in whole or in part to another existing or a new Partner or terminate all or part of the R& D activity
4. Approve participation of Collateral Funders in CISMAC
5. Approve representation of Collateral Funders in CISMAC advisory, management and governing structures.
6. The Board shall support CISMAC to achieve the maximum potential of studies within the adopted timeframe. The Board in liaison with the EC shall make recommendations of amendments to the CISMAC description and budget, taking local opportunities for and impediments to study implementation into account.
7. The Board will review performance of PMTs if the TAG or the Director/Scientific Coordinator so requests, and approve annual reports. It is empowered to terminate studies and accordingly revise funding to study sites in consultation with the Director.

Members of the board, SSAC and TAG will complete a declaration of conflict of interests when they take up their functions. The declarations will be reviewed annually and revised, if required.

Annex 4 – Protocol Development and Review Procedures

Step	Actions	Responsible
PICO ¹ development and justification	<ul style="list-style-type: none"> • Identify Study domain. • Review the literature • Formulate the research question in PICO format • Justify study in relation to: <ul style="list-style-type: none"> ○ what has been done and the results of previous studies ○ the value of the proposed study: innovation and impact ○ feasibility and opportunities for capacity development/research strengthening 	PMT ²
Review and feedback	<ul style="list-style-type: none"> • Submit to EC³ • Review and feedback 	PMT EC, WHO ⁴
Extended-PICO development	Develop “extended” PICOs, including <ul style="list-style-type: none"> • Hypothesis and Objectives • Flow Chart • Study procedures • Intervention & co-interventions • Key outcome measures • Selection of participant population, inclusion & exclusion criteria • Trial size estimates • Randomization • Blinding • Implementation plan, staff recruitment & training • Field organization • Follow up & subject retention • Handling protocol deviations, losses-to-follow-up and withdrawals • Data collection & management • Quality assurance and quality control • Adverse event reporting/ Clinical & safety monitoring • Plan of analysis • Time schedule • Ethics 	PMT (EC+WHO support)

Review of extended-PICOs and feedback	<ul style="list-style-type: none"> Review and feedback including areas of Health Economy, Medical Anthropology, Equity, Life course studies, NCD markers, Embedding Observational Studies Summary of feedback for full protocol development: recommendations, indications of technical support (e.g. consultant support, organization of workshop), and degree/extent/amount of financial support. 	EC, WHO, Cross-cutting Advisors, External Experts*
Protocol development and submission	Development of the Detailed Study Protocol ⁵ – a face-to-face meeting of PMT is strongly encouraged (resources may be used from Base Project Fund)	PMT (support by EC, WHO, External Experts)
Protocol review	Review of the protocol for technical comments and decision on level of financial support.	EC, WHO, External Experts
Local approvals	Submission of the protocol for institutional approvals (ethical and administrative)	PMT
Study Implementation Agreement and PRC ⁶	<ul style="list-style-type: none"> Development of Study Implementation Agreement Review of the Study Implementation Agreement and signatures Payment of first PRC installment 	CISMAC AT ⁷ PMT institutions CISMAC AT
Monitoring and support of implementation	<ul style="list-style-type: none"> Submission of progress and financial reports, half-yearly Review of progress and financial reports for continued disbursement of PRC Site visits by monitors and technical advisors DSMB⁸ meetings 	PMT EC, AT EC, WHO, DSMB, SSAC ⁹

*Review and feedback by CISMAC EC, Cross-cutting advisors and EC appointed advisors, experts and monitors is expected to take 4-6 weeks.

¹PICO = Research question formulated indicating Study **P**opulation, **I**nterventions, **C**omparator(s), **O**utcome measurements

²PMT = Project Management Team | ³EC = CISMAC Executive Committee

⁴WHO = World Health Organisation | ⁵For Protocol formulation use: CONSORT (<http://www.consort-statement.org>)

Lancet (<http://www.thelancet.com/protocol-reviews>)

Trials (<http://www.trialsjournal.com/authors/instructions/studyprotocol>)

STROBE (<http://www.strobe-statement.org/index.php?id=strobe-home>)

⁶PRC = Project Running Cost | ⁷AT = Administration Team

⁸DSMB = Data Safety Monitoring Board

⁹SSAC = Strategic and Scientific Advisory Committee

Annex 5: CISMAC – Guidelines for Authorship, Publication and Dissemination

1. Guiding Principles

Publications and dissemination of findings from the studies supported by CISMAC will follow the guidelines provided by the *International Committee of Medical Journal Editors* and will be oriented by the following principles:

- Promotion of timely publication and access to high quality information resulting from the Studies,
- Promotion of young researchers, particularly from the low and middle income country (LMIC) institutions - so that they lead analyses, prepare and publish scientific manuscripts, are appropriately reflected as authors and are supported to disseminate Study findings,
- Transparency, with the provision of an honest, accurate and clear account of the Study being reported, so that no important aspects of the Study have been omitted; and that any discrepancies from the Study as planned (and, if relevant, registered) have been explained.

2. Scope

These guidelines apply primarily to manuscripts but should also be observed in the preparation of abstracts, presentations at conferences and additional vehicles for the dissemination of Study findings.

3. Coordination of the publication and dissemination process

The CISMAC Scientific Coordinator will lead and appoint members to a Publication Committee (PC) to coordinate the publication and dissemination process to promote the adherence to the Guiding Principles presented above. The PC will comprise a subset of the Technical Advisory Group members and if required other scientists. The PC will gather the information on planned publications for all CISMAC supported studies and provide comments and suggestions to Project Management Teams (PMTs) regarding:

- priorities for development of manuscripts to present study results
- assistance in manuscript preparation
- adherence to the above Guiding Principles on authorship and transparency.

The Principal Investigator (PI) of each Study is responsible to ensure that all reports that are to be published (manuscripts, abstracts, web-pages) and disseminated are first communicated to the PC for consideration.

4. The publication process

As a prerequisite for publishing the results of a CISMAC supported study, the PI (or the investigator he/she tasks) should submit a proposal in the format of a one page concept paper. Each concept paper should include:

- Proposed title and names of potential authors, including the person(s) who will lead the writing team, how the authorship will be presented and the expected role of each individual author in terms of (i) study conceptualization and/or protocol development, (ii)

acquisition of the data, and (iii) analysis and/or interpretation of data and writing of the manuscript.

- The question to be addressed by the manuscript and the relevance of the proposed question.
- Timeline for completion of analysis and writing the manuscript.

The PC will keep a record of all above-mentioned proposed publications and review each proposal to provide feedback to the investigators. Comments and suggestions will be provided within 4 weeks of receiving the proposal.

All completed manuscripts based on data or material from CISMAC supported studies should be shared with the PC before submission to a journal. The PC will include the manuscript in the CISMAC publication records and confirm adherence to the Guiding Principles. The PC should be informed of the journal's response to the submission and receive a notification when the manuscript is published. Lists of manuscripts under preparation and publications resulting from CISMAC supported work will be maintained by the PC.

5. Dissemination of findings

Investigators will be encouraged to share with the PC their plans for dissemination of the study results in conferences and through other media. The PC should be made aware of the intention to disseminate the information and receive a copy of the draft communication as early as possible. This will facilitate the provision of feedback and any required assistance to facilitate translation of research findings into health policy and programmes. The PC will also aim, when reviewing the dissemination plan, to enhance the coordination with work by other CISMAC members.

6. Authorship

All individuals who make substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work should have the opportunity to participate in the review, drafting, and final approval of the manuscript. The plans on authorship of the main study should be defined as early as possible by the PMT, listed in the Detailed Study Protocol, and communicated in writing by the PI to the PC. This enables the PC to compare the authorships and authorship sequence between the time of finalizing the Detailed Study Protocol and the writing and submission of manuscripts. The initially projected roles may change over time; the actual contributions should be reflected in the final authorship list and authorship sequence (see below).

The examples presented below may be considered by the study teams in developing and internally discussing their proposals for authorship:

- **Multi-site Studies**

a) for publications related to the main Study objectives, authorship may be presented as “..... Study Group”; with the names of the members of the Study Group detailed in an appendix or footnote in alphabetical order. The roles of the different members of the Group will also be listed.

b) for publications related to secondary study objectives, authorship may appear as “X, Y, Z for the ... Study Group”. The Study Group will be detailed in an appendix or footnote.

- **Single-site Studies**

For publications related to site-specific studies, the authorship may be defined by the individual site and might appear as “X, Y, Z et al.” from the specific institution.

CISMAC support (RCN Project No 223269) should be acknowledged in all publications.

Adequate visibility should also be given to CISMAC in all publications and presentations of research supported with CISMAC funds in ways which will be decided upon by the CISMAC Executive Committee.

Order of listing the authors

Paper(s) reporting on main study findings:

Most manuscripts will involve authors from Norwegian and LMIC institutions. The decision on the order of listing authors should be made by the study team based on each individual's contribution to the (i) study conceptualization and/or protocol development, (ii) acquisition of the data and (iii) analysis and/or interpretation of data and writing of the manuscript. An author of a paper presenting the main study findings needs to have made substantial contributions in all the above three items. In addition, all authors need to provide their final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The two lead investigators (usually one from an LMIC and one from a Norwegian institution) will be expected to be listed as the first and last authors of the manuscript that will present the main study findings. In all manuscripts developed, the decision on who will be the first and who will be the last author should be made together by the two investigators, referring to the guidelines below.

- In all manuscripts the first author and the last author should preferably represent different members of CISMAC: one coming from an LMIC institution, the other from a Norwegian institution. In cases of equal contribution as first author, co-authorship will be presented, with authors listed alphabetically.
- The decision on the order of listing authors beyond the first and last position should be based on scores of the author's contributions to the aspects listed as (i) to (iii) above. In calculating an individual's score, a higher weight will be placed on the contribution to (ii) data acquisition (40%) than to (i) conceptualization and/or protocol development (30%), and (iii) data analysis and/or interpretation of data and manuscript writing (30%). Individuals would be listed as authors according to the level of their scores –
 - Highest score: first author
 - Second highest score: last author
 - Third highest score: second author
 - Others in order of score: third to second last authors

EXAMPLE: Let us say that six investigators A, B, C, D, E and F fulfil the criteria of being authors having made contributions to all 3 aspects, but their levels of contribution varied in intensity

between major and minor contributions. Assume that authors A and D, one from an LMIC and one from Norway, led the PMT that developed and conducted the study. Let us say that the contributions of each of these scientists were as follows:

- (i) Conceptualization, development of protocols, Standard Operating Procedures, questionnaires, training, standardization and piloting (total 30%): 9% for A (*major contribution*), 3% for B (*minor contribution*), 3% for C (*minor contribution*), 9% for D (*major contribution*), 3% for E (*minor contribution*), 3% for F (*minor contribution*)
- (ii) Data acquisition (total 40%): 4% for A (*minor contribution*), 4% for B (*minor contribution*), 4% for C (*minor contribution*), 12% for D (*major contribution*), 12% for E (*major contribution*), 4% for F (*minor contribution*)
- (iii) Analysis and writing (total 30%): 9% for A (*major contribution*), 3% for B (*minor contribution*), 3% for C (*minor contribution*), 9% for D (*major contribution*), 3% for E (*minor contribution*), 3% for F (*minor contribution*)

Then, the total contribution of each author and proposed order of authorships is:

A: 22%	Last author
B: 10%	Third, fourth or fifth
C: 10%	Third, fourth or fifth
D: 30%	First author
E: 18%	Second author
F: 10%	Third, fourth or fifth

In case of equal contribution as for B, C and F, authors will be listed in alphabetical order. Their equal contributions will be indicated through a footnote or another suitable mean.

Paper(s) reporting on findings from secondary analyses:

Study investigators and other CISMAC scientists are encouraged to take the initiative for development of additional manuscripts to present other study results. To be an author on a paper emerging from such secondary analyses, he/she will have to make (1) substantial contributions to the conception or design of the work; or to the acquisition, analysis, or interpretation of data for the work; and (2) drafting the work or revising it critically for important intellectual content. In addition he/she should provide final approval of the version to be published; and agreement to be accountable for all aspects of the work thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The investigators that play significant roles in all the above areas in secondary analysis studies should be considered when deciding who should appear as authors. The order or the names will be dependent on their relative contributions. It is expected, nonetheless, that one of the lead investigators of the main study will be invited to be the second or last author in manuscripts presenting the findings from secondary analyses.

Whenever possible, each author's contribution will be described in terms of his/her actual work in the study.

Corresponding author

Among the authors of the manuscript, one should be identified and proposed by the PMT to be the corresponding author. This decision should be confirmed by the PC based on each author's overall contribution to the study but also taking into account political considerations, particularly within the Partner country, and pragmatic considerations, such as the author's availability to respond to requests following publication, expected need for interactions with stakeholders at local and international levels, and additional aspects that the group of authors and PC may deem important. Additional guidance on the role of the Corresponding Author has been developed by ICJME and is presented below.

Contributors listed in acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgments section. Financial and material support should also be acknowledged.

As indicated under the Guiding Principles, CISMAC will adhere to the recommendations developed by the ICJME. For ease of reference, these recommendations are provided below.

ICJME Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals:
http://www.icmje.org/roles_a.html (accessed on 10 September 2013; updated versions will be applicable)

Defining the Role of Authors and Contributors

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II.A.3 below. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3.

Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process, and typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. Although the corresponding author has primary responsibility for correspondence with the journal, the ICMJE recommends that editors send copies of all correspondence to all listed authors.

When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.

Non-Author Contributors

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. “Clinical Investigators” or “Participating Investigators”), and their contributions should be specified (e.g., “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” “provided and cared for study patients”, “participated in writing or technical editing of the manuscript”).

Because acknowledgment may imply endorsement by acknowledged individuals of a study’s data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

Annex 6 CISMAC Guidelines for Data Ownership, Sharing, Storage and Distribution

Ownership of data involves 3 entities: the institution that submitted the grant application and at which the implementation of the project will normally be based, the PIs and the funding entity.

The ownership of the Study data will rest with the institution that developed the Detailed Study Protocol and had it approved by the CISMAC Management and is the site in which the project implementation is based (heretofore named “the Partner”). It will normally employ at least one of the PMT leaders, often also the PI. The Partner will control the funding and the disbursement of funding; it will be responsible for ensuring that funded research is conducted responsibly and ethically as reflected in the CISMAC Study Implementation Agreement.

Although the Partner owns the project data, the PMTs and The Project Owner, i.e. the University of Bergen, represented by the Centre for International Health (CIH), will also have certain rights to access and use the data. The PI of each Study will have stewardship over the Study data; he/she will control the implementation, publication, and copyright of any research, subject to institutional agreement. The PI will hold custody of the data on behalf of the Partner.

The CISMAC Project Owner will, on behalf of RCN, have specific stipulations for how data will be retained and shared:

Data Retention

Data collected in CISMAC Studies should be retained for a minimum number of 5 years after the last expenditure report has been approved. Once the minimum storage period has been met, each CISMAC PI must in consultation with the CISMAC Management, decide whether to continue to store the data. The possibility of creating a depository of all data collected as part of the CISMAC-supported efforts should be considered. Although data can be kept indefinitely, the PIs and CISMAC Management must evaluate the benefits and risks of extended storage. Continued storage of confidential data increases the risk of possible violation. The monetary cost of retention and security are additional concerns.

If data have to be stored longer than 5 years, PIs should consider completely anonymizing the data. The decision of destroying the data should be made in consultation with the Partner and CISMAC Management. When the decision has been made to end data storage, data should be thoroughly and completely destroyed. Effective data destruction (onsite shredding and secure destruction of written and electronic records) should ensure that information cannot be extracted or reconstructed.

Data Sharing

Study data are expected to be shared and reported. Data sharing should occur once a study has been completed. Data sharing and reporting will in most instances be accomplished by publishing results in a scientific journal. Specific guidance has been developed by CISMAC for the planning and presentation of authorship in publications. Before publication, there will be no obligation on the PIs to share any preliminary data that have been collected. After a study has been published, published information related to the study may be considered open data. Other researchers may request raw data or miscellaneous information related to the project in order to verify the published data or to further their own research project. However, each project should evaluate its ability to share raw data in terms of specific needs and budget constraints. CISMAC encourages “timely release and sharing”, defined as sharing data to be published no later than the acceptance for publication of the main findings from the final data set. All CISMAC funded studies are expected to address data-sharing in their protocol. Access to raw data may initially be given only to the project team (for the

first 3 years, for example) and then be opened to all CISMAC members for an additional period, before becoming available to other groups upon request. CISMAC acknowledges that data sharing may be complicated or limited in some cases by organizational policies, local IRB rules and national laws and regulations. The rights and privacy of individuals who participate in the research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

Annex 7 – CISMAC Guidelines on Travel and Per diem

The work carried out by CISMAC will occasionally require travels to places away from the individual's institution or place of residence. CISMAC aims to reduce its costs and carbon footprint, and enhance its efficiency, and has therefore developed a set of guidelines which will apply to travels funded by CISMAC, both those paid by Partners (i.e. from Base Project Funds and Project Running Cost resources) as well as those covered by core funds at the University of Bergen.

Before deciding on the need for duty travel, the Project Management Team (PMT) Leader of the institution from where the travel will be paid should examine whether the objectives of the travel can be attained through using modes of communication such as email, video/tele- or web-conferencing.

The PMT Leader at each institution should interact with the CISMAC Administration Team to achieve uniformity in the application of these guidelines, and can at any time consult the CISMAC Administration Team in Bergen in the assessment of a given travel or travel claim.

If the need to travel is confirmed, such duty travel should take place according to the following guidelines:

- The source of funding has to be identified. If the funding is local project funding, the local rules and regulations for travel and per diem are to be followed. If the funding is from core funds located at UiB, the UiB travel regulations are to be followed.
- Air travel will take place using the most direct route, on safe and reliable carriers, according to international airline security rating standards.
- Adherence to the United Nations security alerts, which are continuously updated for affected areas, must be the overriding consideration when deciding to travel. Non-stop flights should be preferred, as well as other modes of transportation (train, boat, bus) when feasible.
- Travel should take place on the most direct route, and the least expensive economy class ticket will be provided for an approved itinerary.
- Should the travellers wish to use a more expensive carrier or ticketing, an indirect routing or to extend the official itinerary for private purposes, they may do so provided all costs of the changes, deviation or extension are at the travellers' own expense. Such modifications must be clarified by the PMT Leader prior to purchase of the ticket. Exceptions from the above regulations may be authorized by the CISMAC Administrative Leader, using as reference existing UN and UiB travel regulations.

Annex 8 – Definitions

The following definitions apply:

CIH	Centre for International Health. The CISMAC Management based at CIH is, on behalf of UiB, responsible for implementation of CISMAC
CISMAC	Centre for Intervention Science in Maternal and Child Health. Centre of Excellence (RCN Project No 223269)
Consortium Agreement	Agreement between Centre for International Health at the University of Bergen (CIH), Norway and Partners in CISMAC, RCN Project No 223269. It defines roles and responsibilities, regulates the organization and implementation of CISMAC Studies as well as rights and obligations of CISMAC Management and the Partners
Partners	Signatories to the Consortium Agreement with the Project Owner (University of Bergen). Includes LMIC Partners responsible for administration and implementation of CISMAC Studies and STS Partners who have advisory, supporting and/or monitoring roles and/or provide technical input for implementation of CISMAC Studies and in the inclusion of cross-cutting aspects
MOF	Faculty of Medicine and Dentistry, UiB – supports CISMAC Management in implementation of CISMAC
Project	The Project, CISMAC, comprises Studies undertaken the Partners and CIH-UiB. CISMAC has its own advisory, management and administration structures
Project Owner	University of Bergen. Receives funds from RCN on behalf of the CISMAC Consortium
RCN	Research Council of Norway
Study	A CISMAC Study is undertaken by one or more Partners and implemented in accordance with Base Project Fund and Study Implementation Agreements