



Guiding Principles*

V1.2 112820

**Please acknowledge The iPOP Study if adapting this document.*

This document outlines the overall Guiding Principles of the [iPOP Study](#) in order to promote collaboration, transparency and equity among all Team members. This is not a legal document. Data sharing and processing, subawards, and intellectual property will be governed by separate legal agreements.

1. Overall Goals and Vision

We have agreed to collaborate on the International Perinatal Outcomes in the Pandemic (iPOP) Study. We agree to the following guidelines as we work together. We enter into this agreement voluntarily, and we can leave the agreement voluntarily as described below.

The goals of the collaboration are:

- To conduct epidemiological studies on the impact of COVID-19 pandemic lockdowns/mitigation measures on perinatal outcomes and the potential underlying mechanisms, with robust, generalisable and reproducible findings
- To develop methodology and protocols for the iPOP Study
- To establish a research infrastructure for future studies on perinatal health
- To enable publication and dissemination of results, with engagement of stakeholders
- To identify new research questions, and leverage funding for future studies
- To provide reliable data inclusive of low-middle-income countries (LMICs) to inform the development of interventions and policies to enhance perinatal health during (and after) the pandemic, focusing on maternity care, maternal stress/workload, and gender equality.

2. General Principles

- Research will be carried out in accordance with relevant legal, health and safety, ethical and regulatory requirements
- Research outputs will be managed in a way that aims to achieve the greatest health benefits
- Research datasets will be shared and preserved in a way that maximises their long-term value wherever possible
- The research team will respect confidentiality of all research materials, methods and results, until approval for dissemination
- Research protocols will be registered and/or published in the public domain

3. Governance, Roles and Responsibilities

We will adopt a **Team Science** approach, recognising the contribution of all team members on any outputs or publications. Team Science refers to a collaborative effort to address a scientific challenge that leverages the strengths and expertise of professionals trained in different fields.

Team members

Team members are expected to make timely contributions as specified during protocol development, project delivery and publication planning. These responsibilities might include, but are not limited to: development of protocols, contributing data, analysing data, guiding interpretation of results, presenting results, drafting and editing papers, engaging with relevant stakeholders, and other contributions as agreed.

Governance

The iPOP Study Governance Structure is shown in **Figure 1**.

- The Team is led by the **Leadership Core**, comprising five iPOP co-leads who facilitate decision-making and communication among the Team, and a Project Manager
- Three **Working Groups** (WGs) are co-Chaired by the Core Leaders: Protocol Development (Stock/Zoega), Mechanisms (Azad/Burgner), and Knowledge Users (Azad/Brockway)
- Sub-WGs (e.g. statistics, perinatal outcomes, air quality, maternal stress) are co-chaired by other iPOP members with relevant expertise. All iPOP members are welcome to join WGs of interest.
- Further WGs and sub-WGs may be added depending on scientific and strategic direction on the advice of the Steering Committee and External Advisory Group
- The WGs are supported by two **Platforms**: the LMIC Platform and the Data & Infrastructure Platform
- Chairs of the main WGs and Platforms form the **iPOP Steering Committee**
- An External Advisory Group comprised of experts in relevant research areas provides non-binding strategic advice to the iPOP leadership regarding the scientific direction and management of the iPOP team

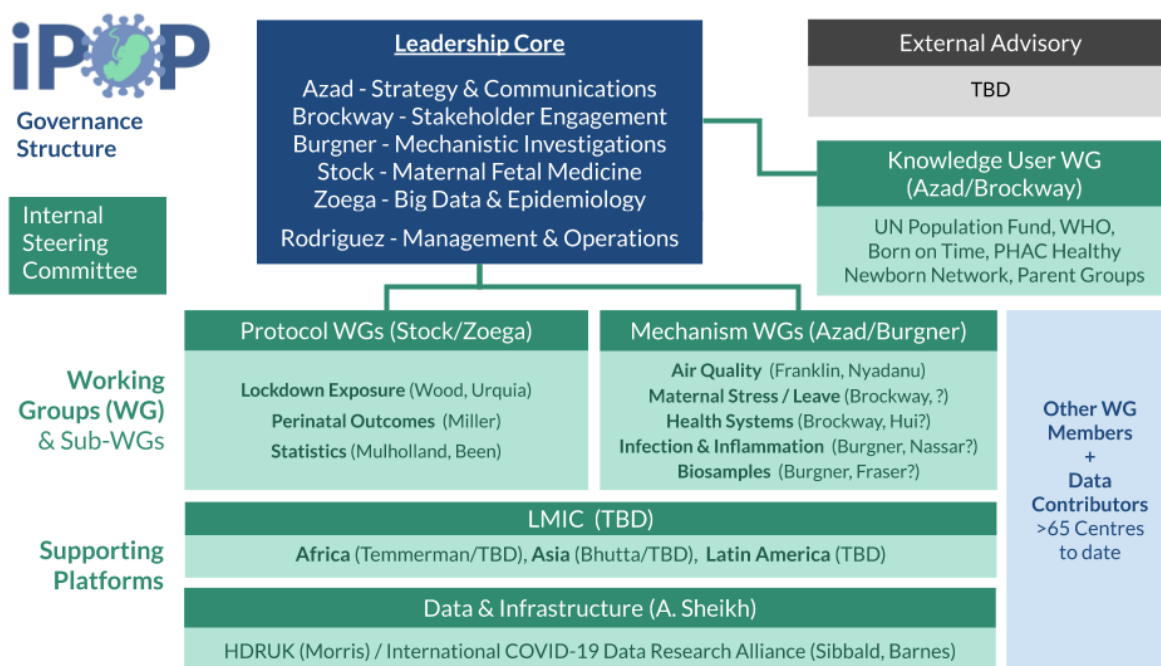


Figure 1. iPOP Governance Structure

Data Contributors

The agreement to contribute data will be made by each team member on the basis of the agreed protocol. The Team member will then work with the iPOP Project Management team and data controller/custodians to facilitate relevant approvals and provision of data. Data will be analysed as specified in the protocol, and managed as per the data management plan, in line with legislative requirements and funder guidelines. **Once analyses have commenced, data cannot be withdrawn.**

Linked and sourced data originating from iPOP collaborators will only be shared with approval of the providing data controller/custodian, as we are not the custodians of the primary data. If approvals allow, however, we will lodge resulting anonymised datasets within a data-sharing repository. These datasets will be credited to the people who created/collected them and will be linked to any publications through the metadata.

Honest and trustworthy reporting on data sources along with quality of data provided by collaborators is integral to the iPOP Study.

4. Research Integrity

As a Team, we will conduct responsible research. We will also maintain high quality research standards, while acknowledging mistakes or limitations.

We acknowledge that researchers are susceptible to human error and may engage in differences of opinion about interpretations or judgments of data. We also acknowledged that researchers work under difficult constraints, such that publication pressures, limited resources and other contingencies can push against the desire to maximize quality.

The research integrity of iPOP rests on the judgment and conscience of each Team member/collaborator. Research misconduct, i.e. fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results, will not be tolerated.

5. Data Protection

It will be assumed that any Team member sharing data within the iPOP Study does so in accordance with relevant and applicable legal and regulatory standards and obligations including but not limited to, confidentiality, data protection and intellectual property, and access governance agreements. iPOP collaborators must adhere to these policies and processes.

All collaborators must respect the iPOP principles of data protection and processing, which include the following:

All collected data must be

- Processed fairly and lawfully
- Collected for specified and legitimate purposes
- Adequate, relevant and not excessive in relation to the purpose
- Accurate
- Absent of personal identifiers (names, addresses, etc.)
- Stored not longer than necessary
- Processed under the responsibility and liability of the data Controller for the provided data set
- Handled according to the EU GDPR rules (when hosted in the UK)

The iPOP Study ensures confidentiality and security of the processing of data for electronic files. Data will be safeguarded by an appropriate level of security, technical and organisational measures to prevent unauthorized disclosure or access, accidental or unlawful destruction, accidental loss or alteration, and unlawful forms of processing.

Disclaimer: The summary above is provided for information purposes only and does not replace the relevant regulatory agreements of the iPOP Study.

6. Communications & Document Sharing

The iPOP Leadership Core and Project Management team will coordinate communications. iPOP collaborators will be added to the iPOP Slack Workspace and Google Group after completing the iPOP Intake Form. Documents will be shared using the Google Drive platform. Meetings will be held using Zoom. These platforms facilitate efficient communication and collaboration, and minimize email burden.

Slack

Our primary communication platform is Slack. This free platform facilitates efficient realtime and asynchronous communication among the iPOP Team, including group discussions in themed channels and private messaging between members. All members are encouraged to participate in Slack conversations (see: [how to use Slack](#)).

The primary Slack channels in the iPOP workspace are:

- **#general**: general announcements/discussions
- **#documents_for_comment**: documents for team feedback will be shared here prior to finalization. Each document will have a deadline for response. Team members must opt-in for authorship on specific documents using this channel.
- **#methods**: discussion of exposure and outcome measures, data collection, analysis plans and protocols

Other channels include:

- **#funding**: sharing/discussing relevant funding opportunities
- **#literature**: sharing/discussing published (or preprint) literature relevant to iPOP
- **#lmic**: topics of special relevance to LMICs
- **#media_articles**: sharing/discussing relevant mainstream or social media stories
- **#random**: for non-work-related discussion or topics unrelated to other channels

Google Group Email Distribution List

Using Slack is the best way to keep updated on iPOP news and operations. All updates will be posted on Slack. We will only email major announcements and occasional updates, using the iPOP Google Group.

Google Documents

We use Google Documents for sharing and co-developing documents (see: [The Beginners Guide to Google Docs](#)). This platform allows live editing by multiple collaborators simultaneously, and avoids having multiple versions of the same document in circulation. Given the size of the iPOP team, we strongly prefer not to receive comments as email attachments.

Documents will be shared on the Slack **#documents_for_comment** channel. Collaborators will have “suggesting” access (equivalent to “track changes”), allowing for **suggested edits** and/or **comments**.

7. Authorship, Credit, and Responsibility

Authorship

Authorship on any publications or presentations will be available to those who meet [International Committee for Medical Journal Editors \(ICJME\) criteria for authorship](#). If a member of the Team does not contribute as initially agreed, and fulfil criteria for authorship then that person will be removed as a co-author, as determined by the iPOP leadership group in consultation with the Team members.

The order of authorship for the co-authors will be based on contributions to the project.

If appropriate to the journal, the acknowledgements of the paper will describe each co-author's specific contributions. The contributions of other collaborators who are not co-authors will also be described in the acknowledgements.

All co-authors share some degree of responsibility for the entire paper as an accurate, verifiable research report. Co-authors are responsible for the accuracy of their contributions, but may have only limited responsibility for other results.

All co-authors must give their permission for publication prior to submission of each version of the paper.

iPOP researchers are expected to comply with the [UNESCO Policy Guidelines for the Development and promotion of Open Access](#) or applicable funding agency guidelines.

8. Confidentiality, Presentations & Media

Confidentiality

All Team members agree to keep project activities and materials **confidential** unless approved by the Leadership Core. This includes:

- Any meeting, written or oral conversation related to the iPOP project
- Any information, facts, data and any other matters of acquired knowledge, either directly or indirectly, as a result of project activities
- All drafts, preparatory information, documents and any other material relating to iPOP.

Presentations and Generic Materials

Generic materials about the project will be created for dissemination and shared with the Team (e.g. project summaries, infographics and website). All co-authors can give presentations of **published** work, using material in the paper, providing they reference the paper and their co-authors and the funders. Ideally, they will also notify the co-authors of these presentations beforehand.

Discussion or presentation of other iPOP activities or unpublished data outside the Team **must be approved in advance by the Steering Committee**. The Steering Committee must be informed of proposed outputs/activities at least 2 weeks in advance to allow sufficient time for adequate discussion, and opportunity for involvement of the other iPOP collaborators.

Media Inquiries

Media inquiries relating to iPOP publications and other outputs should be directed to the iPOP Project Management team. Press releases will be generated centrally by the iPOP Leadership Core and disseminated to collaborators for local release and editing as needed. Team members should acknowledge the contributions of other co-authors and the funders during interviews and encourage reporters to contact them.

9. Contingencies

Timelines for Feedback

All Team members agree to reply to communications concerning the project, especially drafts of any outputs, within a reasonable period of time (e.g. 1-2 weeks for protocols and manuscripts).

Paper Submission Process

No Team member can block publication of the paper other than because of concerns related to scientific soundness (e.g., the data collection, analyses and presentation were completed incorrectly). Concerns related to policy, management, or scientific implications are not grounds for a co-author to block publication. If a majority of Team members believe the paper should be published based on sound science, the paper will move forward. Every reasonable effort should be made by the leadership group and others to reach a consensus on moving forward with a publication.

Resignation from the Team

Team members may voluntarily remove themselves from the project, and from co-authorship, at any point if they no longer have time for the project or they disagree with some aspect of the project or paper. If a Team member voluntarily leaves the project or is asked to leave the Team because they are opposed to the paper being published, the Team members and Leadership Core will need to discuss with the dissenting member if his/her contributions can still be used, and perhaps described in the Acknowledgements, or will have to be removed from any publications.

Related or Spinoff Projects

Team members are free to develop their own collaborations and directions using the ideas and data from the collaboration, once it has ended. Team members should make every reasonable effort to inform each other when starting new collaborations and spin-off projects

that result from iPOP. We anticipate that Team members may continue to work together on follow-up projects, but this needs to be discussed among the group, and should not be assumed.

10. Funding

The iPOP Leadership will pursue funding for this project from organizations that align with our Guiding Principles. Initial funding and in-kind support for the iPOP Study has been provided by the [International COVID Data Alliance \(ICODA\)](#).

Team members are welcome to pursue local funding in alignment with our Guiding Principles to support their local efforts related to iPOP (e.g. data collection and cleaning; regional data analysis). The iPOP Leadership Core will gladly provide a Letter of Support for such applications if a written request is submitted at least 2 weeks in advance, including a link to the funding opportunity website, a list of the applicants, and a detailed summary of the research project and budget.

11. Conflict of Interest

All Team members will disclose to the Team any real or perceived conflicts of interest related to this project.

All Team members will disclose to the Team whether they or any close family members or associates will benefit financially from this project and paper.

12. Agreement Form

Please click the link below to complete the following Google Form indicating your agreement with this Guiding Principles document: iPOP Consortium Guiding Principles Agreement and Conflict of Interest Form.

The deadline for completion is **Thursday, December 10, 2020, at 4 PM CT**.