Responsible conduct of research guidelines

1.0 Introduction

All those engaged with research have a duty to consider how the work they undertake, host or support impacts on the research community and on wider society.[1]

IPH has a fully functional institutional ethics committee (IEC) that is functioning in accordance with the National Ethical guidelines for Biomedical & Health Research by the Indian Council of Medical Research (ICMR) dated 2017. The IEC maintains standard operating procedures (SOP) that are available and can be referred to for all aspects of ethics oversight of research at IPH. In September 2017, Director IPH has set up a committee on research conduct (CRC) that shall be responsible for the following:

1. Formulation of **policies related to research conduct** at IPH
2. Establish an institutional mechanism for **oversight over research projects** with respect to alignment with the highest standards of scientific research conduct and integrity
3. Implement a **grievance redressal and complaint mechanism for researchers** with respect to research conduct, authorship and dissemination of research

In line with this mandate, the following document has been prepared to put together all guidelines and policies with respect to research conduct and practice at IPH. While preparing the guidance, CRC has taken into account the national and international standards and guidance on the various topics related to research conduct, as well as adapted them to the processes and systems at IPH.

The following policies and guidance shall be binding on all research conducted at IPH. Wherever there is a need for amendments or a flexible interpretation on a case-to-case basis, researcher may contact the AD (Research) and/or IPH IEC Member-Secretary for help/assistance.

1.1 Scope

The guidance covers research conduct and practice with respect to health research undertaken by the various thematic areas (called clusters) at IPH including all kinds of health policy and systems research, implementation research and studies on new/innovative health systems interventions or observational studies. The guidance does not cover areas outside of these clusters such as clinical trials on new medicines/vaccines or previously untested medical devices/technologies, handling of research on recombinant DNA/hazardous material research or research on non-human participants. If research is proposed on topics outside of these clusters, it shall require a collaborator/institution with experience and competence to work on these topics.

[1] The concordat to support research integrity. Universities UK. 2012

The guidance covers various areas of responsible conduct of research including protection of human participants of research, health and safety of researchers, issues with respect to planning and conducting research (conflict of interest, data acquisition, management, sharing and ownership, reporting research, responsible authorship), research misconduct, registration of clinical trials and collaborative research (with other national and international organizations and groups).

This research guidance shall apply to all research conducted at IPH including all collaborative research projects, research proposed by future/ongoing research fellowship programmes and research by visiting fellows/research chairs.

The current guidance covers all research at IPH, primarily of the following types:

a) Research funded by grants, CSR engagements or fellowships
b) Research conducted within ongoing technical assistance/publichealth/health systems strengthening projects
c) Research funded by IPH (either directly by financial resources committed by IPH or conducted by researchers on their time outside of committed research projects)

IPH shall apply the following four principles and require researchers to uphold 14 primary responsibilities as a part of their research conduct.

2.0 Responsible and ethical conduct of research at IPH: Principles and practice

2.1 Principles for responsible conduct of research

1. **Honesty** in all aspects of research: in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.
2. **Accountability and rigor** in the conduct of research: in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.
3. **Professional courtesy and fairness** in working with colleagues and research participants
4. **Care and respect** for all participants in and subjects of research, including humans, animals, the environment and cultural objects and traditions.

2.2 Code of practice for researchers at IPH

1. **Integrity**: Researchers shall take responsibility for the trustworthiness of their research.
2. **Adherence to regulations**: Researchers shall be aware of and adhere to all Indian national, state and local government regulations and policies related to research, legal, health and safety and ethical requirements. Researchers must obtain all necessary licenses and approvals from relevant authorities and these must be in place throughout the research. Researchers must also consider and manage any health-related findings in research and risks of research misuse.
3. **Research methods**: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence, and report findings and interpretations fully, in line with established standards for the methods they use.
4. **Research documentation**: Researchers should keep clear, accurate records of all research in ways that will allow verification and replication (if possible) of their work by others.
5. **Research findings**: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.
6. **Authorship and acknowledgement**: Researchers should take responsibility for their contributions to all publications, funding applications, reports, and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria. Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.
7. **Peer review**: Researchers should provide fair, prompt, and rigorous evaluations and respect confidentiality when reviewing others' work.
8. **Conflict of interest (in research)**: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications, and public communications as well as in all review activities. *See also institutional conflict of interest policy that covers all work undertaken by IPH staff, as part of the IPH institutional policies manual.*
9. **Reporting irresponsible research practices**: Researchers should report to the IPH CRC and/or IEC any suspected research misconduct, including fabrication, falsification, or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.
10. **Failure to report misconduct**: Research misconduct can put individuals at risk, if, for example, the misconduct affects information that is used for making medical or

public decisions. Failure to report research misconduct also undermines professional self-regulation. Any willful failure to report misconduct shall be construed as a negligence of duty and appropriate disciplinary action may be initiated by the Director/governance.

11. **Responding to irresponsible research practices**: The current guidance notifies procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions shall be taken promptly, including correcting the research record.
12. **Research environment**: Researchers at IPH and the IPH management seeks to create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.
13. **Societal underpinnings of research**: Research at IPH shall respond to the need for advancing scientific knowledge towards achieving an equitable society and hence the need for researchers to acknowledge the wider social role that their research ought to contribute to.

2.3 Ethical conduct of research[2]

Research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants should be built into the design of the study. *Do no harm* (non- maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world. While conducting biomedical and health research, the four basic ethical principles should guide us. They are:

1. respect for persons (autonomy),
2. beneficence,
3. non-maleficence, and
4. justice.

They have been enunciated for protecting the dignity, rights, safety and well-being of research participants. These four basic principles have been expanded into 12 general principles. To assist researchers to assess the extent to which their research approaches are in line with these 12 general principles, a checklist of questions is in Annex 1. This is a non-binding guidance provided for resaerchers to to pose before, during and after conduct

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2 Adapted from the National Ethical Guidelines for Biomedical & Health Research Involving Human Participants (ICMR 2017)

of research. They could be applied to biomedical, social and behavioral science research for health involving human participants, their biological material and data.

3.0 Guidelines for responsible conduct of research at IPH

3.1 Initiating research at IPH

Research at IPH is primarily guided by our mission for strengthening health systems and could be complemented by intellectual curiousity and other scientific goals. In this approach, the research begins with clearly framed objectives and research questions (in some research approaches, researchers may frame hypotheses that their study tests in order to advance current scientific knowledge on the research topic). In line with this, researchers are encouraged to follow the most appropriate and scientifically relevant research method that is applicable to the research, and follow the best guidance available. Researchers are expected to have conducted a review of literature relevant to their research topic and aim to build upon existing knowledge on the topic. Researchers shall strive to not contribute to the already increasing body of research that is not of use (called research waste), usually because it asks the wrong questions, is badly designed, not published or poorly reported.

In order to ensure effective and ethical implementation of all research, all new research proposed at IPH shall require an approval before any formal proposal for funding is made to any external entity on behalf of IPH and/or on behalf of any Faculty/staff representing IPH. Depending on the nature of the proposal, a two-step or a one-step process is foreseen.

In a scenario where the PI or team-lead level person is to be recruited on receipt of the funding, and if such person is already identified or involved in the application process or is an applicant himself/herself, then the procedure as specified under hosting of fellowships at IPH section shall be followed.

Tentative approval (Template 1) shall only be used for submissions of preliminary rounds in multi-stage proposals.

Approval to host proposed project at IPH (Template 2) shall apply wherever a final proposal for full funding is being requested.

Wherever there is no multi-stage process and a full proposal is being asked for by the funder, then template 2 may be used directly instead of a 2-stage process.

Template 1: Tentative approval
Expression of interest/tentative approval shall be the initial stage for informing IPH management about the intention to submit a proposal.

The requirements for this step shall be the following:

1. **Details of proposed project** including at least the following must be sent to AD-Research with a copy to AD-Admin: concept note/draft proposal mentioning (Template for tentative approval attached)
   (i) Objectives and/or research questions
   (ii) Proposed methodology and/or study design to be followed

(iii) Proposed budget after approval from AD-Admin/Finance Officer (even if sub-headings of the budget are not final yet, the overall budget and minimum break-up consisting of institutional overheads, program direct costs and brief details of budget lines as per funder requirements need to be supplied)
(iv) Proposed list of co-investigators, partners and any other individuals and/or organisations need to be provided in a table
(v) Name and details of the funder along with full link to the EoI/RFP/grant call/Email requesting proposal

2. Tentative approval over email from current team-lead/cluster-lead outlining that the time to be spent on proposal (if successful) shall not interfere with existing project implementation. If there is an alternate plan to be implemented involving new team-lead level hiring if the project funding is successful, then this has to be mentioned and must meet the approval of the cluster-lead; if cluster-lead is her/himself applying, then an email approval from Director in response to such a plan outlining the time to be spent/alternate plan for time to be spent shall be needed. This tentative approval over email shall be sent to AD-Admin and a no-objection from AD-Admin shall be needed before finalising the template)

Once the template for tentative approval has been submitted to AD-Research over email, tentative approval to engage with the external funder via EoI/draft proposal shall be granted over email, no later **than four working days**.

Wherever AD-Research is involved in submission, they shall follow the same process with Director and vice-versa.

Template 2: Approval to host proposed project at IPH

1. **Details of proposed project including at least the following:**
   (i) Draft proposal mentioning Objectives and/or research questions,
   (ii) Proposed methodology and/or study design to be followed,
   (iii) detailed budget (as approved by Finance Officer and/or AD-Admin),
   (iv) Full list of co-investigators, partners and any other individuals and/or organisations involved in a table/list along with mode of engagement (whether under existing MoU/new MoU proposed or alternate arrangements)

2. Project initiation plan, if successful, including at least the following and with approval of the cluster-lead and AD-Admin:

(i) Percentage FTE of current and/or proposed team-lead towards this project,
(ii) Duration for which this proposed percentage FTE shall be provided,
(iii) Whether proposed project provides for this percentage FTE, if not, proposed plan to secure this time within existing project/institutional commitments
(iv) List of any other staff of IPH involved/to be involved along with their percentage FTE, duration and whether funding available in proposed project for this time (there is no need to provide clarity on the operational staff to be hired under the project)

Once the template for internal acceptance of a project in IPH has been submitted to AD-Research over email, approval shall be granted over email, no later than four working days. Wherever AD-Research is involved in submission, they shall follow the same process with Director and vice-versa.

Checklists for due diligence check (For both template 1 & 2)

For both of these templates, the checklists for AD-Admin and AD-Research shall be as follows. In the event of the template not providing sufficient details to make a determination on any of these, they may be returned.

Checklist for AD-Admin approval

1. **Budget approval**: Has the Finance Officer reviewed and approved the budget? Does it meet IPH guidance on securing sufficient research overheads and/or institutional costs
2. **Team/Cluster-lead support**: Is there sufficient support from team-lead/cluster-lead to proceed?
3. **Plan for project leadership**: Is there a plan for ensuring smooth implementation in case the proposal comes through? For eg. is there clarity on percentage time that applicant will spend on the proposed project and if yes, then how will their current project be affected, and what is the plan for the same?
4. **Time compensation of PI**: Is there appropriate compensation for the applicant-PI? If not, what is the justification to proceed without costing their time, given IPH's grant-funding based salary structure
5. **Source of funding**: Is the proposed source of funding accessible to IPH and in keeping with our legal status as an NGO (Society)?
6. **Statutory/compliance issues**: Are there any other issues with statutory/legal compliance of **the proposal if successful, especially regarding IPH's policies on conflict of interest, source of funding** and other institutional strategic considerations

A structured response to these questions may be provided by AD-Admin to ensure appropriate decision by AD-Research. Alternately, if there is overwhelming support to proceed with the proposal, then the same may be conveyed via email.

Checklist for AD-Research approval (For both template 1 & 2)

7. **Scope of proposed research:** Is it within the ambit of vision and mission of IPH? Has an appropriate cluster been identified and the cluster-lead consulted?
8. **Proposal fit to call:** Is the proposal complete? Does it respond appropriately to the CFP/RFP/EoI in terms of its fit to the call?
9. **Proposal fit to IPH research eco-system:** Are the objectives/questions sufficiently clear and implementable within the IPH research framework, in terms of research infrastructure available, access to field areas (if any) or laboratories etc (if not, does the proposal identify appropriate measures to address this). Can IPH ethics committee and our current research conduct guidelines sufficiently cover the proposed research
10. **Proposal fit to team:** Does the team proposed match the expertise needed to implement the proposal successfully? Has the proposal sufficiently tapped into expertise within IPH and/or within our associates/partner institutes.

AD-Research shall await input from AD-Admin and further apply the above checklist. A structured response to these questions may be provided by AD-Research to document the decision. Alternatively, if there is overwhelming support to proceed with the proposal, then the same may be conveyed.

If the above due diligence is complete, AD-Research shall convey approval to applicant over email and they may then proceed accordingly. All AD-Research approvals
shall be copied to the Director and IPH MC for their information along with the documentation of the due diligence as per checklists above for their review.

In the event that the due diligence check as per this checklist fails, then the proposal may not be allowed to proceed to submission and the same shall be conveyed to the proposed applicant. Applicants may approach the Director as an appellate authority and he/she may overrule the previous decision by providing appropriate reason.

3.1.1. Research advisory board at IPH

IPH shall constitute a Research Advisory Board (RAB) in order to review and provide advice on the quality and outcomes of research at IPH. The RAB shall meet at least once every year. Further, RAB members may be invited by the IEC member-secretary and/or AD-Research for providing specific inputs or conduct peer-review of new projects/proposals to be implemented at IPH.

Operational procedures for the RAB:

1. **Constitution**: Based on inputs from IPH staff and governing board, DIrector shall constitute the RAB. Director may delegate these functions to AD-Research or other competent staff to coordinate the constitution of the RAB and its periodic meetings.
2. **Membership**: The RAB shall comprise (at least) six members. RAB members shall be established researchers with an appropriate academic track-record and shall represent one or more sectors and disciplines relevant to the research interests at IPH.
3. The RAB shall meet at least once every year on or before the IPH Annual Day, or in alignment with any other event being organised by IPH.
4. The date, agenda and the reports to be presented at the RAB meeting shall be circulated at least one month in advance. Meetings may be convened via video-conference to ensure maximum participation.
5. At the meeting, the Director and/or AD-Research shall present the following:
    a. Review of all research projects completed and ongoing at IPH focusing on objectives, methods and scientific/public/policy impact
    b. Summary of IEC reviews and decisions
    c. Any new proposals/ideas under consideration for the coming year
    d. Inputs of RAB members to the presentations
    e. Discussion on agenda items raised by RAB members
    f. All RAB members may provide written/oral inputs on the direction of IPH research, quality of the research process and outputs and inputs on strategic direction of research at IPH
6. A report of proceedings of the RAB meeting shall be shared by Director/AD-R every year.
7. Membership of the RAB shall be an honorary position and shall not entail employment at IPH. Fees to compensate travel/incidental expenses may be reimbursed.
8. Upon acceptance to be a member of the RAB, IPH shall provide a formal letter stating the tenure, role and other terms of reference related to the RAB.
9. The membership to the IPH RAB shall be for a tenure of three years and can be renewed upon mutual agreement between IPH and the member.

3.2 Protocol design, consultation and internal peer review

Researchers should initiate discussions about their research objectives and study questions within their teams and/or research clusters. Wherever possible, researchers should aim to seek internal peer-review of their proposal before submission to external agency.

Wherever this is not possible due to tight deadlines, researchers shall fix a date for a presentation in the form of a talk/seminar at IPH. In general, all research projects shall be presented as a

talk/seminar at IPH before initiating data collection. These requirements may be relaxed especially in the case of competitive grants that have typically undergo a peer-review process organized by the grantmaking agency.

For grants/fellowships that are managed/hosted at IPH, the proposed PI shall typically be employed at IPH at the time of introducing the grant/fellowship application or shall join IPH when the grant is activated. In the latter case, when Faculty plan to join IPH for a grant/fellowship, a formal procedure approved by IPH shall apply. In case Adjunct Faculty/Honorary Associates are applying as PI on research grants/fellowships, then they shall provide an undertaking to IPH stipulating the fulfilment of all supervision and administrative requirements under the grant in case the application is successful. Suitable modifications in their Adjunct Faculty contract and/or a revised contract may be considered in addition to the undertaking, if recommended by the ADR in consultation with the MC.

3.3 Planning research fellowships at IPH

In the case of future research grants or fellowships that are being planned by associates/adjuct faculty or visiting researchers, this has to be done in collaboration with IPH Faculty at the level of team-lead or cluster-leads. Discussions need to be initiated with team-leads or cluster-leads well in advance of submission of proposal to external agency (see below). All future research fellowships shall have to be in line with the vision and mission and research objectives taken up by IPH. If funded, they will have to be located within one of the existing clusters of IPH (see guidance on process for creating new research clusters). Research fellowships of short duration (<1 year) may be supervised by a cluster/team lead. Fellowships exceeding 1 year and those requiring employment at IPH shall need to go through the following process:

a) Potential research fellow identifies a research cluster that could host the proposed research
b) Presentation and internal peer-review by the cluster/team members
c) Open seminar at IPH followed by an interview by MC
d) MC members give inputs to Director

Based on the above process and inputs to the Director by MC members, the Director shall then provide letters of support as required by external agency. Reasons for inability to host fellowship at IPH include poor fit with IPH vision, mission and research objectives, inadequite commitment by at least one existing team/cluster leads, and technical/operational feasibility issues related to the proposed research.

3.4 Researcher capacity building

The AD Research shall coordinate with cluster and/or team leads to facilitate and encourage on-the-job training and capacity-building of early career researchers. Wherever relevant, early career researchers are expected to consider enrolling in one or more of IPH's courses on research methods, academic writing and public health. Early career researchers may also discuss with their respective team/cluster leads about enrolling in external online courses that are relevant to their research projects.

3.5 Data acquisition, management, sharing and ownership

There is no single best way to collect data. Different collection techniques are needed for different types of research. Irrespective of the choice of data collection method, the following shall guide the implementation of data collection, management, sharing and ownership of this data. Research project principal investigators shall ensure that all of their research staff shall put these into practice.

3.1.1 Sensitivity: Researchers should be sensitive to participants and use bestpractices for data collection.

3.1.2 Accuracy: Data collection involves physical process of recording data in hard copy, soft or electronic copy, or other permanent forms. The physical formats for recording data vary considerably, from measurements or observations to photographs or interview recordings. To be valuable, research data must be properly recorded. Research leads shall have the responsibility of ensuring sufficient training to data collectors.

3.1.3 Appropriate and reliable methods: Research and data collection must be conducted using appropriate and reliable methods to provide reliable data. The use of inappropriate methods in research compromises the integrity of research data and should be avoided.

3.1.4 Permissions and approvals from IEC and other authorized agencies: Data shall be collected in line with the approvals granted and conditions specified by the IPH IEC. Any deviation in process of data collection, adaptation of the tool and/or other incidental data collected that was not declared to the IPH IEC in the approved protocol shall have to be intimated to the IPH IEC. Wherever other institutions are involved (including government institutions), researchers shall enter into MoUs (as per procedure established by IPH) and shared with the IPH IEC.

3.1.5 Data ownership and responsibility: Ownership issues and responsibilities need to be carefully worked out well before data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. For biological samples, donors (study participants) maintain the ownership of the sample. She/he could withdraw both the biological material and the related data unless the latter is required for outcome measurement and is so mentioned in the initial informed consent document. IPH or partner institutions participating in the research shall be deemed to be custodians of the data/ samples.

3.1.6 Protocols: All primary data for research purposes shall be collected using a procedure declared in a study protocol and approved by the IPH IEC.

3.1.7 Data protection and storage: Once collected, data must be properly protected, as it may be needed at a later stage to confirm research findings, establish priority, or be re- analyzed by other researchers. Responsible data handling begins with proper storage and protection from accidental damage, loss or theft. Care should be taken to reduce the risk of fire, flood and other catastrophic events. Computer files should be backed-up and the back- up data saved in a secure place at a site that is different from the original data storage site. Full details of data protection and storage shall be declared to the IPH IEC.

All hard and soft-copies of data collected (including raw data spreadsheets, questionnaires, transcripts and recordings) shall be shorted for a period of five years after the completion of the research project. See data sharing for making anonymised datasets available on public platforms for wider sharing with the research community.

The research PI shall be responsible for identifying and organising space for storage of hard-copies in a secure manner in coordination with the Administrator and AD (Research). Soft-copies shall be handed over to the IPH research repository (see below).

3.1.8 Data sharing: This is important as research data is valuable and needs to be shared, but deciding when and with whom to share may raise difficult questions. Once a researcher has published the results of their study, it is generally expected that all the information about that study, including the final data, should be freely available for other researchers to check and use. Data should be shared or placed in a public domain in a de- identified/anonymized form, unless required otherwise, for which applicable permissions/re-consent should be sought unless obtained beforehand. Full details of the data sharing shall be declared to the IPH IEC. Research team-lead/PI shall take responsibility for obtaining clearances from collaborating institutions/consortia for such sharing. Wherever there are valid reasons for not sharing data in public domain, team- leads/PI may then submit this to the IPH repository only.

3.1.9 Internal research outputs: Team-leads/PIs shall strive for disseminating study findings and outputs both within IPH (seminars, workships, posters) as well as with the wider research community and the public. All research projects shall ensure to present at least two seminars (one upon securing funding and/or ethics approval, and the second one upon completion of the study).

3.1.10 Research repository: A research project repository shall be created and maintained by the IPH Administrator in coordination with AD (Research) for ensuring long-term storage of approved study protocols, password-protected soft-copies primary data collected and all final reports of research projects. The repository shall be maintained in a way that allows retrieval by other IPH researchers or collaborators subject to conditions for access to such data specified to the IPH IEC.

3.2 Registration of studies in public databases

According to the Declaration of Helsinki on ethical principles for medical research involving human subjects, "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." In 2017, India (via ICMR) has signed a joint statement on public disclosure of results from all international trials. The Clinical Trials Registry–India (CTRI), linked to WHO registry, was launched in 2007 by ICMR, as a free and online public record system for registration of clinical trials, PG thesis and other biomedical research being conducted in India.

Trial registration in the CTRI is **voluntary** for other biomedical and health research (mandatory for clinical trials). All clinical research involving human participants including any intervention such as drugs, surgical procedures, devices, biomedical, educational or behavioral research, public health intervention studies, observational studies,

implementation research and preclinical studies of experimental therapeutics and preventives or AYUSH studies may be registered prospectively with the CTRI. Trial registration involves providing information regarding the study, investigators, sites, sponsor, ethics committees, regulatory clearances, disease/condition, types of study, methodologies, outcomes, etc. Registration of research in CTRI ensures that more complete, authenticated, readily available data on research is available publicly. This improves transparency, accountability and accessibility. Registration of health policy and systems research studies that do not use clinical trial approach is currently optional/voluntary.

3.3 Open and unrestricted access to published research

IPH expects researchers to publish in high-quality, peer-reviewed journals that are widely indexed on international platforms such as PubMed, Google Scholar etc. appropriately chosen to maximize research impact and public benefit. IPH believes that maximizing the distribution of these papers - by providing free, online access - is the most effective way of ensuring that the research can be accessed, read and built upon. Hence, researchers are expected to build in costs related to publishing their papers in open access format into research grants. Wherever this is not possible (or in case of research undertaken in public interest without specific funding), researchers shall strive to secure funding to ensure free and open access publication of the papers. In case of research published in paywalled journals, researchers are required to make available pre-print versions on public/open databases such as SSRN (or any other) or researcher networking sites such as ResearchGate (or any other).

Identifying a responsible, credible and widely accessible journal shall be the responsibility of the researcher. In view of recent widespread proliferation of poor quality journals that do not incorporate sufficient checks and balances for quality of articles (predatory journals), researchers should ensure that they seek inputs from peers, team/cluster leads to avoid publication in such journals.

3.4 Authorship

Authorship confers credit and has important academic, social, and financial implications. Authorship also implies ***responsibility and accountability*** for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

IPH researchers shall follow the guidance of International Committee of Medical Journal Editors (ICMJE) on authorship, which is largely accepted as a standard and is endorsed by the World Association of Medical Editors (WAME).

3.4.1 Who should be an author?

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

1. Substantial contributions to the conception or design of the work; or theacquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. 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 below).

These authorship criteria are intended to preserve 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.**

3.4.2 Who 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. Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, corresponding author shall obtain written permission to be acknowledged from all acknowledged individuals.

3.4.3 Ghost/gift authorship

Authorship should never be gifted and ghost (proxy) authors are not acceptable.

3.4.4 Authorship order and primary author

The primary author should be the person who has done most of the research work related to the manuscript being submitted for publication. Research performed as part of a mandatory requirement of a course/fellowship/training programme including student research should have the candidate as the primary author. All efforts must be made to provide the candidate with an opportunity to fulfil the second, third and fourth criteria of

the ICMJE guidelines. The primary author is typically steering/organizing the writing and/or submission of the paper and may (or may not) become the corresponding author. Order of authorship shall be based on a mutual agreement and assessment of contributions by all authors and shall be openly declared at the relevant section of the published paper.
All authors are required to agree on the text representing their contributions.

3.4.5 Prior discussion on authorship

The authorship of research should be considered at the time of its initiation of the research study. Researchers are encouraged to identify to the greatest detail feasible the possible papers foreseen in a research project and distribute roles in terms of primary authors fairly across the research team, ensuring balance across skills and competencies, providing opportunities for junior/young researchers to take lead on specific components of the project and ensuring that there is no discrimination/arbitrariness in identifying possible primary authors. It shall be mandatory to declare these plans in the study protocol submitted to the IPH IEC.

3.4.6 Inclusive and enabling environment for authorship

Cluster and team leads and PIs shall be responsible to enable team members to contribute if they are willing, to the authorship process. This shall especially be the case with the field staff who tend to get excluded. Their involvement should be foreseen from the stage of the study protocol and conceptualizing of the paper itself. Teams shall create an enabling environment where the invitation to join research dissemination and authorship shall be as i**nclusive** as possible across team members.

3.4.7 Authorship disputes

The primary author shall take the final call whenever there is a dispute over authorship claims. Researchers shall seek to address any disagreements by using/applying the ICJME criteria. In cases where the list of potential authors has not been able to reach an agreement, the team may choose another IPH Faculty as an independent arbiter to facilitate agreement. If this too fails, the competing authorship order may be summarized and a non- binding advice sought from the IPH CRC. In case the IPH CRC advice fails to address the disagreement, the case summary and the IPH CRC advice may be sent to the IPH Director, who shall take a final and binding decision based on his best judgement of the material presented and keeping in mind the authorship criteria of ICJME. If the Director is an involved party to the disagreement, then AD (Research), AD (Policy) and AD (Education) in that order may be approached.

3.4.8 Implementers and other partners as authors

Many of IPH research clusters routinely work with implementers (including doctors, ANMs, and other health workers in government and private sector), NGOs and community-based organizations using implementation research and participatory action research methods.
Researchers shall strive to involve and invite participants from these settings into the

authorship process in an inclusive manner. Researchers shall strive to include and involve implementers, communities and other non-research partners in the research process (including authorship) *a priori* and ensuring that these authorship relationships shall align with the broad criteria set out by ICJME, albeit with a more flexible interpretation.
Researchers shall ensure that authorship sharing, and inclusiveness is done in a planned and responsible way and not as a gift or a favor for the partner participating/facilitating the research.

3.4.9 Authorship for data collectors especially in qualitative data collection: Role of the qualitative "data collector"

In some instances, such as in qualitative research involving narratives, in-depth inquiry, case studies and observations often involve a deeper engagement with the research participant and require a reflexivity on the part of the data collector, to a higher extent than in classical structured population health surveys. Research assistants or others who engage in qualitative data collection shall receive appropriate training and researchers shall make all efforts in trying to invite and include qualitative data collectors, especially when they have been involved in substantial qualitative data collection, into the authorship process, always ensuring compliance with the ICJME criteria. The guidance here is to ensure that younger researchers/junior researchers should not be sidelined in determining authorship and every effort should be made for a more inclusive authorship, while keeping in mind the ICJME criteria.

3.5 Conflict of interest

Conflict of interest (COI) refers to a set of conditions whereby professional judgement concerning a primary interest, such as participant's welfare or the validity of research either is, or perceived to be unduly influenced by a secondary interest. The secondary interest may be financial or non-financial, personal, academic or political. This is not inherently wrong, but COI can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data and the ethical review of research. It is, therefore, necessary to evolve procedures to identify, mitigate and manage such COI which can be at the level of research, ethics committee or at the level of institution.

IPH has a policy at the institutional level on conflict of interest. All researchers shall abide by the IPH COI policy.

Researchers shall:

1. ensure that documents submitted to the IPH IEC include disclosure of COI (financial or non- financial) that may affect their research
2. guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and

3. prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

3.6 Research misconduct

Research misconduct involves fabrication, falsification and plagiarism of data, which are serious issues both nationally and internationally.

Research misconduct includes the following:

1. Fabrication is the intentional act of making-up data or results and recording or reporting them.
2. Falsification is manipulating research materials, equipment or processes, or changing or omitting/suppressing data or results without scientific or statistical justification, such that the research is not accurately represented in the research record.
3. Plagiarism is the "wrongful appropriation" and "stealing and publication" of another paper or another author's "language, thoughts, ideas, or expressions" and the representation of them as one's own original work or duplicating one's own publication (self-plagiarism).

3.6.1 Investigating research misconduct

Research misconduct, if suspected or witnessed, needs to be reported immediately to the AD (Research) or to any member of the IPH CRC. AD (Research) on receipt of any complaint shall inform the IPH CRC and seek a meeting to discuss and investigate allegations of misconduct. IPH CRC investigations shall be done in a timely, fair and transparent manner and the results shall be made available in the public domain.

3.6.2 Whistleblower protection

All communication about research misconduct shall be dealt with in a confidential and responsible manner during the investigation, and the results publicised only upon full completion of the process. IPH CRC shall ensure protection of both whistleblower and the person accused of research misconduct.

3.7 Research funded by industries associated with health risks

In view of the overwhelming evidence of interference by tobacco industry in health research and public policies, researchers at IPH shall not participate directly (receive funding) or indirectly (be authors or provide technical support) in research involving individuals applying for, holding, or employed under a research grant from the tobacco industry.

In the case of research involving individuals applying for, holding or employed under a research grant from food, alcohol and pharmaceutical corporations, researchers from IPH shall subject their decision to participate to the following conditions:

1. Justify to the IPH management and to the IPH IEC, the need for participating in the research
2. Exercise full disclosure at all steps of the conduct of the research
3. Document and disclose the role of the participating researcher and the corporation in all stages of the research
4. Put in place procedures to manage conflicting interests wherever they occur

In research involving industry funding and/or participation, the IPH MC and/or the IPH IEC may suggest modifications and/or restrict participation based on institutional and ethical reasoning.

3.8 Researchers relationship with commercial organizations

IPH wishes to ensure that the useful results of its research are applied for the public benefit. However, IPH recognizes the importance of protecting and exploiting intellectual property arising from research as a means of achieving this public benefit. Accordingly, IPH encourages, where appropriate, scientifically productive relationships between its researchers and commercial organizations. At the same time, it wishes to ensure that the intellectual integrity of researchers and their freedom to carry out research in public interest is not compromised by such relationships.

3.8.1 Consultancies in select industries: Researchers shall not serve as consultants to industries posing health risks, including but not limited to arms manufacturers, tobacco, alcohol, food and pharmaceutical industries.

3.8.2 Directorships in commercial organizations: Researchers may serve as non- executive directors of commercial organizations but may not serve as executive directors. In all such instances, researchers must disclose to IPH (a) benefits in cash and/or (b) benefits in equity of any level, received either as compensation for work undertaken for a commercial organization, or in consideration of the transfer of intellectual property. Researchers holding equity in a commercial organization must make a declaration of interests to their host organization if they, together with members of their immediate family, hold, control or manage, directly or indirectly, (a) any level of equity in an unlisted company, or (b) equity in a listed company in excess of 1 per cent of that company's equity interest. 'Immediate family' includes spouse or partner; minor children; and adult children (but only in so far as the researcher has knowledge of the interests of the adult children).

3.9 Mentoring young researchers/interns/students and other trainees

Mentoring is one of the primary means for one generation of researchers to pass on their knowledge, values and principles to succeeding generations. Mentors, through their experience, can guide researchers in ways above and beyond what can be gathered from reading textbooks. All researchers are encouraged to identify mentors for their research as

well as provide mentorship within their research teams. The AD Research shall steer overall institutional mentorship mechanisms, and all cluster leads are expected to play a mentorial role within and across clusters for young researchers.

The relationship between mentors and young researchers and/or students/interns under their guidance/supervision should enable the latter to become responsible researchers. A mentor should be knowledgeable, teach and lead by example and understand that trainees differ in their abilities. She/he should devote sufficient time and be available to discuss, debate and guide trainees ably.

3.10 Collaborative research

IPH encourages researchers to collaborate within and with other research and non-research organizations in order to achieve our vision.

3.10.1 Preparation for collaboration: Wherever IPH researchers are entering into such collaborations outside IPH, they are expected to initiate a dialogue and reach a mutual understanding with respect to sharing techniques, ownership of materials and data, intellectual property rights (if applicable), joint publications, managing research findings and managing COI. Researchers should familiarize themselves with all aspects including local, national and international requirements for research collaboration including necessary approvals, memorandums of understanding (MoUs) and material transfer agreements (MTA) and seek IEC approvals in all collaborating institutes.

3.10.2 Ethical considerations in collaborative research: IPH researchers shall ensure that all participants in collaborative research should have access to the best nationally available standard of care. If there is exchange of biological material involved between collaborating sites, the IPH IEC shall always be informed about the nature of the exchange and this may require appropriate MoU and/or material transfer agreements to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

3.10.3 Enabling IPH IEC access to collaborating sites: The collaborating researcher shall establish a mechanism for communication between the IECs of different participating centres should be established. In case of any conflict, the decision of the local IEC based on relevant facts/guidelines/law of the land shall prevail.

3.10.4 International collaboration: While on one hand collaboration in health research could be seen as a humane interest in the health of civil society, on the other hand it could create the impression of exploitation by one country experimenting on the population of another poorer one. For all collaborations with IPH, the participating researcher shall ensure that the research work in India shall be in line with the latest ethical guidelines and relevant regulatory requirements before the sponsor agency/country initiates collaboration.

3.10.5 IPH as an equal partner: In all such collaborations, IPH shall be deemed an equal partner with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and intellectual property rights related to research in India, as may be considered appropriate.

3.10.6 Primacy of the IPH IEC: Collaborating researchers shall ensure good communication between international partners and in case of any conflict, the decision of the IPH IEC and IPH CRC (as applicable), based on relevant facts/guidelines/law of the land, shall prevail. IPH CRC shall strive to protect against imposition of moral or ethical standards of the sponsoring country (ethical imperialism) which may not be in agreement with India's ethical and regulatory requirements. Researchers shall bring any such instance to the attention of the IPH CRC in case they come across any such instances during their collaboration.

3.10.7 Forbidden proposals: IPH researchers shall not accept any international proposals which cannot be conducted in the country of origin.

3.10.8 Submission to the Health Ministry's Screening Committee (HMSC): All biomedical and health research proposals involving foreign assistance and/or collaboration should be submitted to the Health Ministry's Screening Committee (HMSC) for consideration and approval before initiation. The secretariat for HMSC is located at the ICMR Headquarters, New Delhi. As per the requirements of HMSC, all research involving international collaboration – either technical, financial, laboratory or data management must be submitted to HMSC.

3.10.9 Transfer of biological material: Any research involving exchange of biological material/specimens with collaborating institution(s) outside India must sign an MTA justifying the purpose and quantity of the sample being collected and addressing issues related to confidentiality, sharing of data, joint publication policy, IPR and benefit sharing, post analysis handling of the leftover biological materials, safety norms, etc. Export of all biological materials will be covered under the existing Government of India (GOI) guidelines for transfer of human biological materials.

3.10.10 Mutual respect and collaboration agreement/MoU: The guidelines, regulations and cultural sensitivities of all countries participating in collaborative research proposals should be respected by IPH researchers. An appropriate MoU should be in place to safeguard mutual interests and ensure compliance of the above guidance.

3.11 Compliance with responsible conduct of research

All research proposals submitted to the IPH IEC shall provide details of compliance with Annex 3 and 4, whereas Annex 1 and 2 are self-assessments which are optional.

1. **Annex 1**: Compliance with ethical principles for conduct of research

2. **Annex 2:** Responsible research compliance checklist
3. **Annex 3**: Proof of research team training on ethical principles
4. **Annex 4**: Proof of having read the policies and guidance for responsible conduct of research

4.0 Reference documents

1. National ethical guidelines for Biomedical & Health Research Involving Human Subjects, 2017, ICMR
2. Good research practice & other award policies of the DBT India Alliance (site accessed June 2018)
3. On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition. Published by Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine (USA). http://biblioteca.ucv.cl/site/colecciones/manuales_u/12192.pdf
4. Singapore statement on research integrity
5. Introduction to the Responsible Conduct of Research by the US Human & Health Services Office of Research Integrity. See https://ori.hhs.gov/sites/default/files/rcrintro.pdf
6. IPH policies on human resources and finance
7. IPH IEC Standard Operating Procedures

Annex 1: Checklists for self-assessment of ethical principles in research proposals (Optional and for self-assessment)

Use the following checklist to self-assess your research with all members of your research team. If submitting this self-assessment to IEC, cross-reference page numbers/documents in your proposal so that the IPH IEC review could take this into account in their review.

No.	Principle	Reference to section in proposal (if applicable). If not, tick the box to indicate compliance with this principle
1	*Are human participants essential for this research?* **(Principle of essentiality)**	
	Is the participation of human participants voluntary? **(Principle of voluntariness)** Researchers shall respect the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time. The informed consent process should ensure that participants' rights with respect to voluntary participation are safeguarded.	
	Does the selection of participants for research equitably/fairly distribute benefits and burdens without any arbitrariness or discrimination? **(Principle of non-exploitation)** Wherever research is planned with vulnerable populations, sufficient safeguards to protect them should be ensured.	
	Is there a likelihood of the research creating/deepening social, cultural or historic	

	divisions or disturbances to community relationships? **(Principle of social responsibility)**	
	Does the research include processes to ensure privacy and confidentiality of participant information, identity and documents? **(Principle of ensuring privacy and confidentiality)** **Exceptions:** Wherever there are special circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the IPH IEC for valid scientific and/or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.	
	Is there a procedure envisioned to minimise risk and provide appropriate care and compensation in case of harm? ***(Principle of risk minimization)***	
	Is the researcher/team qualified and competent to conduct the research? **(Principle of professional competence)**	
	Does the research seek to maximise benefits to research participants and/or society, either directly or indirectly? **(Principle of maximisation of benefit)**	
	Has the research/team identified institutional arrangements for the appropriate conduct of research in line with all regulations and guidelines? Is there sufficient infrastructure, financing, research workforce and capacity building oopportunities? **(Principle of institutional arrangements)**	

	Has the research/team identified clear pathways for communicating the outputs of the research to the widest possible audience and place their results in public domain for independent validation and assessment by peers? ***(Principle of transparency and accountability)***	
	Does the researcher identify clear responsibilities for the team and all other stakeholders in the research? Do they ensure that all stakeholders are aware of their participation and role in the research? **(Principle of totality of responsibility)** All stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.	
	Are there sufficient procedures to ensure sustainable use of resources and if possible ensure protection of the environment at all stages of research? **(Principle of environmental protection and sustainability)**	

Annex 2: Self-assessment of responsible research compliance checklist

Use the following checklist to self-assess your research with all members of your research team. If submitting this self-assessment to IEC, cross-reference page numbers/documents in your proposal so that the IPH IEC review could take this into account in their review.

No.	Responsible conduct	Remarks/reference to section in proposal addressing this.
1	Mentorship	
2	Any relevant declaration with respect to Research funded by industries associated with health risks	
3	Disclosure of researchers relationship with commercial organisations	
4	Disclosures related to COI if any	
5	Whether data acquisition, management, sharing and ownership sections included? If yes, are there any deviations foreseen from the policies and guidance of IPH?	
6	Open and unrestricted access to published research In case no funding available, provide plan on how this will be accomplished	
7	Authorship plan included? Any deviations foreseen from the authorship guidance of IPH	
8	Have you read the sections related to research misconduct?	
9	Is your study a trial covered under the Drugs & Cosmetics Act? If yes, provide CTRI registration number.	

	If under category of other biomedical/health research, consider submitting to CTRI. If not, specify reason. Any other public repository where you plan to make your research protocol available	
10	Is your study a collaborative research? If yes, have you read the policies and guidance for collaborative research by ICMR and by IPH? If yes, ensure compliance with guidance. Provide MoUs/Collaboration agreements that are in line with the IPH policies **For international collaborative research studies, provide:** HMSC approval (if applicable). If not, explain. Ethics approval status of all collaborating institutions Material transfer agreements (if applicable) Authorship and publication plan Compliance with IPH guidance and policies	

Annex 3: Proof of research team training on ethical principles

All members of the research team at IPH shall undergo or provide proof of training on ethics. Such training could be a certificate of a training programme organised by a University/academic institution on the topic of ethics in health research within 12 months of the initiation of the research.

Wherever prior training is not available, it shall be mandatory for the researchers to complete any the following free online training course and provide a certificate.

Protecting Human Research Participants Online Training Course by the US National Institute of Health

https://phrp.nihtraining.com/

Annex 4: Proof of having read the policies and guidance for responsible conduct of research

Provide the following undertaking signed by all the IPH researchers listed on the proposal

I have read and understood the IPH guidance and policies with respect to responsible conduct of research and shall abide by them. I shall also ensure full compliance with ethical guidelines laid out in the IPH IEC SOP, the ICMR guidance and follow all other rules and regulations that are applicable to the conduct of my research.

Signed