

Research Governance Framework

1. Purpose and Scope

- 1.1. This research governance framework (RGF) sets out the principles of good governance for all research activities supported by Sightsavers. It outlines how research should be designed and undertaken to ensure compliance with national and international guidelines; protect the rights, dignity, safety and wellbeing of all those that participate in research; and promote effective dissemination and use of research findings.
- 1.2. The RGF is applicable to all staff and partners, who host, conduct, participate in, fund and manage research for and on behalf of Sightsavers both in the UK and overseas.
- 1.3. The RGF is applicable to stand alone research projects and to the studies integrated within programmes. The RGF covers the whole of the research cycle from concept development and literature review, through ethics clearance and implementation, to dissemination and publication of results.
- 1.4. The RGF is complementary to and should be implemented alongside the Programme Implementation Manual (PIM); the Quality Standards Manual; and other Sightsavers' policies and guidance.

2. Design and Implementation of research

- 2.1. Research funded and undertaken by Sightsavers aims to provide a sound evidence base to support demonstrable, scalable, cost-effective programmes and advocacy in health, education and social inclusion.
- 2.2. All Sightsavers' research should
 - address a clearly defined question or problem;
 - adhere to a pre-defined study protocol;
 - receive ethics clearance from appropriate review bodies prior to the commencement of data collection, where appropriate;
 - apply systematic methods and validated tools, where they exist;
 - use internationally accepted principles and procedures; and
 - exhibit critical and careful judgement in the interpretation of findings.

- 2.3. Research should only be undertaken where there is a clear gap in knowledge. Existing literature, especially systematic reviews, should be considered to avoid unnecessary duplication.
- 2.4. The concept of a research project should be written using a Research concept template (available on IRIS). Once approved a full research proposal will be developed. All research proposals approved for funding should have a study protocol, which will outline background, research aims, objectives and questions, study design, methods and tools for data collection and analysis. All studies should have a Principal Instigator (PI), who will take responsibility for the delivery and quality of research.
- 2.5. The Sightsavers research team should be consulted at the conceptual stage for all integrated and standalone research; the team can support Country Offices and their partners in the development of study protocols and facilitation of academic collaborations.
- 2.6. Proposals and protocols should be subject to independent scientific review on their quality and relevance. All study protocols, research tools and data analysis plans should be agreed with the Sightsavers research team and be stored in a central location for a wider use across the organisation. All anonymised data sets (e.g. survey data files; transcripts) should be passed to the Sightsavers research team in an agreed format and stored in a central location.
- 2.7. Research must only be undertaken by appropriately qualified staff; this may be through academic collaborations, independent consultants or the involvement of Sightsavers' research advisors. Researchers involved in Sightsavers' studies are expected to work collaboratively with the Sightsavers' research team, relevant Programme Development Advisers (PDAs) and Country offices and to ensure that Sightsavers' programme staff understand the purpose and process of research and how it can contribute to more effective policies and programmes.
- 2.8. To ensure a high quality research, those involved in research with Sightsavers must at all times demonstrate the following:
 - honesty and integrity;
 - regard for the safety and well-being of others;
 - respect for diversity;
 - openness; and
 - clear and supportive management.

- 2.9. Wherever relevant and practical, service users, community stakeholders and practitioners will have the opportunity to participate in the design, implementation, analysis and reporting. Consideration to how barriers to participation can be removed accounting for cultural differences, local behaviour and norms, religious beliefs and practices, gender roles and disability should be given during planning studies and communicating findings.
- 2.10. Research findings must be open to critical review by scientific and professional channels, any arrangements for peer review should be proportionate to the scale of the research and the risks involved.

3. Collaborations and partnerships

- 3.1. A formal written agreement should be in place for all collaborative research projects that clearly specifies the responsibilities of each party involved in the project. This should consider matters such as intellectual property, confidentiality, data management, responsibility for ethical approval and reporting obligations. All research agreements should be approved by the Sightsavers' research team and the Sightsavers' legal adviser.
- 3.2. Where relevant, the ownership of data and tools created in the course of the research must be agreed with partners at the beginning of the research programme. This agreement will also include procedures for retention, access, copy and retrieval of data for programming and other non-commercial reasons.
- 3.3. It is likely that other agencies and institutions Sightsavers collaborating with will have their own research governance framework and code of practice. Sightsavers would always expect both frameworks to be followed. Any difference should be resolved at the proposal stage.
- 3.4. Sightsavers is committed to working towards more equitable partnerships. This includes developing the organisational capacity of partners to undertake, understand and use research. Opportunities for this and skills transfer or training should be considered and included in the design wherever possible.

4. Ethics

- 4.1. Whenever research involves human subjects, their organs, tissue or data, the study protocol should be reviewed independently to ensure ethical standards are met. An appropriate ethical clearance must be sought and received before

the commencement of data collection, including piloting. The approval should be sought from national or local bodies with formal ethical approval systems in the country in which the research is undertaken. In addition, there may be requirements for ethical approval from collaborating institutions in the UK or elsewhere.

- 4.2. Participation in research should always be voluntary and free from external pressure, whether this be direct participation in research activities or indirect through the provision of personal data or human tissue and organs. Appropriate arrangements must be in place for obtaining informed consent from participants. Any information that may affect a prospective participant's willingness to participate should not be withheld. Additional authorisation and approvals may be required for information sourced through secondary data sets such as databases or registries.
- 4.3. All participants should have the right to withdraw from research and withdraw any data concerning them at any point without fear of penalty.
- 4.4. Extra care is needed when seeking consent from children and vulnerable adults such as those with mental health problems, learning difficulties or disability. Arrangements must be made to ensure that relevant information is provided in an accessible and appropriate form and that the role of parents, carers, or supporters is clearly understood.
- 4.5. Confidentiality of personal information and the anonymity and privacy of study participants must be maintained. Circumstances or requirements that may limit this obligation should be communicated to prospective participants.
- 4.6. Where at all possible Sightsavers will avoid undertaking any research that may require the use of animals. In instances where there are no alternatives, research requiring the use of animals will only be done in collaboration with institutions that are appropriately licensed and rigorously respect all animal research protocols.
- 4.7. For all clinical trials and surveys involving human subjects and requiring clinical interventions including trial of medicines, the research protocol must comply with the ethical principles outlined in the World Medical Association Declaration of Helsinki and with any other international and European Union guidelines applicable. All study participants requiring medical treatment must be referred to treatment services.
- 4.8. Additional guidance and input for all studies involving humans can be sought from the relevant PDAs and research advisors.

5. Health and safety

- 5.1. Safety of participants, research and other staff must be the priority at all times. Sightsavers Health and Safety and Travel and Security policies must be strictly observed in all research projects.

6. Data management and Records

- 6.1. Research data must be retained intact for an agreed period of time; the data should be stored securely at all times (e.g. in a locked storage facilities and password protected computers).
- 6.2. Data should be fully anonymised prior to depositing in data storage facilities. This process should include removing all personal identifiers (name, initials, date of birth, post code etc.) as well as removing other types of identifiers where it may be possible to identify a participant, e.g. very rare diagnosis, name of organisation. Where there are differences between the Data Protection policies of donors/collaborating organisations and Sightsavers, both must be adhered to.
- 6.3. Electronic data should be stored on computer systems which are properly housed and managed, and backed up to protect against system failure or accidental deletion of files.

7. Dissemination and Use of information

- 7.1. We conduct research for the benefit of service users; professionals; and the public and one of the key objectives of Sightsavers research is to contribute to global knowledge and evidence-based policy-making. We aim to disseminate our research findings - positive or negative – as widely as possible and through a variety of formats, including peer-reviewed publications; scientific conferences; professional networking; and advocacy tools.
- 7.2. The methods, timings and costs of research dissemination should be included in the initial proposal. Any potential delays due to matters of intellectual property rights and/or commercial in confidence should be taken into account.
- 7.3. Results should be shared in a format and language understandable and accessible to all participants, partners and countries in which Sightsavers works. Accessibility of findings to people with visual impairments and other disabilities should be considered.

- 7.4. Country Offices in consultation with PDAs and other staff are expected to organise internal review and discussions on how findings, both positive and negative, may be integrated into Sightsavers programmes and advocacy work; A variety of national and local fora should be used for dissemination of Sightsavers' publications and study reports to local stakeholders.
- 7.5. Sightsavers access to data policy is guided by the requirements of donors contributing to each specific research. For example, for projects supported by the donors practicing Research Open and Enhanced Access Policy, there will be free access to anonymised data sets within an agreed period of time from the end of the project
- 7.6. Where Sightsavers has supported research studies, either through the provision of funding or access to data, it requires this to be recognised and where appropriate to share intellectual property rights. Acknowledgement of Sightsavers contributions in printed and online sources should adhere to Sightsavers' Brand Guidelines where possible.
- 7.7. Authorship in peer-reviewed publications will be credited to those partners and individuals who have made a substantial intellectual contribution to the study conception, design, analysis and interpretation of data, in addition to participating in the drafting, reviewing and/or revising of an article for intellectual content. Individuals who have contributed but do not meet these criteria will be listed in the acknowledgements.
- 7.8. A list of expected peer-reviewed publications, the lead author and the co-authors for each paper should be agreed in the beginning of the project. The lead author assumes overall responsibility for the manuscript; serves as the managerial and corresponding author; and provides a significant contribution to the project and writing up.
- 7.9. Research findings, positive or negative, as well as information about dissemination should be widely circulated across the organisation and be available via Sightsavers information and learning systems (IRIS, webpages, Newsletters).

8. Finance and Procurement

- 8.1. Purchasing and expenditure of funds should take place in accordance with the terms and conditions of any grant or contract held for the research and Sightsavers own procurement policy and standard financial operating procedures and policies.

9. Conflicts of interest

- 9.1. Conflicts of interest can be defined as conditions where professional judgement concerning a primary interest, for example academic knowledge may be unduly influenced by a secondary interest, for example financial gain. Conflicts of interest can include financial, academic, personal, political, religious, legal, ethical, moral or other interests.
- 9.2. Researchers must fully disclose any actual or potential conflicts of interest in particular, managers, supervisors, funding bodies and publishers. Steps must be taken to resolve the conflict of interest where possible. A record must be retained of all actual or potential conflicts of interest and any actions taken to resolve the conflicts.

10. Research misconduct and responding to allegations and complaints of misconduct

- 10.1. Misconduct in research may involve fabrication, falsification, misrepresentation of data and/or interests and/or involvement, plagiarism and failure to exercise a duty of care in following protocols.
- 10.2. All staff have a responsibility to report any suspected cases of research misconduct.
- 10.3. Misconduct in research may provide grounds for disciplinary action, and possibly dismissal.