MARIE STOPES INTERNATIONAL
Children by choice, not chance

Upholding ethical standards in MSI research

Annual report for the MSI Ethics Review Committee 2014

Contents

Lists of acronyms

ERC	Ethics Review Committee
FWA	Federal Wide Assurance
GRN	Global Research Network
IRB	Institutional Review Board
LSHTM	London School of Hygiene and Tropical Medicine
MSI	Marie Stopes International
NGO	Non-governmental organisation
PEER	Participatory Ethnographic Evaluation Research
RME	Research, monitoring and evaluation

For citation purposes: MSI Ethics Review Committee. Annual report of the MSI Ethics Review Committee, 2014. London: Marie Stopes International, 2015.

1. Foreword

Marika McAdam,
Co-Chair MSI ERC

Isolde Birdthistle,
Co-Chair MSI ERC

2014 was a productive year for the Marie Stopes International (MSI) Ethics Review Committee (ERC). In addition to reviewing 27 protocols for studies in 13 host countries, the ERC worked closely with MSI to develop 'global goods' to strengthen the design of research protocols across MSI's global research network (GRN).

This annual report takes stock of our achievements and lessons learned in 2014. At the outset, it highlights key metrics that track progress of the ERC by quarter and year. It showcases the spectrum of countries that submitted research protocols for review, including the Democratic Republic of Congo (DRC), Myanmar and Papua New Guinea which submitted protocols for the first time.

This report aims to offer researchers and programmatic staff across MSI an insight into the work we do including and beyond protocol review. We also offer this report to the members of the ERC, to illustrate how their contributions feed into the bigger picture of what we do, and enable critical reflection of our work. In accordance with our commitment to learn from challenges and share lessons for the benefit of others, we also offer this report to our external partners in the research ethics community.

In 2014, the ERC had several opportunities to engage with MSI beyond protocol review. We created working groups comprised of both ERC members and members of MSI's GRN to develop guidance on research involving minors, which we launched at a webinar in October. We also drafted Community Engagement Guidelines to help strengthen MSI's engagement with host communities before, during and after research studies. We also created a global template for mystery client study protocols, to avoid the need for review of studies that follow the global protocol without deviation.

We used the year to enhance engagement with partners beyond MSI. In this respect, a highlight of 2014 was our presence at the Public Research in Medicine and Research's 'Advancing Ethical Research Conference' in Baltimore in December, where we presented two posters. We also started a collaboration with the Ethical Review Committee of Kenya Medical Research Institute (KEMRI) to prepare a joint manuscript on dual ethical approval requirements, reflecting the experiences of both an international and a national ethics committee.

We are proud of the support we have given to MSI in the design and review of important yet often sensitive research studies on sexual and reproductive health in low and middle-income countries. We appreciate MSI's sustained commitment to responsible research and the protection of research participants. We look forward to continued collaboration with Research, Monitoring and Evaluation (RME) staff in London and globally, as well as the International Operations Department in strengthening research ethics across the organisation.

Marika McAdam, Co-Chair, MSI ERC
Isolde Birdthistle, Co-Chair, MSI ERC

1.1 MSI note

Barbara Reichwein,
Head of Global
Research, Monitoring
& Evaluation

Olivia Nuccio, MSI
Ethics Lead

At MSI, we keep the client at the centre of everything we do. Producing high-quality evidence is crucial to delivering excellent services, one woman at a time. The MSI ERC is a pillar of quality assurance and expert advice which guarantees that our programming is informed only by the highest quality, ethically sound research and evidence.

The ERC had a great year in 2014. The committee reviewed protocols swiftly, which is important to a fast-paced organisation with a focus on service delivery. The committee made important improvements to research protocols and produced global goods that will guide MSI research excellence for years to come, thus building capacity and contributing to an institutionalisation of research ethics across organisation.

Looking ahead, we have big plans for continuing to strive for cutting edge research and the ERC plays a critical role in this. In 2015, we have commissioned an independent case study of the ERC, with the objective of assessing its achievements, capturing lessons learned, and informing our future MSI and ERC collaborations. Further, we will explore ethical considerations around the analysis of routine data and continue to benefit from ERC support in implementing an exciting, client-focussed research agenda.

We thank the committee and each of its members for their support and personal commitment to the clients we serve. We wish you a successful year.

Barbara Reichwein, Head of Global Research, Monitoring & Evaluation
Olivia Nuccio, MSI Ethics Lead

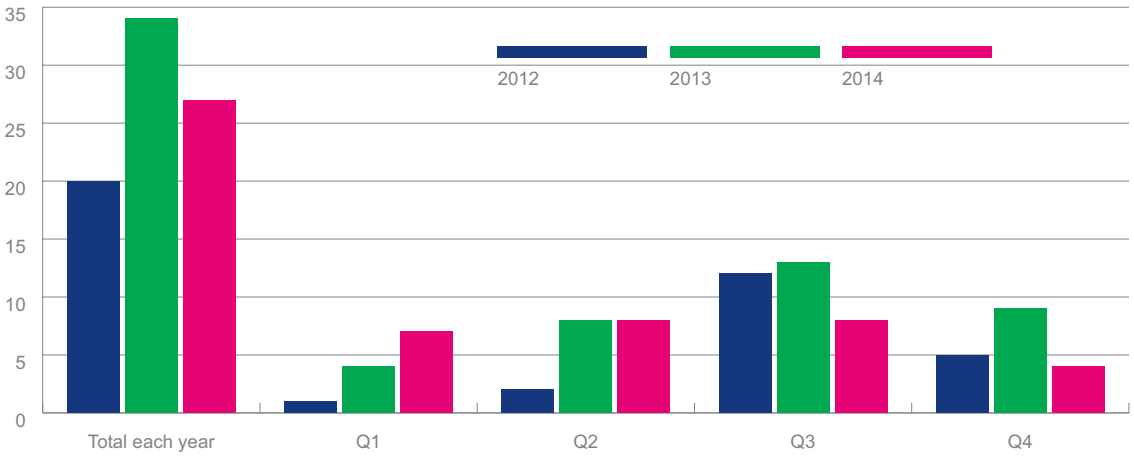
2. Protocols reviewed in 2014

Submissions by year and quarter

The ERC reviewed 27 research protocols in 2014 for research or evaluation activities, a decline from 34 submissions by MSI in the previous year (Figure 1).

Unlike previous years, which saw a surge in submissions in the third quarter, the number of submissions in 2014 was steady across the first three quarters, with relatively fewer in the fourth quarter.

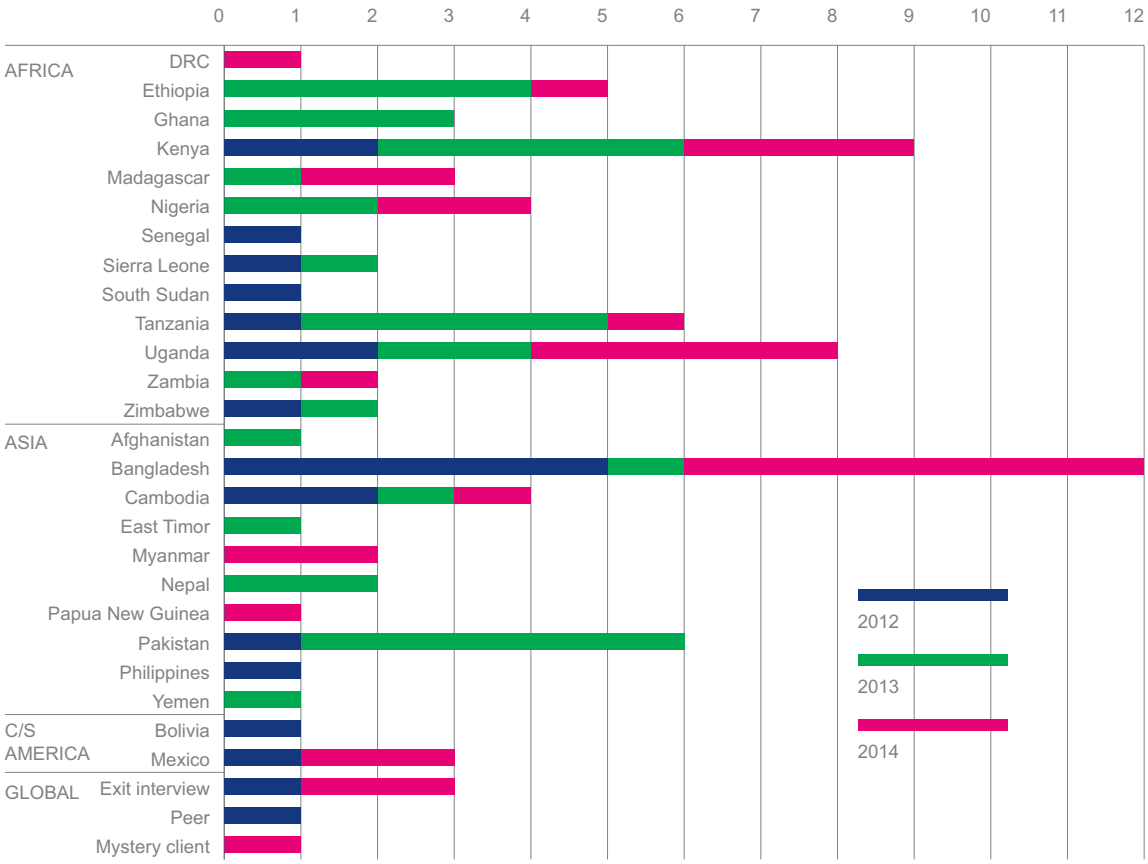
Figure 1
Number of research protocols submitted to the ERC by year and quarter



Submissions by country and region

Figure 2 lists the host countries for proposed research in 2012-2014. In 2014, the ERC received protocols for studies in 13 different countries: eight countries in Africa; four in Asia; and one in Central/South America. Protocols were submitted for the first time for research taking place in the DRC, Myanmar and Papua New Guinea. One protocol was for a multi-country study in three host countries: Kenya, Tanzania and Uganda. To date, the host country with the most submitted protocols is Bangladesh, with 12 submissions over three years, followed by Kenya with nine and Uganda with eight.

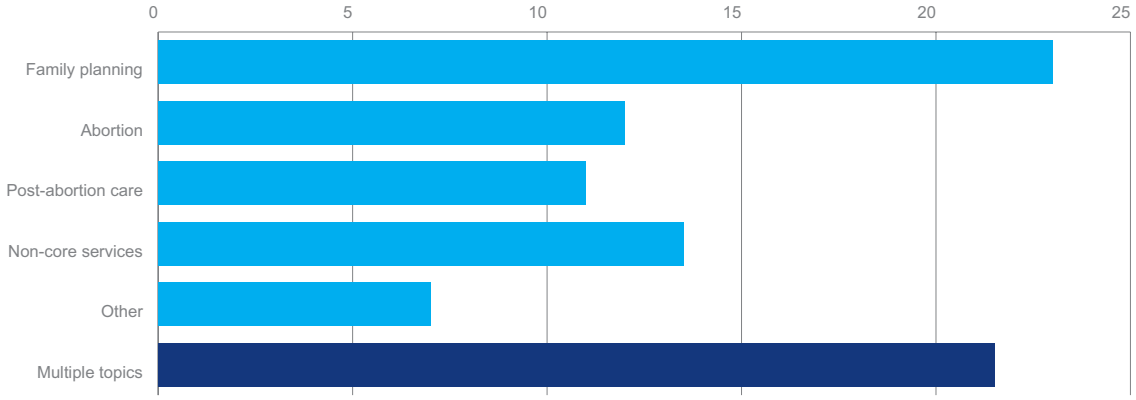
Figure 2
Number of research protocols submitted to the ERC by host country and region (2012-2014)



Submissions by topic and setting

Figures 3 and 4 show the topics and study settings for the protocols submitted in 2014. Studies were most often designed to take place within MSI clinics followed by mobile outreach units, and to address questions around family planning, followed by abortion and post-abortion care. It was common for protocols to address multiple topics and to be conducted in different study settings within the same study.

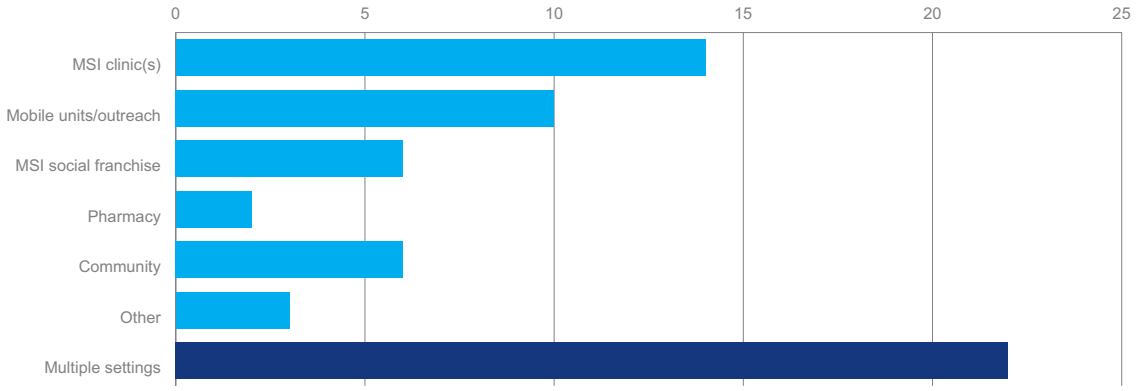
Figure 3
Research topics for protocols submitted to the ERC in 2014



Other:

- HIV/SRH integration (4)
- Stigma/discrimination (2)
- Call centres (1)

Figure 4
Study settings for protocols submitted to the ERC in 2014



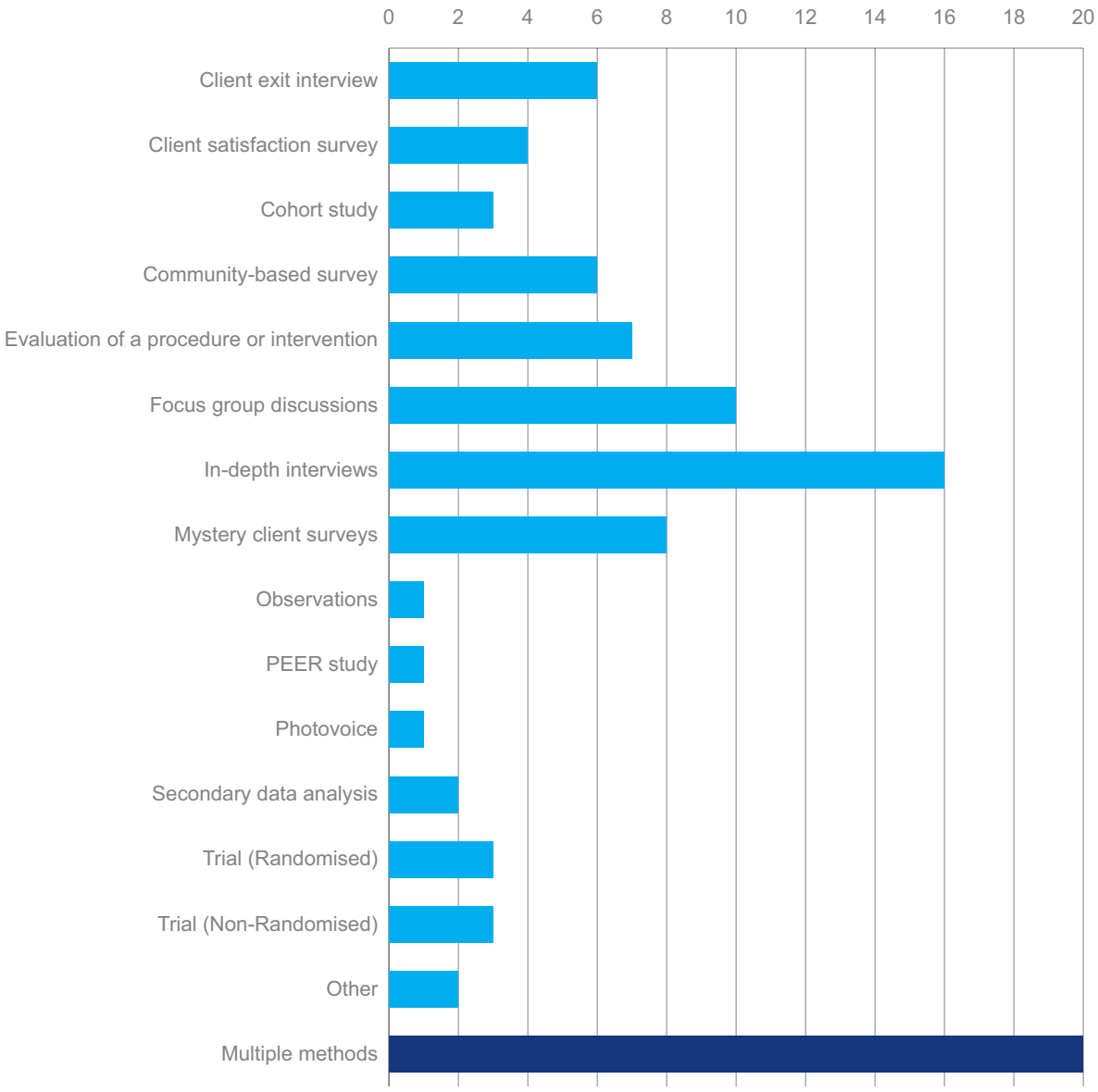
Other:

- Non-MSI channels (2)
- Telephone / Call centre (2)
- Public sector clinics (1)
- Other NGO clinics (1)

Submissions by study design

It was also common for protocols to combine a mix of research methodologies, as shown in Figure 5. Qualitative research methods were most often proposed, particularly in-depth interviews and focus group discussions. Mystery client surveys and client exit interviews were also popular methodologies, while cohort studies and trials were less often proposed.

Figure 5
Research methodologies for protocols submitted to the ERC in 2014



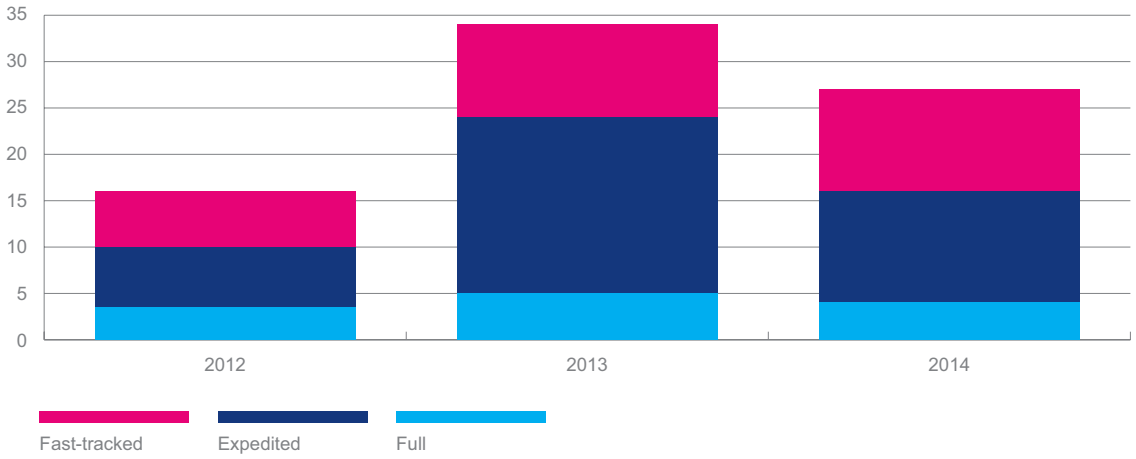
Types of review conducted by the ERC

As shown in Figure 6, the 27 reviews conducted in 2014 were of the following types:

- 11 reviews were fast tracked because the protocol was an amendment of a previously approved protocol and/or had already received approval from another international ethics body (most often Population Council followed by LSHTM.
- 12 were expedited reviews because the studies were considered to carry no more than minimal risk of harm to participants, as defined in the ERC's Terms of Reference.
- Four were full reviews because the studies were considered to involve greater than minimal risk of harm to participants.

The number of protocols submitted as amendments (seven) was much higher than in previous years. By comparison, no amendments were submitted in 2012 and only one was submitted in 2013. We also received one request for IRB exemption in 2014, which we could not grant as the research was determined to have already started (and ethics review cannot be conducted retrospectively). No submissions were made for continuing review, i.e. for studies continuing beyond the 12 months of original ethics approval.

Figure 6
Type of ethics reviews conducted by the ERC by year



3. Key changes in 2014

"As noted above, the MSI ERC received a lower number of study protocols for review in 2014 compared to 2013. Anecdotal investigations revealed that one of the main reasons behind this was due to the surge of submissions at the end of 2013 (n=22 in quarters 3 and 4), which resulted in a significant number of studies being implemented in 2014. Due to the volume of studies implemented, analysed and disseminated in 2014, less time was left to design new study protocols."

MSI Ethics Lead

MSI and ERC staff changes

At the beginning of the year we invited ERC members to renew their commitment to the ERC and its work in 2014. This measure was in response to difficulties we had encountered recruiting an adequate number of reviewers in the busiest periods and the resulting uneven distribution of the workload between members. Existing ERC members were invited to commit to review a minimum of four protocols annually and to consider being involved in other non-review work on an ad-hoc basis, including working groups to produce global goods. All but one ERC member renewed commitment to the work of the committee, reducing our number from 11 to 10 voting members.

Our year started with some MSI staff changes of major significance to the committee. In May, our MSI ERC Ethics Coordinator Monika Milinauskyte accepted another opportunity at MSI, and Shefali Shah took on the role of MSI ERC Ethics Coordinator on a part-time basis, alongside her work as RME Communications Officer. In September, Thoai Ngo left MSI and his role as the Head of Global Research. Subsequently, Barbara Reichwein has been appointed as the Head of Global Research, Monitoring and Evaluation. MSI worked hard to ensure that all these staff transitions were seamless for the continued functioning of the ERC, and we are very grateful for the enthusiasm and energy that Shefali and Barbara have brought to MSI's work with the ERC.

Changes to procedure

After a decision by the committee to trial 'real time' meetings with a quorum of members for all full reviews, the ERC held its first such meeting on 3rd June, with some members participating from the London office in person, and others joining from various countries and time zones via Skype. The meeting proved a valuable learning experience, raising key considerations on how we can make meetings efficient and productive without sacrificing depth and detail. In the subsequent bi-annual meeting of the ERC, the decision was taken to continue conducting full reviews in this way, and to revise the MSI ERC Terms of Reference accordingly in 2015.

4. Emerging issues

In 2014, the question arose as to what constitutes an MSI clinical trial, and what the ethical implications are of a given RME activity being considered a clinical trial. In anticipation of ethical issues arising in this context, ERC offered a discussion note to MSI, to explain international definitions of 'clinical trials' and to direct RME staff to relevant international guidance and other resources. The discussion note outlined a series of questions to assist MSI in approaching its clinical trial work, including:

- What is the MSI definition or understanding of 'clinical trial'?
- Do some MSI 'evaluations' meet this definition, whether clinic-based or not?
- What MSI policies or guidance is in place to govern trials?
- What common themes before, during and after MSI trials emerge in terms of:
  - Random allocation of an intervention / service
  - Control group protection
  - Participant selection and recruitment
  - Community participation
  - Adverse events
- Post-research access to treatment, care or behavioural interventions.
- What ethical principles ensure that human subjects are protected in MSI trials?
- Are the MSI ERC's review considerations adequate to address the ethical issues that may arise in MSI trials?

As an interim measure and basis for further discussion, the ERC proposed the following ethical safeguards to MSI in the conduct of trials.

1. Check that proposed trial adheres to Good Clinical Practice standards.
2. Register the study with a trials registry and results database e.g. ClinicalTrials.gov of the US National Institutes of Health[1].
3. Check the study adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement checklist (for randomized designs) or the Transparent Reporting of Non-Randomized Designs (TREND) checklist for non-randomized designs.[2]
4. Establish an external monitoring body and mechanism to ensure a process for stopping trials in the event of Adverse Events or safety concerns.
5. Ensure the appropriate standard of care for the 'control' group.[3]
6. Address post-trial access to care.

[1]Also see the WHO International Clinical Trials Registry Platform: http://www.who.int/ictrp/en/

[2]CONSORT: Consolidated Standard of Reporting Trials http://www.consort-statement.org items / http://www.cdc.gov/trendstatement/ The Consort Statement contains a checklist of 25 items that must be reported as well as a flow diagram. TREND: Transparent Reporting of Evaluations with Nonrandomised Designs http://www.cdc.gov/trendstatement/

[3]See for instance, pp.7 and 89 of the Nuffield Report

5. Global goods

Ethics guidance for RME activities involving minors

Because young people are at the greatest risk of morbidity and mortality due to unplanned pregnancy, they are a priority group for MSI. This is reflected by their inclusion into high-impact CYPs, a key MSI performance metric, and MSI's growing body of programming and RME activities focused on youth. To support MSI in ensuring that study protocols involving minors are developed in accordance with best ethical practice, the ERC prepared Ethics Guidance for RME activities involving minors.[4]

Draft guidance was prepared by the ERC co-chairs and disseminated to MSI staff and ERC members prior to the ERC bi-annual meeting in April, where several excellent suggestions were made during the closed meeting for further revision. The guidance was disseminated in August and September, and launched with a webinar held on 1st October. The webinar was well attended by approximately 20 participants across seven MSI country programmes as well as the London office.

The guidance specifies the special considerations the MSI ERC gives to protocols involving minors, above and beyond the guiding questions on the Ethics Review Form, which applies to all protocols. The document stresses that any protocol involving minors should clearly explain how risks posed to minors are outweighed by benefits, and take a 'do no harm' approach that puts the best interests of the young person first. A table is also offered in the guidance, setting out how those principles can be fulfilled in practice, with illustrative examples from MSI and other research projects.

Ethics guidelines on community engagement

In general, protocols submitted to the ERC in the three years of its operation have lacked adequate information on engagement with communities and stakeholders in the study settings. Additionally, the ERC itself was not entirely clear on its requirements in respect of community engagement in the design and implementation of research, monitoring and evaluation activities. In response, the ERC prepared Ethics Guidelines on Community Engagement.

A working group was established to develop Ethics Guidelines on Community Engagement, comprised of ERC members and MSI staff (from both RME and Operations teams). Led by a member of the ERC, the working group commenced its work in mid-April. Following input of the working group members, draft guidelines were discussed and adopted with minor changes by the ERC at the bi-annual meeting in November.

The Community Engagement Guidelines offer MSI research staff guidance in increasing community participation in designing and conducting research, monitoring and evaluation activities. Specifically, the guidelines explain what community engagement is, and why it is important and how it can be done, with practical examples also offered. Finally, a list of additional tools and recommended reading has also been included for further information.

Mystery Client Study Global Protocol template

Owing to the high number of mystery client surveys conducted by MSI, and the correspondent high volume of mystery client protocols submitted to the ERC, the ERC provided guidance in 2013 on how to ensure that mystery client surveys maximise protection of the people who pose as mystery clients and the providers who are observed. In 2014, MSI and the ERC took this effort further by developing a global protocol template for MSI mystery client surveys. Accompanying the global protocol is a 'deviation checklist', which prompts researchers to indicate if and how their mystery client survey differs from the global protocol.

The global protocol and deviation checklist were reviewed in detail by a quorum of ERC members, and approved in November 2014, with those involved in its authorship ineligible to vote. Any new MSI mystery client survey that adheres to the global template without deviation is considered approved by the ERC (provided that local ethics review is exempt or granted).

Deviations from the protocol can have ethical implications (meaning that the balance of harm and benefits may change), in which case an application for ethics review must be submitted to the ERC as an amendment to the global protocol, with deviations highlighted.

Lessons learnt from MSI ERC working groups

To strengthen ownership of global goods across organisation, three joint working groups were created, comprised of members of the MSI ERC as well as staff from MSI Research and Operations teams. The substantive objective of the joint working groups was to develop tools grounded in the realities of MSI's work, including an Ethics e-Learning Module, Ethics Guidelines on Community Engagement and a Global Protocol for Mystery Client Studies. The practical objective was to promote institutional buy-in by strengthening collaboration between the ERC and MSI.

Working groups provided a vehicle for collaboration to create high-quality global goods that team members across the organisation can access to improve the quality of their work. However, there were many challenges associated with the working group process in 2014; none were as participatory as envisaged at their inception; challenges in appointing and empowering leads, and discussions about working group composition resulted in significant delays. Work was not equally distributed between members, resulting in select individuals assuming responsibility for producing substantive content. Nevertheless, the opportunity to comment on drafts led to an acceptance of the final products and a sense of shared ownership.

On the basis of these experiences, working groups will not be established in the future. Instead, the responsibility for substantive drafting will be allocated to one or two ERC members only, with working groups reconceived as 'review groups' and representatives encouraged to comment on drafts and encourage the uptake and use of final products.

6. Impact and benefit of ERC for MSI and beyond

How did the MSI ERC add value beyond MSI?

The following examples illustrate the value added by the MSI ERC to the global research ethics community in 2014.

- Other non-governmental organisations requested the ERC to **share its experience** and conduct **reviews of their research protocols**. The MSI ERC discussed and decided against reviewing non-MSI protocols, or sharing the ERC at this stage e.g. via a co-funding arrangement, but the ERC Co-Chairs informally offered support and advice to these organisations.
- Two of the three posters that the MSI ERC submitted for presentation at the Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research Conference were accepted. In December, Co-Chair Isolde Birdthistle travelled to Baltimore to represent the MSI ERC at the conference and **presented two posters**. One poster was titled "Upholding the ideal of 'dual approval' for externally-sponsored research: a reality check" and the other was titled "Strengthening NGO and IRB cooperation through the establishment of joint working groups on ethical issues."
- In 2014, the ERC Co-Chairs commenced work on two research **manuscripts** on the ethics of mystery client studies in service provision research, and secondly on multiple ethics approval requirements of externally-sponsored studies. The latter manuscript is being drafted in cooperation with the ethics committee of the KEMRI.

[4]Referring to people below the age of majority which is generally 18 but can vary in jurisdictions.

7. Plans for the future

Key issues raised at the ERC bi-annual meetings in 2014 directly determined priorities going forward. These include the following:

- The need to revise our **Terms of Reference** to reflect changes made to our operating procedures, particularly with regards to full review procedures and other areas relevant to FWA compliance.
- The need to strengthen our approach to **continuing review** and monitoring of approved RME activities, in accordance with regulatory compliance.
- Understanding what it means to be an **independent** ethics committee: independent from the researcher and the sponsor (Marie Stopes International in both cases) and avoid conflict of interest (as per paragraph 23 of the Helsinki Declaration).
- **Learning from researchers** in the GRN. The ERC Chairs drafted an online survey for members of MSI's GRN, to capture their experiences engaging with the ERC and other ethics review committees, with a view to learning from and strengthening the work we do and the support we give to MSI. MSI was concerned about the workload of GRN members, so we look forward to issuing the survey at a more optimal time.

In addition to leading ethics reviews and working with MSI to strengthen ethical approaches across the organisation, in 2015 the ERC Co-Chairs will work to:

- **Recruit** additional members into the committee.
- Create a **handbook** that draws together all relevant processes, forms, guidelines and other documentation for MSI applicants for ethics review as well as ERC reviewers.
- Publish **journal articles** that share the experiences of the ERC for the benefit of the wider ethical community.

Further resources

- MSI Ethics Review Committee Terms of Reference (MSI, 2012)
- MSI ERC Guidance for RME Activities with Minors (October 2014)
- MSI Ethics Guidance for Community Engagement in RME activities (November 2014)
- Mystery Client Global Template (November 2014)
- MSI Ethics Review Committee brief (one page)

Acknowledgements

With thanks to the Ethics Review Committee Members who served in 2014: Dr Jean Amoura (OB/GYN, MSc), Dr Fabian Cataldo (MA, MRes, PhD), Gillian Elam (BSc, MSc), Dr Nigel Field (MB, PhD), Kimberley Green (MSc, PhD), Dr Sue Mann (MBChB, MSc), Karen Newman (BA), Dr Clare Tanton (MSc, PhD).

And special thanks to the Ethics Coordinator, Shefali Shah and MSI Ethics Lead, Olivia Nuccio.

For more information, please visit:
http://www.mariestopes.org/data-research/ethics-review-committee

Contact us at:
ethics@mariestopes.org

Marie Stopes International
1 Conway Street
Fitzroy Square
London W1T 6LP
United Kingdom

T +44 (0)20 7636 6200
F +44 (0)20 7034 2369

info@mariestopes.org
www.mariestopes.org

Registered Charity No.
265543

Registered Office
1 Conway Street
Fitzroy Square
London W1T6LP
United Kingdom

Company No.
1102208

Population Council
One Dag
Hammarskjold
Plaza, 9th Floor
New York,
NY 10017, USA
T +1 212 339 0500