MSI Ethics Checklist:

Which research, monitoring and evaluation (RME) protocols do NOT need review by the MSI Ethics Review Committee?

April 2013

Marie Stopes International country programmes conduct a wide variety of activities which generate data about and from their clients. Some of these activities **monitor** projects and collect routine data; some of the activities are **research** projects that generate specific types of unique data.

The checklists below are offered to researchers and RME Advisors to help determine whether activities are 'monitoring' that in most cases do not need ethics approval, or 'research' that must be submitted to the MSI Ethics Review Committee (ERC) for review.

Table 1 - Is the RME activity planned…'monitoring'?

Is the planned RME activity…

Continuous?	☐
Tracking progress of a project/programme against pre-determined indicators?	☐
Focussing mostly on inputs or service statistics?	☐
Collecting routine data?	☐
An internal management exercise?	☐
Conducted in order to improve performance?	☐
Likely to involve no more than minimal risk of harm to participants? *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (by Common Rule)*	☐

If you checked all of these boxes, then your RME activity is considered a **'monitoring'** activity and does not need to be submitted to the MSI ERC. Otherwise, please continue to Table 2, overleaf. Also see Page 2 if you are planning a mystery client study.

Table 2 – Is the RME activity planned…'research'?

Is the planned RME activity…

Periodic/at end of a time period?	☐
Exploratory?	☐
Measuring changes in outcomes, such as changes in behaviour, knowledge or attitudes?	☐
Requiring data collection beyond routinely collected data?	☐
Focussing on the 'why' and 'how'?	☐
Including objectives of promoting accountability, informed decision-making and learning?	☐

If more boxes were checked in Table 2 than in Table 1, it is safe to assume that your RME activity is considered **'research'** and will need to be submitted for ethics review to the MSI ERC.

Refer to this checklist for each new, planned RME activity in your work plan, and discuss with your MSI RME Advisor whether or not you need to submit your protocol for review. If it is still unclear whether your RME activity requires review after discussion with your MSI RME Advisor, they can send an inquiry to the MSI ERC to get their advice. If it is deemed that ethics review is not required, the ERC can provide a letter confirming this decision.

Specific guidance in the case of Mystery Client studies

Should I submit a Mystery Client protocol for ethics review…?

No *if* MSI employment contracts (in the study setting) explicitly state that staff will be subject to clinical audits, then the use of mystery clients in routine quality of care audit purposes within MSI clinics is acceptable and does not need ethics review.

Yes *if* mystery clients are used in MSI settings that do not have routine audits specified in their employment contracts *or* where they are used outside MSI clinics *or* for non-routine purposes (i.e. to answer a research question or test a hypothesis), then ethics approval should be sought.

For any further questions on this checklist or the policies/processes of the MSI ERC, please contact the MSI Ethics Lead, Cristin Gordon-Maclean (cristin.gordon-maclean@mariestopes.org).

References

Research, Monitoring and Evaluation Team, Evidence and Innovation, Health Systems Department. M&E Manual, Version 2: Strengthening M&E across the MSI partnership. London: Marie Stopes International, 2013.