Roles and responsibilities of a Medical Research Ethics Committee (MREC):

A qualitative study investigating views and experiences of committee members

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Conflict of interest statement

Benjamin Drukarch is a member of the MREC of the VU University Medical Center (VUmc) since 2013. All other members of the research team declare no (potential) conflict of interest.

The project forms part of the research program “Quality of Care” of the EMGO+ institute, VUmc, Amsterdam and has been approved by the MREC of the VUmc.
Features of research integrity

- Research integrity is about “the performance of research to the highest standards of professionalism and rigour, in an ethically robust manner”

- Research integrity is vital because it creates trust, which is at the heart of the research process. Researchers “must also be trusted by society since they provide scientific expertise that may impact people’s lives”

(Briefing Paper Research Integrity, Science Europe, December 2015, www.scienceeurope.org)
MREC’s contribute vitally to the integrity of the process of medical research with humans (at least) at two levels:

1) guardians of ethical quality (explicit task, before and during study)

2) guardians of research quality (implicit task, primarily before study)
MREC’s and research integrity (I): guardians of ethical quality

In The Netherlands:

1) Medical scientific research with human subjects is governed primarily by a law known as the WMO (Ministry of Health, 2002; Dutch abbreviation)

2) Protection of rights, safety and well being of research participants is the primary task of MREC’s, as defined in the WMO

3) MREC’s, as a result, judge medical research proposals foremostly by weighing (potential) benefits against (potential) risks of human participation, in addition to pertinent aspects of participant autonomy and information
MREC’s and research integrity (II): guardians of research quality

In The Netherlands, MREC’s foster medical research quality by:

1) Judging scientific and methodological validity of proposed study

2) Providing feedback to investigators to enhance their methodological and ethical expertise
MREC’s and research integrity (III): literature

Discussion of the role and responsibilities of MREC’s as guardians of ethical and research quality abounds in literature (e.g. J.P. de Jong et al., 2012 (Sociol. of Health & Illness); E. Garrard and A. Dawson, 2005 (J. Med. Ethics); M. Guillemin et al., 2012 (J. Empir. Res. Human Res. Ethics); D. Hunter, 2007 (J. Med. Ethics))

However

Only very limited information is available concerning the way in which MREC members themselves view and value their role(s) and responsibilities (R. Klitzman, 2011 (PLoS One); 2012 (BMC Res. Notes); 2013 (Clinical Trials))

Thus

There still is an incomplete picture of the contribution of MREC’s to (fostering of) responsible research practices in medical research
Aim

To obtain insight into the views and experiences of individual MREC members concerning the role of an MREC as impartial judge of admissibility of medical research proposals and their own position in this process.
MREC’s and research integrity (V): research questions

1) What is the perspective of MREC-members on their own role in the “daily” task of evaluation of proposals (which roles are identified and how are these fulfilled) ?

2) Which responsibilities and interests are felt in “daily” practise and in which way and to what extent does this influence the evaluation process?

3) Which tensions/conflicts are experienced, which dilemma’s are the result of these and how are these dealt with?
MREC’s and research integrity (VI): research methodology

1) A qualitative pilot study is initiated, in which approximately 10 members of the MREC-VUmc will be interviewed individually using a prepared topic list. Data gathering/interviews will be stopped once “saturation” occurs. “Purposeful sampling” will ensure proper spread of variables between participants, like sex and (professional) function in MREC (physician, ethicist, participants representative, pharmacist/clinical pharmacologist etc.)

2) 6-8 interested MREC-VUmc members will be invited for a focus-group in which the themes and issues identified by an “iterative analysis” of the outcomes of the interviews will be validated and discussed in depth (enrichment).

3) Written informed consent will be obtained for participation in, and (audio) recording and transcription of the interviews and the focus-group session. To improve reliability and ensure integrity, anonymized transcripts will be analyzed and coded by at least two members of the research team. If anonymity cannot be guaranteed, this will be discussed explicitly with the participant(s) involved.
1) Recruitment has started one month ago. Complete study, including interviews, focus-group and data analysis and initial reporting (see under), is expected to take 6 months.

2) The outcome(s) of the study will be communicated first to the board and members of the MREC-VUmc in the form of a written report. The research team aims to publish the data in an international, peer-reviewed journal dedicated to medical (research) ethics. Furthermore, results will be presented at (inter)national meetings focusing on Medical Ethics and/or Research Integrity.
Thank you for your attention!

I look forward to taking your questions!