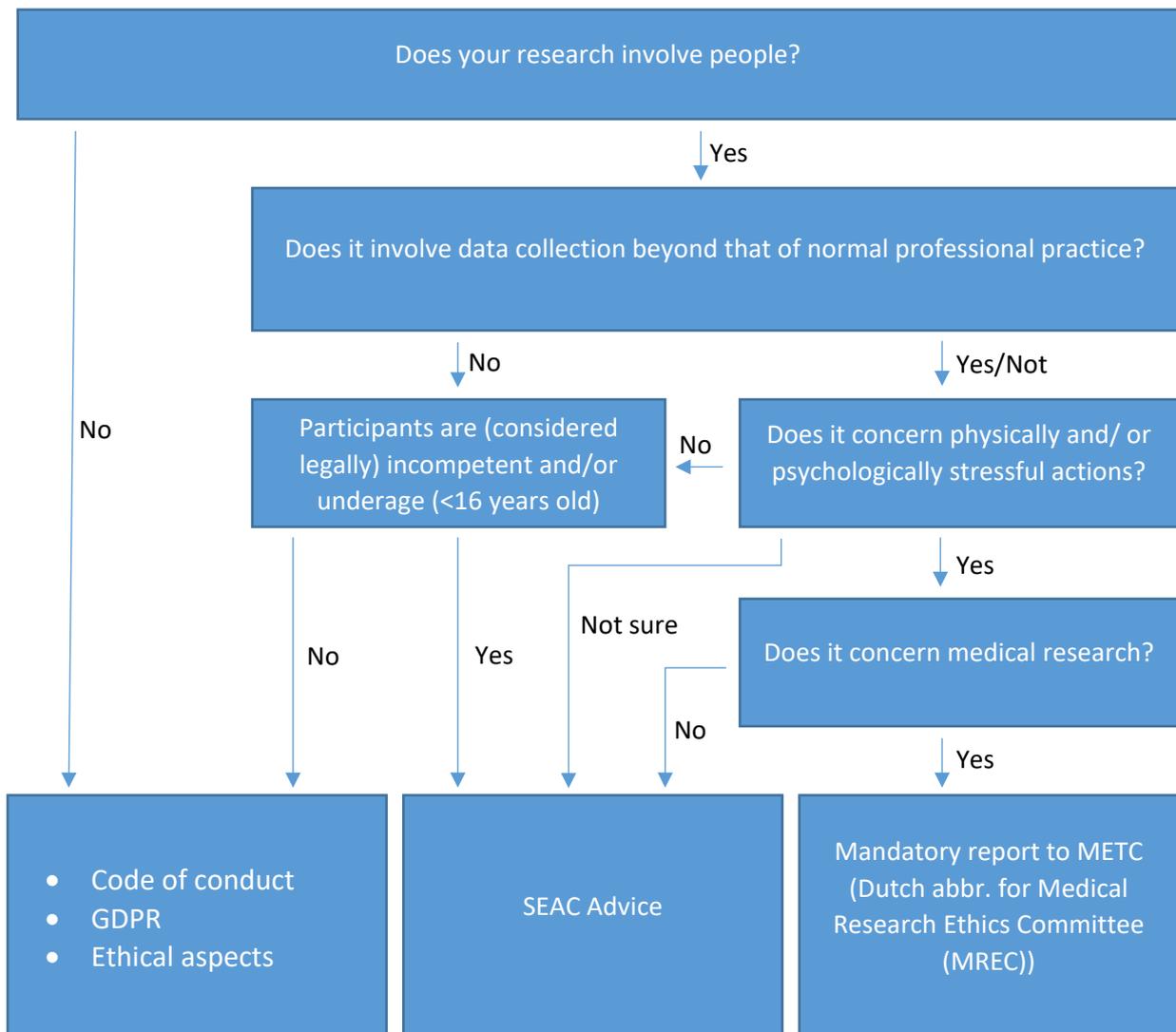


Self-check Saxion Ethical Advisory Committee



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Clarification:

Research is subject to the Medical Research Involving Human Subjects Act (Dutch abbr. - WMO) if:

1. it is a medical study, and
2. if the test-subjects are subjected to action or required to follow behaviours that infringe upon their physical and/or psychological integrity.

"Medical research is research that seeks to answer a question in the field of disease and health (etiology, pathogenesis, symptoms, diagnosis, prevention, outcome or treatment of disease), by systematic collection and analysis of data, and the research aims to contribute to medical knowledge that is also applicable to populations outside the direct research population."

Ref: CCMO (Central Committee on Research Involving Human Subjects) <http://www.ccmo.nl/nl/uw-onderzoek-wmo-plichtig-of-niet>.

Please note: Medical research may also include behavioural science, paramedical, and nursing research, provided that this research can in principle lead to new insights into medical science or medicine and also involves research in which subjects are subjected to actions or required to follow behaviours.

** you can find more information about (in)competency here: <http://www.ccmo.nl/nl/onderzoek-bij-wilsonbekwame-volwassenen>

*** Examples involving psychological stress are questionnaires/ interviews containing questions about disturbing events. Physical stress includes research in which the subject is made to experience pain or discomfort.

**** Special personal data are data that are so sensitive that their processing can seriously affect a person's privacy. This includes things like information on religion or beliefs, political affiliation, criminal history or sexual life.

**** Requirements that a study must meet according to the Dutch code of conduct for scientific integrity.

1. Research protocol: Who, what, how, with whom, for how long, etc.
2. Restricted collection of: only necessary data, lawfully obtained.
3. Permission: informed consent. Advisory Committee/ Medical Ethics committee (Dutch abbr. - METC), (if applicable), Data Protection Officer Saxion/ Authority Personal Data (if applicable).
4. Protection against unauthorized perusal, inspection and modification - description in Data Management Plan (DMP).