

STRENGTHS Incidental findings policy; Deliverable 9.4

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Approved by STRENGTHS consortium and Project Advisory Board d.d September 29, 2017

Incidental findings are defined as observations of potential clinical significance that are unexpectedly discovered in research participants and unrelated to the purpose or variables of the study.^{1,2} Examples of such incidental findings are unexpected genetic abnormalities or misattributed paternity or parentage in genetic family studies, or brain tumors identified during structural magnetic resonance imaging (MRI) of the brain, etc.²

STRENGTHS will collect qualitative data in healthy Syrian refugees and key stakeholders in eight project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt and Sweden) on health needs of Syrian refugees to inform cultural adaptation of the scalable WHO programmes to reduce psychological distress in Syrian refugees. In addition, barriers and levers to scaling up the WHO evidence-based low-intensity interventions will be examined by interviewing key stakeholders such as policy and decision makers in health care.

Further, pragmatic trials evaluating the effectiveness of low-intensity interventions that aim to reduce psychological distress in Syrian refugees will be conducted across eight sites (Jordan, Lebanon, the Netherlands, Switzerland, Germany, Turkey, Egypt, and Sweden). STRENGTHS assessments consist of interviews and self-report instruments measuring levels of distress (anxiety, depression, posttraumatic stress and psychosocial functioning), and health costs. The assessments do not include measures associated with incidental findings, such as brain imaging methods, plasma tests, or similar biological or somatic assessments. Therefore, the STRENGTHS Consortium deems incidental findings very unlikely during the course of STRENGTHS.

A recent guidance note of the European Commission for research in refugees, asylum seekers & migrants³ recommended that findings which are discovered unintentionally, such as indications of human right violations, domestic violence, forced marriage, etc. are handled appropriately.

If, during inclusion of participants, or during other assessments as part of the STRENGTHS study participants show severe psychiatric disorders (e.g., psychosis) or other problems (e.g., suicidality) that require immediate specialist treatment and follow-up, individuals will be referred to available specialist mental health care upon consent.

¹Illes J, Kirschen MP, Edwards E, et al. Ethics. Incidental findings in brain imaging research. *Science* 2006; **311**(5762): 783-4.

²Wolf SM, Lawrenz FP, Nelson CA, et al. Managing incidental findings in human subjects research: analysis and recommendations. *J Law Med Ethics* 2008; **36**(2): 219-48, 1.

³Guidance note — Research on refugees, asylum seekers & migrants: European Commission, 2016.

Note that within STRENGTHS, serious adverse events (SAEs)⁴ reported spontaneously by the participant or observed by the investigators will be handled in line with the procedures outlined and approved by the national accredited ethics review committees. In addition, all adverse events and SAEs will be monthly reported to the STRENGTHS Safety Board (SB; see Annex 1, page 50). The role of the SB is to monitor all ethical, legal and societal issues that arise within the STRENGTHS project. The SB will ensure that the safety, rights and wellbeing of the participants will be reviewed and interim analyses will be considered in case safety issues are (suspected to be) violated. Relevant issues will be discussed periodically (on a six month base) in a meeting, but if issues arise between these meetings, the SB will be requested to plan an additional meeting.

In case the research uncovers unexpected findings of a sensitive nature such as information related to national security or criminal behavior by the respondent or their organization, advice will be sought from the national ethics review committees on how this information should be dealt with.

If during the course of STRENGTHS measures are added that may produce incidental findings as defined above, an updated version of the STRENGTHS Incidental findings policy will be provided to the European Commission.

⁴CCMO. SAEs, SUSARs and SADEs. 2017. <http://www.ccmo.nl/en/saes-susars-and-sades> (accessed September 21, 2017).

