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21024788 - Request for notification

By mail of 20th April 2021 you have requested whether above research project must be notified to the Danish Committee System on Health Research Ethics.

As defined by the "Danish Act on Research Ethics Review of Health Research Projects" Section 2 the project does not constitute a health research project but considers an interview- and questionnaire-based study, which does not include biological materials or interventions. The project thus can be initiated without approval from The Committees on Health Research Ethics for the Capital Region of Denmark.

In Denmark, it is the responsibility of the committee system, to evaluate health research projects. Defined as: clinical trials involving live born human individuals, human gametes intended for fertilization, fertilized human eggs, embryonic cells and embryos, tissue, cells and genetic material from humans, embryos etc. or deceased persons, as well as clinical trials of medicines in humans, and clinical trials of medical devices.

Health research primarily comprises research within medical subjects, clinical and socio-medical-epidemiological research. In addition to research of somatic diseases, it also covers psychiatric and clinical-psychological diseases and conditions as well as odontological and pharmaceutical research.

Register research projects and questionnaire-based surveys are to be notified only if human biological material is included in the project. In case of interview based surveys similar regulations apply.

Health research projects, solely involving anonymous human biological material, and collected in accordance with legislation at the site of collection, need only be notified to the Committee System of Ethical Research, if the project involves fertilized human eggs and genetic material cf. Section 25 and 27 (2) in the "*Act on Artificial Insemination used for fertilization in connection with medical treatment, diagnostics and research etc*."

It is a requirement, that the biological material is fully anonymous. This means the material must not be individually identifiable; no code must be available for the data.

Trials, involving cell lines etc. are not to be notified, if originating from a trial regarding the collection of cells or tissue, which have obtained the required permission.

As a matter of form, our rejection to evaluate your project constitute neither an ethical nor a negative evaluation of the content of the project.

For additional inquiries, please contact the Secretariat for the Committees of the Capital Region at +45 38666395 or by e-mail: vek@regionh.dk.

Complaints procedure

Any decision concerning approval and rejection from the regional committee may be brought before the National Committee on Health Research Ethics no later than 30 days from receipt of the decision from the regional committee, cf. section 26(1) of the Committee Act

The complaint must be submitted electronically with the use of digital signature and encryption in case of confidential protocol content (confidentialities). The complaint must be justified and copy of the decision from the regional committee must be enclosed as well as the case files used for the decision. Please forward to dketik@dketik.dk

Kind regards,

Anne Brunsgaard
Konsulent