Requirements and guidelines for registration and disclosure of medical and health-related studies involving human participants

Introduction and background

The guidelines have been developed as a follow-up of the WHO's Joint statement on public disclosure of results from clinical trials, which the Research Council of Norway (RCN) joined in 2017. Prospective registration of studies and rapid publication of results are important to ensure full transparency in medical and health studies involving human participants. This will further promote ethical and moral perspectives and support accountability and integrity in – and benefit from – research.

The guidelines will promote good practice for prospective registration and reporting from such studies. The aim is to ensure transparency and increased probability of positive effects from RCN funded studies involving human participants.

The guidelines apply to calls for proposals, starting in 2020.

Registration of medical and health studies involving human participants*

The guidelines apply to projects which are fully or partially funded by the RCN and require pre-approval by the Regional Ethics Committee (REC):

1. **Clinical intervention studies ****
   Any research study that prospectively assigns human participants or a group of humans to one or more health-related interventions to evaluate the effects on health outcomes.
   Interventions may include e.g. pharmaceuticals, surgical procedures, equipment***, behavioural interventions, education programmes, quality improvement interventions and change processes.
2. **Public health intervention studies**
   Studies in which there is a public health intervention to promote or protect health, or prevent ill-health, in communities or populations rather than in individuals.
3. **Observational studies**
   Studies in which the researcher assesses outcomes in groups in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle of behaviours, or interventions that are part of routine care and not influenced by the researcher.
   The guidelines also apply to studies involving human tissue and/or cells when it requires consent and approval from REC.
4. All such studies that are fully or partially funded by the RCN must be registered in one of the following registries:
   - ClinicalTrials.gov
   - Other ICMJE approved trials registries (see question 7)
5. The registration must be completed before the first participant receives the first intervention in the trial, or within a short time afterwards. Information about the selected registry, the study's registration number and the date of registration should be submitted to the RCN via My RCN Web as soon as possible after the study registration.
6. The requirement also applies to studies that have started before receiving funding from the RCN. In case these have not been registered, registration must be completed as soon as possible.
7. The RCN expects the study protocol**** and Statistical analysis plan (SAP) to be made publicly available prior to the start of the study. Furthermore, information on how this information can be obtained must be included in the registry. When registering ClinicalTrials.gov, this information can be entered in the summary field.
8. All relevant fields in the selected registry must be completed and updated on a regular basis (at least annually) until the study has been completed and the results published or made publicly available. Approved changes to the study protocol must be updated in the registry as soon as possible. If the study is terminated before the scheduled end-date, the registry must be updated with information on the date of termination and the number of participants in the study at the time of termination.
9. Information about the study being funded by RCN, with reference to project number, must be included in the registration. When registering in ClinicalTrials.gov, this can be entered in the "other identifiers" field.
10. The **project manager** is responsible for ensuring that study registration and registry updating are done. The **Project Owner** (see definitions of the roles in the contract) is accountable to the RCN.
11. Costs related to registration may be covered within the frame of the RCN's project funding if specified in the budget.
12. All studies planning to include participants in Norway should also be registered in helsenorge.no/kliniske-studier (in Norwegian).

Reporting

1. Results from studies funded by the RCN must be published as soon as possible. For more information see the *General Terms and Conditions for R&D Projects*.
2. The RCN recommends that summaries of the study results are published in the registry where the study is registered within 12 months of the conclusion of the study. In ClinicalTrials.gov, this can be added to the "results section".
3. The registration number for the study must be included in all publications from the study and must be specified in the article summary/abstract.

Monitoring of registration and reporting from studies funded by the RCN******

1. The RCN will follow up the registration through project reporting throughout the project period.
2. The RCN will regularly publish aggregated figures indicating the degree of compliance with the guidelines.

Useful links and guides

- Joint statement on public disclosure of results from clinical trials (pdf)
- ClinicalTrials.gov
- ICMJE approved registries (see question 7)
- International Standards for Clinical Trial Registries (pdf)
- EQUATOR Network Reporting Guidelines for Main Study Types
- The Research Council of Norway's Policy for Open Research (pdf)
- helsenorge.no/kliniske-studier (web page in Norwegian)

* We emphasise that the RCN's guidelines cover a wider range of studies than the WHO statement.

** The World Health Organization's (WHO) definition.

*** The guidelines also apply to the testing of medical devices, i.e. diagnostic/observational testing of equipment outside the present CE marking.

**** As a minimum, it is expected that a protocol synopsis or summary is made available.

***** The summary of the study results should contain the following as a minimum: “Summary results” here are defined as including the following as a minimum: baseline characteristics, participant flow, primary and secondary outcome measures, and adverse events including all serious adverse events and important anticipated or unanticipated adverse events. An example of a format for providing results: https://clinicaltrials.gov/ct2/about-site/results. Note that “summary results” refers to analyses conducted on data, not to primary data disclosure itself. “Summary results” in this statement are synonymous with “key outcomes” in the 2015 WHO statement on public disclosure of results.

****** This point will be updated and expanded on.

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