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SECTION I: ROLE OF RESEARCH ADVISER ☐ Not Applicable

All research conducted in academic institutions by students/trainees, including postdoctoral fellows, shall be under the supervision and guidance of a senior research or faculty adviser.

The senior research or faculty adviser shall:

1. Guide the student or trainee in the development of a scientifically and ethically sound research protocol;
2. Assist the student or trainee in the addressing ethical and scientific concerns raised by reviewing bodies;
3. Serve as a model in intellectual humility and refer the student to other persons with expertise in social, legal, and other considerations affecting the research;
4. Supervise the student or trainee in the proper collection and recording of data including the duty to maintain the confidentiality of information and the privacy of human participants for all the phases of the research processes including the disposal or archival of data;
5. Review interim and final reports for accuracy and consistency;
6. Share responsibility and accountability with the student/trainee for the ethical conduct of the research; and
7. Ensure that the research to be undertaken by undergraduate students involves only minimal risk.

Name of Research Adviser	Click here to enter text.
Signature of Research Adviser	
Date Signed	Click here to enter a date.

SECTION II: CURRICULUM VITAE OF RESEARCH ADVISER

Education and degrees awarded	*• degree title (most recent first), educational institution, major subject, graduation date, contact details to facilitate verification of the highest degree earned)*
Other education and training, qualifications and skills	*• other studies aiming at a degree, qualifications or supplementary education and training: name of educational or training programme, extent of education and training, organiser, start and completion (estimated) date of education or training*
Linguistic skills	*• mother tongue • other languages: achieved proficiency and certificate date or self-assessment of proficiency. As an option for a self-assessment of one's language skills, the instructions for the Europass Language Passport can be found at http://europass.cedefop.europa.eu/en/documents/language-passport/templates-instructions, p. 4)*
Current position	*• current position, employer and place of work, start and end date of employment relation (possible part-time nature of work must be stated, brief job description if necessary) research career phase if not directly evident from the foregoing: 1) First Stage Researcher or doctoral student; 2) Recognized Researcher or post-doctoral researcher; 3) Established or independent researcher; 4) Leading Researcher or professor/research). • grant researcher: source of funding, purpose of grant and funding period • full-time student: institution and major subject • secondary occupation, additional work experience, other commitments and potential conflicts of interest relevant to the application (e.g. commitments in a company)*
Previous work experience	*• earlier employment relations and grant periods (the most recent one first) incl. longer-term visits abroad: job description, employer and place of work or funding organisation, start and end date of the employment relation (possible part-time nature of work must be stated, brief job description if necessary) • earlier secondary occupations, additional work experience, other commitments and potential conflicts of interest relevant to the application (e.g. commitments in a company) • career breaks: family leaves, military or non-military service*

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	terms, other leaves of absence (with start and end dates), other reasons NB The inclusion of the above data is optional, but it may have a positive impact on the evaluation of applications and the eligibility of the researcher, for instance, when the application presumes a specific career stage.
Research funding as well as leadership and supervision	*• major research funding (grants and appropriations): source of funding, funding period and amount of funding • role in the preparation of funding applications for a research group (name of principal investigator) • leadership in research work • supervision of post-doc researchers (number of supervised researchers or their names and graduation dates), supervisory role (main/primary/responsible or secondary supervisor) • experience as officially appointed supervisor to undergraduate and post-graduate students/doctoral students (cf. above)*
Merits in teaching and pedagogical competence	*• pedagogical training and competence • involvement in curriculum planning and the implementation of courses: subject, including subject, study hours, course level and duration • development of teaching methods • supervision of theses• merits in the training of responsible conduct of research and innovation practices (subject, study hours, course level and duration) • teaching awards*
Awards, prizes and honours	*• Awards, prizes and honours granted for scientific, artistic or research merits or on the basis of the recipient's academic career*
Other academic merits	*• service as a pre-examiner or as an opponent of a doctoral dissertation, as a member in dissertation committees (abroad) • evaluation of academic/scientific or artistic competence (e.g. title of docent) • member of international peer evaluation committees of funding applications (e.g. European Research Council) • memberships and positions of trust in scientific and scholarly societies • membership in national or international expert groups , evaluation or steering committees, as well as other expert duties • positions as editor-in-chief, editor, or member of editorial boards of scientific and scholarly journals and publication series • referee for scientific and scholarly journals • administrative responsibilities at higher education institutions or at research organisations, responsibilities in the higher education community • invited keynote lectures abroad*
Scientific and societal impact of research	*• total number of publications and, e.g., 10 most important and/or most cited publications according to a relevant database (a list of publications according to the Publication Type Classification used by the Ministry of Education, Science and Culture as a separate attachment) • artistic works and processes • merits related to the production and distribution of research results and research data • merits related to the application of research results • invention disclosures, patents and other commercialisation-related merits (e.g. spin-off companies and trademarks) • merits in science communication and expert assignments in the media*
Positions of trust in society and other societal merits	*• significant positions of trust, expert duties and assignments (also research-based policy-advice tasks) • other social merits, honours, medals, decorations and Finnish military rank (optional)*
Other merits	Click here to enter text.

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SECTION III: ROLES and RESPONSIBILITIES of the PRINCIPAL INVESTIGATOR

For the purposes of this set of guidelines, the term "researcher" refers to an individual or group of individuals who conceptualizes, initiates, and conducts a study. On the other hand, the term "investigator" refers to an individual or group of individuals who are responsible in the conduct of clinical trials involving investigational new drugs or devices, usually commissioned and sponsored by pharmaceutical companies or manufacturers. The "Principal Investigator" is the lead implementer of the clinical trial protocol. "Co-Investigators" (Co-Is) are a subset of key personnel who have special responsibilities in clinical trials. "Sub-investigator" is a term used to identify study team members who make critical clinical trial-related procedures and/or to make important trial-related decisions. Generally, these are also study Co-Is but may also include study team members with critical and important trial-related roles. All investigators have the same responsibilities pertinent to protection of human participants and ensuring credibility of data, but they perform their tasks based on clear delegation of responsibility emanating from the principal investigator.

Eligibility requirements for conducting research on human participants vary depending on the role of the researcher or investigator. Research personnel shall be appropriately qualified by training and experience to perform their research responsibilities.

Investigators or researchers shall be responsible for the protocol and the conduct of study. These responsibilities are particularized as follows:

1. Preparing the research protocol and ensuring its ethical acceptability by submission to the REC for review.
2. Obtaining ethical approval of the protocol, and for cooperation with the REC in the conduct of the clinical trial.
3. Bearing ultimate accountability for all activities associated with the protocol, including compliance with adopted international guidelines, national and local laws, institutional policies, and ethical principles.
4. Consulting or collaborating with colleagues in the scientific or academic community to which he or she belongs and seeking advice from authoritative bodies possessing expertise in ethical, legal, social and other issues that the researcher may encounter throughout the research process; from the crafting of the proposal up to the disposal or archiving of data.
5. Performing or delegating to qualified co-investigators or research staff all the necessary tasks to carry out their studies; while remaining ultimately responsible for proper conduct of the study and fulfillment of all associated obligations.
6. Providing members of the research team with sufficient oversight, training, and information to facilitate appropriate safety procedures and protocol adherence.
7. Ensuring that adequate resources (facilities, equipment, supplies, and personnel) exist to:
    a. Conduct the research (e.g., through internal or external funding for staff, facilities and equipment);
    b. Protect subjects; and
    c. Ensure the integrity of the research.
8. Evaluating the resources available at each site where the research will be conducted, in multicenter/sited studies
9. Applying for ethical review and approval before the conduct of a research/clinical trial. Thus, the researcher shall factor in the period for ethical review in the research timeline
10. Providing evidence of Good Clinical Practice (GCP) training for clinical trials (NOTE: A GCP training certificate is valid for three years, and a local GCP training is preferred to ensure that the investigators are informed of the local regulatory requirements of the clinical trials).
11. Obtaining informed consent from each prospective research participant (or the participant's legally authorized representative) before the participant begins to participate in the research (including any related eligibility testing not conducted solely for clinical purposes), unless the appropriate REC has approved a waiver of consent, or waiver of documentation.
12. Having adequate time to enlist the necessary number of participants to the research.
13. Providing a copy of the signed informed consent form to the research participant, and retaining a copy in both the research record and regular medical record (as applicable).

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14. Informing the REC if a researcher or investigator can no longer fulfill his or her duties for any reason including, but not limited to, traveling for a prolonged period of time.
15. Cooperating, at all times, with the REC in fulfilling its responsibilities, and shall provide all information required by the REC as part of the review process such as all key personnel who contribute to the scientific development or execution of a study in a substantive, measurable way.
16. Bearing accountability for the content of all submissions (e.g., initial review, continuing review, adverse event reporting, reportable negative events, progress reports) to the REC and other review units and for ensuring that those documents are submitted in a timely manner, as required by the REC and other review units (e.g., audit teams).
17. Conducting the research as specified in the REC-approved protocol and complying with all REC decisions pertinent to the REC-approved protocol.
18. Submitting to the REC an amendment application for prospective changes in the approved protocol before the change is implemented, unless urgently necessary to eliminate apparent immediate hazards to subjects.
19. Reporting promptly to the REC any additional risks that are identified.
20. Monitoring the effective period of the ethical approval of the protocol and submitting a continuing review application in a timely manner to the REC, for renewal of approval (NOTE: If REC approval for a study lapses for any reason, even if the researcher or investigator has submitted an application for continuing review in a timely manner and has promptly responded to any requests for clarifications or changes, the recruitment of participants shall stop until the REC issues its formal approval, or determines that it is in the best interest of individual participants to continue participating in the research interventions or interactions).
21. Reporting promptly to the REC any of the following:
    a. Unanticipated problems involving risks to participants or others, such as an adverse event or exposure of member(s) of the research team to harm;
    b. Noncompliance with applicable laws or regulations or REC requirements, whether by the researcher or investigator, research staff, or others, even if the noncompliance was unintentional or was discovered in the course of quality assurance or quality improvement activities; and
    c. Disapprovals, suspensions, or terminations of the project by any University or non-University review units or agencies.
22. Cooperating with:
    a. Internal evaluations, inspections, and audits performed by authorized internal oversight authorities, including the RECs.
    b. External reviews (e.g., by industry sponsors or government agencies such as the FDA).
    c. Any external investigation, inspection, or other external review and its outcome must be reported to the REC responsible for the research in question. Researchers should consult with their administrators, the RECs, and as appropriate, the legal counsel for assistance and representation.
23. The researcher or investigator shall disclose all financial and non-financial COI.
24. Complying with all applicable FDA regulations and fulfilling all investigator responsibilities, and in some cases, sponsor-investigator responsibilities, as applicable when conducting research involving FDA-regulated products.
25. Complying with the ICH-GCP guidelines in fulfilling all other duties in clinical trials that require FDA regulation.

Name of Principal Investigator	Click here to enter text.
Signature of Principal Investigator	
Date Signed	Click here to enter a date.

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SECTION IV: CURRICULUM VITAE OF PRINCIPAL INVESTIGATOR	
Education and degrees awarded	*• degree title (most recent first), educational institution, major subject, graduation date, contact details to facilitate verification of the highest degree earned) • title of docent: field, university and date when conferred*
Other education and training, qualifications and skills	*• other studies aiming at a degree, qualifications or supplementary education and training: name of educational or training programme, extent of education and training, organiser, start and completion (estimated) date of education or training • other skills*
Linguistic skills	*• mother tongue • other languages: achieved proficiency and certificate date or self-assessment of proficiency. As an option for a self-assessment of one's language skills, the instructions for the Europass Language Passport can be found at http://europass.cedefop.europa.eu/en/documents/language-passport/templates-instructions, p. 4)*
Current position	*• current position, employer and place of work, start and end date of employment relation (possible part-time nature of work must be stated, brief job description if necessary) research career phase if not directly evident from the foregoing: 1) First Stage Researcher or doctoral student; 2) Recognized Researcher or post-doctoral researcher; 3) Established or independent researcher; 4) Leading Researcher or professor/research). • grant researcher: source of funding, purpose of grant and funding period • full-time student: institution and major subject • secondary occupation, additional work experience, other commitments and potential conflicts of interest relevant to the application (e.g. commitments in a company)*
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Awards, prizes and honours	*• Awards, prizes and honours granted for scientific, artistic or research merits or on the basis of the recipient's academic career*
Other academic merits	*• service as a pre-examiner or as an opponent of a doctoral dissertation, as a member in dissertation committees (abroad) • evaluation of academic/scientific or artistic competence (e.g. title of docent) • member of international peer evaluation committees of funding*

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	applications (e.g. European Research Council) • memberships and positions of trust in scientific and scholarly societies • membership in national or international expert groups , evaluation or steering committees, as well as other expert duties • positions as editor-in-chief, editor, or member of editorial boards of scientific and scholarly journals and publication series • referee for scientific and scholarly journals • administrative responsibilities at higher education institutions or at research organisations, responsibilities in the higher education community • invited keynote lectures abroad
Scientific and societal impact of research	*• total number of publications and, e.g., 10 most important and/or most cited publications according to a relevant database (a list of publications according to the Publication Type Classification used by the Ministry of Education, Science and Culture as a separate attachment) • artistic works and processes • merits related to the production and distribution of research results and research data • merits related to the application of research results • invention disclosures, patents and other commercialisation-related merits (e.g. spin-off companies and trademarks) • merits in science communication and expert assignments in the media*
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