SCTO PLATFORMS

Clinical research core competencies in Human Research Ordinance (HRO) projects

This document outlines the core competencies required for clinical research projects falling under the Human Research Ordinance (HRO). It has been adapted from the Clinical Research Core Competencies (CRCC) Framework for clinical trials and developed by the Education Platform of the Swiss Clinical Trial Organisation.

Competency Domain 1 **Scientific Concepts and Research Design:** Encompasses knowledge of scientific concepts related to design and analysis of human research projects with the exception of clinical trials.			
C.ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
1.1	Health-related knowledge and practical experience	Have sufficient medical and clinical knowledge in the medical area of the research projects to be conducted.	*Statement for HRO chapter 2 also apply to HRO chapter 3 research projects.*
1.2	Scientific principles of a human research project	1. Justify the relevance of the research project and critically review existing research. 2. Use an appropriate methodology. 3. Plan the research project and write the project protocol (or coordinate protocol writing). 4. Conduct the research project in compliance with the project protocol. 5. Comply with ethical and local regulatory requirements. Example: When given a human research protocol, researcher is able to critically review existing research that led to the development of the present project and the evidence that is the basis for the protocol.	*Statements for HRO chapter also apply to HRO chapter 3 research projects.*
1.3	Human research methodology	1. Formulate scientific questions using Population, Exposure, Outcome (PEO) structure as well as objectives (primary and secondary). 2. Translate objectives in testable human research hypotheses; define outcomes and/or endpoints (primary and secondary). 3. Select an appropriate project design.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects* ***except****: "writing a Data Management Plan" which may not be needed.* *Further statements need to be considered:* 1. Assess and adapt project design to available data/samples (design may be constrained by the data). Perform a feasibility study.

		4. Justify sample size and if applicable perform a power calculation for the primary outcome/endpoint, based on justified assumptions: minimal relevant difference, anticipated variability, and attrition rate. 5. Determine which data need to be collected and how, write a Data Management Plan (DMP). 6. Identify appropriate statistical methods and write a Statistical Analysis Plan (SAP) or describe statistical analyses of the primary and secondary endpoints in the project protocol. 7. Evaluate strengths and weaknesses of project designs (including risk of bias) and explain them to others. Example: Researcher determines the following elements in project protocols: key objectives, study design, primary and secondary outcomes and who are the beneficiaries, and ensure the appropriateness of endpoints for hypothesis testing.	2. Consider frequency of missing values and its related risk of bias when determining which data need to be analysed and how. 3. Evaluate thoroughly weaknesses of project designs with further use of data/samples. Example: Researcher adapts project design according to data/samples and variables availability and constraints.
1.4	Plan the inclusion, evaluation, and follow-up of participants	1. Specify "who, where and when" participants are included. 2. Determine eligibility criteria and procedures of recruitment in order to minimise the risk of selection bias. 3. Specify the place (which countries, sites, single or multi centre) and the time (start and end date of the research project) of participant recruitment. 4. Identify and favour methods of assessment at low risk of measurement bias (e.g. validated questionnaires). Describe the outcomes method of measurement. 5. Plan the procedures for the follow-up of participants (e.g. type and frequency of follow-up, number of recalls), if applicable. Example: Researcher identifies the eligibility criteria, the time and frequency of outcome measurements and methods of assessment.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects* ***except*** *statements 4 and 5 since participants are not actively involved in HRO chapter 3 research project. Be aware that participant recruitment needs to be replaced with data/sample selection in chapter 3 research projects.* Example: Researcher plans data extraction from available health records and/or data of previous research projects as characterised by the protocol.
1.5	Analyse and interpret human research project results	1. Describe the data and test the research hypotheses according to the Statistical Analysis Plan (SAP) or statistical analyses as described in the research protocol. 2. Present and interpret the results. 3. Communicate the results to others. 4. Discuss the results in regard to the strength and weaknesses of the research project. Example: When given a project report, researcher is able to paraphrase and summarise results, and to prepare a presentation where results are critically assessed and presented to others.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.* *A further statement is especially relevant for HRO chapter 3 research projects, in which researcher is totally dependent on data at hand:* 1. Recognise the low level of evidence when needed (in case of important weaknesses).

Competency domain 2: **Ethics and participant rights:** Encompasses the care of participants, their rights, and aspects of participant protection in the conduct of human research projects with the exception of clinical trials.			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
2.1	Awareness of the evolution of regulatory framework and principles of participants protection	1. Identify the key documents that build the foundation of human research regulations, know the national laws that regulate human research and ensure the protection of human participants, namely: - Nuremberg code - Declarations of Helsinki and Taipei - Belmont Report - Swiss Human Research Act (HRA) and Human Research Ordinances (primarily HRO) - Data Protection Act (DPA) 2. Comply with and apply the principles, general provisions, and requirements regarding research with humans as set forth in the Swiss Constitution and Swiss Human Research Act (HRA) and DPA. Example 1: Researcher supervises and ensures the regulatory compliance of the research team and research projects. Example 2: Researcher recognises with respect to the research question when to follow HRO chapter 2.	*Statements for HRO chapter 2 also apply to HRO chapter research projects.* Example 2: Researcher recognises with respect to the research question when to follow HRO chapter 3.
2.2	Differentiation of standard of care versus research activities	1. Develop a protocol that appropriately includes distinct research-related activities and standard of care approaches. 2. Know about the difference between standard of care and research project-related activities in terms of performance payment distribution. Example 1: Researcher explains to participant which procedures are usual standard of care and differentiate them from additional procedures that are part of the research project. Example 2: Researcher distinguishes between activities that should be charged to insurance versus those incorporated into research project costs.	1. Ensure that research-related data/biological material (if included) have been collected for patient's medical care or as part of previous research projects in order to fall within the scope of HRO chapter 3. 2. Develop a protocol that specifies source(s) of data/biological material reused in the project (whether they are standard of care data and/or whether they come from data/biological material previously collected in research-related activities) and provide corresponding ICF(s). Example: Researcher plans a further use project including standard of care data and genetic data to be drawn from existing blood samples, realises that more blood samples need to be collected to ensure relevant project results and thus reformulates the research protocol to fall within the scope of HRO chapter 2 allowing further blood samples to be collected.
2.3	Application of the principles and regulations of participant protection and privacy	1. Comply with applicable data protection principles and regulations throughout all stages of a research project. 2. Identify data protection issues and implement appropriate measures to ensure privacy. 3. Ensure participants' privacy, safety, well-being, and rights in a research project. Example: Researcher develops a plan to ensure participant's rights and privacy and integrates it in the research protocol to be evaluated by an independent and competent ethics committee.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects except "participant safety and well-being" which are not applicable in further use of data and biological material research projects. .*

2.4	Awareness of evolution of Informed Consent Forms (ICF) principles for research projects	1. Identify the historical events and key documents, which have led to the development of the current informed consent regulations. 2. Recognise the critical nature of communicating the potential risks or hazards, as well as the benefits of a research project, using terminology and a manner that is understandable by potential participants during the informed consent process. 3. Apply knowledge of the current national and international regulations when drafting an ICF for a research project. Be especially aware of data protection measures. 4. Implement processes and control measures to ensure participant protection regulations' requirements are met. Example: Researcher composes and evaluates the ICF in relationship to the protocol to assure that it meets current regulations and guidelines and provides the information needed for a potential participant to make an informed decision.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.* *Further statements need to be considered to identify adequate ICF to be used:* 1. Assess when General Consent (GC) can be applied and when a specific consent should be proposed to participants. 2. Investigate whether sites to be included in the research project have implemented the General Consent (GC) allowing the further use of health-related data and biological material already collected during standard of care for research purposes. 3. Develop an appropriate information form (and/or consent form) according to the type of data (genetic versus non-genetic and coded versus uncoded) to be reused in the project (HRO, Art. 28-32). 4. Assess surrogate consent by the ethics committee (HRA, Art.34) allowing exceptional further use of data without consent by participants. Example 1: Researcher contacts person in charge of the institutional General Consent (GC) to assess whether further use project can be carried out with the use of GC. Example 2: Researcher justifies the further use of health-related data without consent by participants (HRA, Art. 34) when project mostly includes data from persons that have passed away.
2.5	Inclusion and safeguards of vulnerable populations	1. Identify which populations are considered vulnerable. 2. Be aware that specific regulations and processes exist to protect vulnerable populations. 3. Develop a protocol describing additional safeguards and specific processes of participant protection measures when including vulnerable populations. Example 1: Researcher understands these groups as being vulnerable: children, adolescents, adults lacking capacity, pregnant women, embryos and foetuses, prisoners, patients in emergency situations, mentally disabled persons, and economically or educationally disadvantaged persons. Example 2: Researcher applies his or her knowledge of vulnerable populations to the informed consent process and develops specific ICFs for the recruitment of vulnerable populations.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.* *A further statement needs to be considered:* 1. When reusing data and/or biological material from vulnerable populations, ensure that participants and/or legal representative (if needed) were provided with an adapted and adequate ICF.
2.6	Ethical considerations regarding cultural variation	1. Compare and contrast the ethical principles guiding biomedical research with humans across different global regions (e.g. US American versus European versus Swiss regulations). 2. Examine the pros and cons of conducting research projects in other regions or countries. 3. Assure that multicentric research projects incorporate concepts which recognise varying cultural perspectives and ethical issues across regions.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

		4. Check data protection standards of countries/regions when performing an international multicentric health-related data collection for a research project. Example: Within the boundaries of the protocol, researcher adapts research project processes to the individual needs of participants and their cultural backgrounds.	Example: Researcher identifies differences of data protection standards across countries/regions from which data are planned to be imported from (for instance GDPR applies to European member states) and implements additional measures of safeguarding privacy before the transfer.
2.7	Principles and methods of distributing and balancing risks and benefits	1. Understand the difference between the risk-based research project categorisation criteria “minimal risk and burdens” and “more than minimal risk and burdens” (HRO, Art. 7). 2. Develop and implement processes (e.g. enrolment, project procedures, Serious Event (SE) identification and documentation, continuation of the research project) that appropriately balance risk and benefit. Example: Researcher identifies potential clinical risks associated with a protocol and applies ongoing risk assessment activities during research visits with participants.	1. Be aware that data protection violation is the only participant’s risk in projects involving further use of health-related data. 2. Even if not relevant for risk categorisation according to HRO (Art. 7), inform participants of incidental findings that could result from research projects reusing existing data and/or biological material. Example: Researcher makes sure DPA is adhered to and thus risks of privacy violations for participants are kept to a minimum.

Competency domain 3: **Human research project development and regulation:** Encompasses the knowledge of how human research projects with the exception of clinical trials are developed and regulated.			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
3.1	Historical context for the development of regulatory processes	1. Identify and understand historical and current events that have influenced national and international guidelines and regulatory processes concerning human research. 2. Be able to apply and explain contents of national and international guidelines. Example: Researcher understands why informed consent is necessary for research projects (e.g. non-information scandal of Tuskegee study) and develops a protocol which is compliant with the Swiss regulations on research projects (Human Research Act (HRA) and Human Research Ordinance (HRO)).	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
3.2	National and international content of frameworks for research project approval, safety, and quality	1. Understand and apply the appropriate regulatory guidance for research projects to ensure the safety and rights of project participants. 2. When necessary, compare the Swiss regulatory guidance to the different regulations in other countries. 3. Develop and implement strategies for the conduct of multiregional research projects, determine international site feasibility, and analyse the resources necessary. 4. Determine and schedule regulatory application requirements and timelines for national and international research projects. 5. Monitor project progress and assure that the research project conduct at site meets local, national, and global regulatory frameworks; support others to meet such requirements in the conduct of the project. Example 1: Researcher supervises and ensures the regulatory compliance of the research team and research projects. Example 2: Researcher knows that a regulatory application in another country may need more or other resources than a similar application in Switzerland, for instance when working with the US, where HRO projects are handled as clinical trials. Researcher provides solutions and produces trainings, documentation, and checklists to enable research team to ensure that the relevant regulatory frameworks are adhered to.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects* ***except****: "ensure safety of project participants". Safety is* ***not applicable*** *in further use of data and biological material research projects.*
3.3	Roles and responsibilities during research project development and approval	1. Know the roles and responsibilities of project leaders, sponsors, members of the research team (including CTUs and CROs), and ECs in developing and approving protocols, assessing risks, and assessing the quality of research projects.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

		2. Understand how roles and responsibilities might differ in academia or not-for-profit research as opposed to industry. Example: Researcher identifies the responsibilities of the project leader, knows the processes of research project approval by ECs, and realises where collaborations (e.g. with CTUs) can assure and increase research project quality (e.g. through getting support for developing/using an adequate quality management system).	
3.4	Approval for research projects	1. Coordinate/write submissions for ethics approval and submit required information, reporting and protocol amendments to relevant authorities. Example: Researcher coordinates, reviews, and maintains the required submissions, knows and uses relevant swissethics templates, and provides appropriate updates, for example in the case of SE or discontinuation of a research project.	*Statement for HRO chapter 2 also apply to HRO chapter 3 research project* ***except:*** *SE reporting as mentioned in the example.*
3.5	Safety reporting for research projects	1. Assess the occurrence of Serious Events (SE) and the necessity for safety and protective measures. 2. Coordinate the classification and reporting of SE as well as safety and protective measures. Example: Researcher serves as the point of contact for safety (reporting) issues, communicates SE and safety measures with the involved research team members, takes necessary measures and reports events to the EC within the proper timeframe.	*Statements for HRO chapter 2 projects are* ***not applicable*** *for HRO chapter 3. Safety is not applicable in further use of data and biological material research projects.*

Competency domain 4: **Human research project operations:** Encompasses management of human research project with the exception of clinical trials, safety management, and the handling of personal data and biological material			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
4.1	Roles and responsibilities of the research team	1. Describe own role and review and assess roles of others in the site team as set forth by the institution or organisation, and regulations. 2. Perform role in accordance with Swiss regulations: Human Research Act (HRA) and Human Research Ordinance (HRO). 3. Supervise the research team. 4. Consider audits of research projects to ensure compliance. Example: Researcher assembles, supervises, and manages appropriate research team.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
4.2	Design, conduct and documentation of research projects	1. Successfully implement a research protocol. 2. Ensure that the conduct of a research project complies with Swiss regulations (HRA and HRO) as well as other relevant regulations. 3. Ensure transparency of project conduct through an appropriate documentation. 4. Appropriately resolve any compliance related issues which arise during the conduct of the research project. 5. Ensure that the personnel conducting the research project are appropriately trained. Example: Researcher appropriately mentors and trains research team in the ethical and quality concepts required during the conduct of the research project.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
4.3	Quality Management System (QMS) and Standard Operating Procedures (SOPs)	1. Consider to which extent a QMS with pragmatic SOPs for the research project and for specific sites or laboratories must be in place. 2. Develop guidelines and SOPs to ensure research project procedures will be consistently applied and adhered to. Example: Researcher sets up a QMS for the site, if applicable.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
4.4	Sampling, control, and storage of biological material and health-related personal data	1. Ensure that research project procedures cover sampling, control, storage and data protection of biological material and health-related personal data. 2. Generate labelling guidelines for the biological material. 3. Establish or extend a biobank or a registry that is compliant with applicable legal and ethical requirements and that includes an appropriate documentation and quality management system (QMS).	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects* ***except****: "sampling and labelling of biological material" which is not applicable in further use of data and biological material research projects.* 3. Use a biobank or a registry that is compliant with applicable legal and ethical requirements and that includes an appropriate documentation and quality management system (QMS).

		4. Ensure processes are in place for the shipment of biological material and transfer of project data and make sure that these processes are covered in written agreements such as material and data transfer agreements. 5. Develop Corrective and Preventive Action Plans (CAPAs) when issues in the handling of biological material are detected in order to avoid further deviations. Example: When given a variety of scenarios, researcher implements the maintenance of proper environmental storage conditions, security, and inventory control of biological material.	
4.5	Safety reporting requirements	1. Recognise when a Serious Event (SE) occurs during the conduct of a research project. 2. Apply the reporting timelines and requirements for an SE in Switzerland. 3. Anticipate possible safety issues during research project implementation. 4. Institute measures to minimise risks. 5. Execute the reporting of SEs as well as safety and protective measures to ethics committee. Example: Researcher recognises and reports an SE to ethics committees within the appropriate time frame during the conduct of the human research project.	*Statements for HRO chapter 2 projects are **not applicable** for HRO chapter 3. Safety is not applicable in further use of data and biological material research projects.*
4.6	Participant protection and privacy	1. Understand that research project participants are entitled to protection and privacy and that national and international regulations are in place to protect participants during the conduct of a research project. 2. Set up an appropriate system for research project participant protection. Example: Researcher develops and implements comprehensive and comprehensible patient information and consent procedures and controls compliance with regulatory requirements.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects. Be aware that participant needs to be replaced with data/sample in chapter 3 research projects.*
4.7	Monitoring and audits	1. Consider whether monitoring, quality check, and audits may be of added value for the research project. 2. Develop policies and SOPs in response to monitoring and audit findings. Example: Given an audit report, researcher creates a comprehensive CAPA plan to respond to audits and develops appropriate SOPs.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects. Even data quality checks can be relevant in large reuse of data and biological material research projects (e.g. registry projects).*
4.8	Liability and insurance needs	1. Assess whether insurance/liability is necessary and secure insurance/liability for a research project. Example: Researcher knows about the necessity of a project-specific insurance for category B (more than minimal risks) projects and sets up the insurance needed.	*Statement for HRO chapter 2 projects is **not applicable** for HRO chapter 3. Further use of data and biological material research projects only include data breach and thus minimal risks. Consider specific conditions regarding data breach in contractual agreements in case of data or biological material transfers.*

Competency domain 5: **Project and site management:** Encompasses the content required at the site level to run a human research project with the exception of clinical trials (e.g. infrastructural, financial, and personnel aspects); includes site and project operations (not necessarily encompassing regulatory guidelines)			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
5.1	Determine who shall sponsor, lead, or participate in a research project	1. Provide input and guidance on research project selection at institutional level, including the assessment of the financial and logistical feasibility of conducting the research project at a certain site. 2. Defend research project selection decision-making, including the determination of scientific validity and value, favourable risk/benefit ratio, and operational (logistical and financial) feasibility. 3. Lead the negotiation and creation of tools, guidance documents, and policies supporting the decision-making process in research project selection and participation. Example 1: Researcher completes a feasibility assessment checklist for a new potential research project, including budget estimates. Example 2: Researcher creates a project feasibility tool used throughout the institution to evaluate assessments for recommendations.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
5.2	Financial aspects, timelines, infrastructure, and personnel resources	1. Develop the budget, timeline, and/or infrastructure and personnel resources needed to conduct a research project (project planning responsibilities). 2. Lead budget negotiations and funding agreements. Allocate and manage research budgets and forecasting. Manage personnel assigned to the research project. 3. Monitor the progress of a research project towards milestones and identify trends or risks (e.g. financial constraints) during project execution. Implement mitigation plans. 4. Maintain accurate accounts, manage expenses, synthesise financial information from multiple sources to create reports, and ensure up-to-date financial information is available. Example 1: Researcher analyses a research project budget to ensure all requirements of the protocol are included. Example 2: Researcher generates amendments to a project budget and milestone timelines to reflect new requirements for an amended protocol and to address unforeseen cost issues for the conduct of a research project.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

5.3	Application for funding	1. Know major funding bodies and understand the funding application process, including requirements. 2. Plan costings and resources for funding. 3. Develop risk-based strategies to run research projects cost-effectively. Example 1: Researcher independently writes and submits funding applications. Example 2: Researcher addresses funder`s interests by developing original and scientifically relevant projects.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
5.4	Management and training approaches to mitigate risks	1. Implement risk mitigation measures and mechanisms in a research project, primarily by using or developing a quality management system (QMS). 2. Define key performance indicators for research projects and incorporate them into the project-specific QMS plans. 3. Interpret internal QA data on key performance indicators of a research project and apply strategies to mitigate risk through a CAPA plan. Example 1: Researcher communicates the relevance and overall scope of a project specific QMS plan to the research team. Example 2: Researcher analyses and reports quality audit findings or triggered key performance indicators, presents them during research team meetings to develop project-specific mitigation strategies, and/or to incorporate them in a general QMS training programme.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
5.5	Strategies to manage participant recruitment, retention, compliance (HRO chapter 2) or existing data and biological material (HRO chapter 3), and project activities	1. Articulate expected participant recruitment and retention rates and propose appropriate tools, strategies and procedures for recruitment and retention tracking. 2. Innovate solutions to recruitment and retention challenges incorporating key ethical considerations (e.g. Public and Patient Involvement, PPI) and international/national regulatory requirements. Example 1: Researcher creates a recruitment plan that addresses the needs of the project population and develops participant flyers that may facilitate recruitment. Example 2: Researcher creates innovative solutions that are evidence-based and clearly address the specific needs of hard-to-reach/engage populations for a research project with varying recruitment or retention. The solution includes plans to frequently review the success of the strategies.	1. Check availability of health-related data/biological material according to project-specific inclusion criteria on institutional, regional, national, or international level. 2. Check if institutions/sites to involve make use of General Consent (GC) to facilitate participant recruitment for further use research projects. If needed, develop a specific ICF and contact participants to ask them to consider consenting to the further use of some of their health related-data and/or of sampled biological material. 3. Be aware of Art. 34 Human Research Act (HRA), allowing exceptional further use of health-related data or biological material in case of impossible or difficult contact of suitable project participants or their legal representatives. Example 1: Researcher makes use of automated data query systems on institutional, regional, or national level. Example 2: Researcher selects participants having accepted the General Consent (GC) to reduce effort and time-consuming measures for participant recruitment.
5.6	Legal responsibilities, liabilities, and accountabilities	1. Negotiate, organise, maintain, and appropriately process documents, such as contracts and agreements, insurance policy (if applicable), EC approvals and conflict of interest reporting. 2. Monitor systems and collaborate with institutional bodies (lawyer/ legal adviser, data protection officer or information security officer) to ensure compliance with	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.* *Further statements need to be considered:* 1. Plan the potential further use of research data for research purposes in all project documents.

		legal and ethical requirements as well as data governance in the conduct of a research project. 3. Develop and evaluate legal risk mitigation strategies (e.g. SOPs or guidance documents), associated action plans, and issue resolution. Example 1: Researcher reviews research project documents and checks if all are in line with regulatory requirements to ensure a compliant project site. Example 2: Researcher serves on a conflict of interest board for an institution.	2. Be aware of the policies and conditions for further use of health-related data and/or biological material on institutional, regional, or national level, such as specific data governances. Example 1: Researcher contributes to the development and installation of a GC form at institutional level. Example 2: Researcher develops a project specific ICF stating the source, type of data and/or biological material for a further use project and the conditions of use and transfer to third parties.
5.7	Procedural, documentation, and oversight requirements	1. Apply an advanced understanding of the different roles of all stakeholders (EC, sponsor, project leader, data manager, etc.) and their responsibilities to the compliant conduct of a research project. 2. Be able to accurately interpret regulatory guidance and mentor others in the translation of regulations into everyday practice. 3. Create strategies, policies, and procedures to ensure regulatory compliance (e.g. concerning data governance) at departmental or institutional level. 4. Apply principles of good documentation practice (e.g. project folders). Example 1: Researcher reviews and assesses research project regulatory documents and successfully processes an EC submission for a new research project. Example 2: Researcher generates a task delegation log that outlines roles and responsibilities of research team members in conducting a research project.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
5.8	Performance and oversight of project related tasks	1. Recruit research teams, quality control teams, and oversight committees such as steering committee as needed. 2. Oversee the entire research project conduct including personnel resources, third party activities and site(s) management. Track research project progress and timeliness in terms of recruitment, milestones, objectives and targets, notification and/or reporting deadlines, as well as close-out activities. Example 1: Researcher plans and conducts research project initiation and termination for participants (if applicable), research site(s), committees and third parties, e.g. a laboratory or a biobank. Example 2: Researcher tracks the progress of a research project by means of tracking tools or an appropriate software and determines progress against planned objectives, targets, and timelines.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
5.9	Communication: reporting, facilitating and/or attending meetings	1. Assume responsibility for the quality, coordination, medical (if applicable) and scientific accuracy, and timeliness of relevant notifications and reporting. 2. Report appropriately within the research team (e.g. on workload, logistics, status of the project), to third parties and involved regulatory stakeholders.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

		3. Prepare for, participate, and present at meetings to properly address target audience. Example 1: Researcher collects and assesses Serious Events (SEs), prepares notifications, and sends reports according to regulatory timelines, when required. Example 2: Researcher organises and conducts meetings or teleconferences and ensures that the right people are invited, makes practical arrangements, prepares agendas, writes minutes, delegates tasks, as appropriate.	
5.10	Securing or maintenance of contracts	1. Initiate required contracts (e.g. site agreements, agreements with subcontractors, data access and/or data and material transfer and use agreements) and oversee detailed content and policies. 2. Ensure that specified contracted and/or subcontracted responsibilities are handled and documented according to the signed agreement. Example 1: Researcher appropriately writes and reviews contracts in compliance with potential confidentiality requirements. Researcher signs contracts if authorised by the institution and/or organises the signing of contracts. Example 2: Researcher knows at any time where to find existing third party-contracts (e.g. with a laboratory or a biobank).	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

Competency domain 6: **Data management:** Encompasses how data are acquired and managed during human research projects with the exception of clinical trials, including source data, data entry, queries, quality control, correction, and database lock			
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6.1	Importance of data management in human research projects	1. Understand the purpose of data that are collected in a research project. Example: When reviewing a protocol and CRF, researcher understands the CRF has to match with the protocol and recognises the data points that are associated with the analysis, especially the endpoints/outcomes.	*Statement for HRO chapter 2 also apply to HRO chapter 3 research projects.*
6.2	Origin, flow, and management of data through human research project	1. Apply all aspects of the Data Management Plan (DMP) to a research project with regards to the flow of data (collection, archiving, transmission to an open data repository, etc) from the *participant recruitment site* to the database, including managing of queries. Example: Researcher understands the purpose and scope as well as the process workflow of data collection and data cleaning by resolving queries.	1. Apply all aspects of the flow of data (collection, archiving, transmission to an open data repository, etc) from the *original source* to the database, including managing of queries as described in the research protocol or Data Management Plan (DMP).
6.3	Data collection, capture, management, security, analysis, and reporting - best practices	1. Design a database appropriately for data specifications: choose appropriate data types (i.e. limit free text fields), reflect workflow and the chronological order of data collection, keep data analysable and include all hypothesis (i.e. endpoints/outcomes). Add appropriate user requirements, edit rules, and data validations; build and test the database accordingly and ensure that the database supports an audit trail. 2. Understand all aspects of ethics requirements, especially regarding data protection and security (i.e. pseudonymisation) of participants. 3. Know national initiatives for creating FAIR (findable, accessible, interoperable, reusable) data, apply standards as much as possible within the project and be aware of open data policies. Example 1: Researcher develops an annotated CRF for the project, adds test data and creates a test export. Example 2: Researcher identifies when a change in a CRF draft is needed to avoid recurrent queries.	1. Design a database appropriately to the pre-existing data set, user requirements, and data validations; build and test a database accordingly and ensure that the database supports an audit trail. 2. Understand all aspects of ethics requirements, especially regarding pseudonymisation of subjects. Example: Researcher develops an annotated database for a specific project and adds test data (manually or as a batch import).
6.4	Data quality assurance processes	1. Ensure that data collected in a research project are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available. Example: Researcher enters data from a source document into an eCRF, refers to edit checks and discusses missing data.	1. Recognise whether data collected in a research project are attributable, legible, original, accurate, complete, consistent, enduring, and available. Example: Researcher transfers the pre-existing data set or imports data into an database, refers to data validations and discusses missing data.

Competency domain 7: **Leadership and professionalism:** Encompasses the principles and practices of leadership and professionalism in human research projects with the exception of clinical trials			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
7.1	Leadership, management, and mentorship	1. Train and mentor new research team members. 2. Manage multiple complex human research projects, use effective communication and documentation. 3. Set strategic planning goals and objectives for research project performance. 4. Provide leadership and strategic vision to one's organisation and encourage the evaluation of current service and change where necessary. 5. Encourage a culture of continual improvements in the department, encourage the streamlining of processes, and guide colleagues through the process of change. 6. Contribute to the development and updating of research policies and procedures in one's department or nationally. 7. Share best practices in clinical research to develop capacity, whether within the organisation or further afield. 8. Establish and maintain relationships with a strategic network of scientists and collaborators to facilitate the work of the department and build capacity. Example: Researcher manages research teams, develops budgets, assists with contracts for research projects, and conducts a protocol implementation meeting.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
7.2	Prevention and management of conflicts of interest	1. Assess the risk of ethical and professional conflicts inherent in a research project. 2. Develop strategies and policies to implement and manage the risk of ethical and professional conflicts across a research team as well as functional domains. 3. Take personal responsibility for all decisions and actions. Example: Researcher appraises the potential risks (both ethical and professional) inherent in the conduct of a research project and develops a framework for risk management for a department or a research team.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
7.3	Ethical guidelines and codes applying to human research projects	1. Apply professional and ethical regulations and international guidelines in each facet of clinical research. 2. Evaluate, and modify when required, internal policies and procedures to ensure that the organisation's code of ethical conduct is compliant with national and international regulations and guidelines 3. Mentor, educate, and provide guidance to all research team members on internal processes and procedures which ensure that all aspects of research projects are conducted within the bounds of ethical conduct	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

		Example: Researcher ensures that all national and international regulations and guidelines are reflected in SOPs and processes by adapting any established procedures, processes, or workflows to reflect any new or updated regulations and/or guidelines (e.g. training documentation).	
7.4	Integration of regional and cultural diversity in human research project design and conduct	1. Develop and apply specific strategies or methods for considering culture and region/country when designing and conducting research projects in multiple regions/countries. 2. Validate that regulatory requirements are incorporated into the project design for multi-country research projects. Example: Researcher proposes specific strategies that can be employed in each region/country to ensure cultural and regional appropriateness when initiating a new research project.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
7.5	Interpersonal and organisational skills	1. Listen effectively and encourage open communication, diplomacy, and sensitivity; promote respect and courteous treatment of others. 2. Demonstrate negotiation skills: be able to discuss issues with people who disagree on a topic (conflict management/mediation skills). 3. Demonstrate advocacy and effective networking skills; build alliances and strategic partnerships. Example: Researcher solves conflicts between research team members and sets up new cooperation for a research project and adjusts if necessary.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

Competency domain 8: **Communications and teamwork:** Encompasses all elements of communication between the project leader and the other members of the research team, other collaborators and regulatory authority as well as an understanding of teamwork skills necessary for conducting a human research project according to HRO.			
C. ID	**Competency statement HRO (Short title)**	**Competency level: Project Leader for HRO research projects (collection of data and biological material – chapter 2)**	**Competency level: Project Leader for HRO research projects (further use of data and biological material – chapter 3)**
8.1	Relationship and communication with all stakeholders	1. Ensure relationship and communication with research team members, research sites and third parties (i.e. Patient and Public Involvement (PPI) representative). 2. Understand and describe the relationships and appropriate communication channels between ECs (if applicable FOPH, radiation), research project sites and third parties. Example: Demonstrates appropriate written and oral communication between stakeholders in the research project discussion.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
8.2	Scientific publication and dissemination of research findings	1. Comprehend that a traditional scientific publication describes the results of a research project in a structured and ordered format to contribute to generalisable knowledge and evidence-based practice. 2. Describe the links of research project findings and the current practice context to the relevant human population. 3. Define authorship and role of author and contributor as recommended by the international guidelines and publishers (i.e. International Committee of Medical Journal Editors, ICMJE). 4. Be aware of the concept of plagiarism and of requirements for citing others' work. 5. Prepare and/or deliver (oral or poster) presentations at conferences/meetings. 6. Write and edit manuscripts and apply the different requirements and formats of journals for submission. Example: Researcher reviews and discusses a published research publication associated with his/her research project.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
8.3	Communication of human research project findings to colleagues, advocacy groups and non-scientist community	1. Design reports and relate content and value of research project to colleagues and to the non-scientific community in writing and orally. Get help from PPI representatives to develop reports and information for the non-scientific community. 2. Identify and utilise reliable sources of information which communicate research project findings to the scientific and non-scientific communities. 3. Deliver effective presentation and adapt communication to audience. 4. Act as primary contact for authorities, media, etc. Example: Researcher explains the scientific findings of a research project in terms that can be understood also by the non-scientific community.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

8.4	Integration of multidisciplinary and inter-professional research teams	1. Understand the importance of an interdisciplinary research team and the values each member can bring to the research project. 2. Identify and recognise each member of the research team and his or her respective roles and responsibilities and understand that communication within research team is vital to the success of the research project. 3. Identify the possible major pitfall in logistics of the samples and address the issue with the research team members. Example: Researcher understands the professional roles and practice domains of all members of the research team.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*
8.5	Liaising or acting as a link	1. Liaise regularly and appropriately with the various groups and research team members – clinicians, pathologists, study nurses, PPI representatives and all the other stakeholders – to ensure the smooth and successful execution of research activities. Example: Researcher defines the role of each research team member in the implementation of a guideline or form.	*Statement for HRO chapter 2 also apply to HRO chapter 3 research projects.* Example: Researcher regularly connects with PPI representatives and connects the different team members to each other to ensure understanding and collaboration.

References

Joint Task Force for Clinical Trial Competency. (2020). *The Joint Task Force Core Competency Framework*. MRCT Center. Retrieved from https://mrctcenter.org/clinical-trial-competency/framework/overview/