EDUCATION
PLATFORM

HRA ORDINANCES REVISION 2024/2025: Comparing old and new requirements

HRA ordinances revision 2024/2025: part I 01Nov2024 and part II 01Mar2025

Disclaimer: For projects approved before 01Nov2024, the transitional provisions of the HRA ordinances apply. For this, please consult the SCTO Regulatory Affairs Platform document «Revision of the HRA ordinances – Impact on projects approved before 01Nov2024».

This document is limited to changes to the HRA Ordinances that are relevant to researchers. Changes to the Ordinance on Organisational Aspects of the Human Research Act (OrgO-HRA) are not reflected herein, as they pertain solely to the activities of ethics committees and authorities.

This overview has been prepared by the SCTO Education Platform as a practical resource for sponsors, investigators, and other study staff. For legally binding requirements, please consult the HRA ordinances. For project-specific inquiries, contact your local CTU, the ethics committee, and, where applicable, Swissmedic or the FOPH.

Content

1 Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (ClinO)

General provisions applying to all clinical trials under the ClinO

Terminology/ Wording			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Application for a research project	Change	«authorisation» «authorisation procedure»	«approval» «approval procedure»
Scientific integrity	Change	«Principles and Procedures for Integrity in Scientific Research»	«code of conduct for scientific integrity»
Regulatory authority providing permission for the conduct of a research project	Change	«the Agency»	«Swissmedic»
Notification and reporting	Change	«reported», «reporting»	«notified», «notification» (changed where «reported» or «reporting» was used instead of «notified» or «notification»)
Filing an objection	Change	«to dissent»	«to object»
Amendment	Change	«change» «significant»	«modification» «substantial»

Definitions			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Clinical trial	Change	«… to undergo a health-related intervention in order to study its effects …»	«… means a research project involving individuals that prospectively assigns them to undergo one or more interventions in order to study the effects thereof on health or on the structure and function of the human body» *(ClinO Art. 2 let. a)*
Intervention	Change	«health-related intervention means a preventive, diagnostic, therapeutic, palliative or rehabilitative measure investigated in a clinical trial»	«intervention means any measure to which the participant is subjected and whose effects on this person are to be investigated» *(ClinO Art. 2 let. b)*
Minimal risks and burdens	Change	…means risks and burdens, ...: 6. examinations using ionising radiation, provided that the effective dose is below 5 mSv per research project and per person concerned and: - The medicinal product used is authorised or exempt from authorisation, or - The medical devices bear a conformity mark and no contrast medium is used; …	minimal risks and burdens mean risks and burdens, ...: 6. accompanying examinations involving ionising radiation, provided that the effective dose is below 5 mSv per research project and per participant, no contrast medium is used, and: - The radiopharmaceuticals employed are used in accordance with the authorisation or are exempt from authorisation, or - The medical devices employed bear a conformity mark and are used in accordance with the instructions for use; … *(ClinO Art. 2 let. c no. 6)*
Surplus information	New	-	«surplus information means results relating to a specific person, in particular incidental findings, which arise in the course of a clinical trial and which are not required either for the conduct thereof or to answer the scientific question» *(ClinO Art. 2 let. f)*

Investigational Medicinal Product (IMP)	New	-	«investigational medicinal product means a product which is being tested or used as a reference, including as a placebo, in a clinical trial of medicinal products» *(ClinO Art. 2 let. g)*
Placebo	New	-	«placebo means a product that does not contain an active substance» *(ClinO Art. 2 let. h)*

Investigator Qualification			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Professional qualification	New	-	The clinical trial investigator must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure compliance by calling in appropriate expertise. (*ClinO Art. 6 para. 1 let. c*)

Design & Planning			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Inclusion of relevant groups of persons	New	-	Inclusion of groups of persons that are relevant for answering the scientific question, particularly regarding sex and age, must be ensured. Any exclusion or deliberate underrepresentation of relevant groups must be declared and justified. (*ClinO Art. 4a*)

Information and Consent			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024/01Mar2025**
Information of the trial participant	New	-	The trial participant must be informed about: - The chance that surplus information may appear, and how important it is - both the discovery itself and the choice to know or not know about it. (*ClinO Art. 7 para. 1 let. e^{bis}*) - When the lay summary of the trial results is expected to be published and under what HumRes-number (or old SNCTP-number) it can be found. (*ClinO Art. 7 para. 1 let. h^{bis}*)
Information in case of genetic testing	New	-	1. If genetic testing is done for presymptomatic, prenatal, or family planning reasons and reveals health-related results, the person must be informed about: a. The test's purpose, method, and meaning b. The disorder's type and frequency c. Possible medical, psychological, and social effects d. What the results could mean for them and their family, and their right not to know. 2. In presymptomatic testing, they must also be told when insurers may request genetic data. (*ClinO Art. 7a; HGTA Art. 3 let. e, g, i, Art. 43-44*)
Information in case of prenatal risk assessment	New	-	If prenatal risk assessment is conducted, the pregnant woman must additionally be informed about a. The test's purpose, nature, and meaning b. The possibility of an unexpected result c. Possible follow-up examinations d. Information and counseling centers e. Her rights regarding consent, information, and the right not to know (*ClinO Art. 7b, HGTA Art. 3 let. h, Art. 23*)

Form of consent	Change	Consent had to be obtained exclusively in written form (handwritten signature).	Possibility of eConsent 1. Consent must be signed by hand or electronically. 2. It must: a. Be dated b. Remain readable for the full retention period. 3. Electronic consent is allowed if: a. The person is clearly identified b. The method avoids rushed decisions c. It's securely protected from changes d. The method is explained in the application. 4. The person can choose to receive the consent documents on paper or electronically. (*ClinO Art. 7c*) ***Note:*** See also swissethics guidelines on electronic study information (eIC)
Communication of results	New	-	1. People have the right to know - or not to know – their health-related results from tests that meet current medical standards. 2. Results must be shared with the person if: a. The results must be notified to authorities according to law b. It involves public health measures c. It is required to protect the person (in case he/ she lacks capacity) or others' life or health. (*ClinO Art. 8a*)

Communication and Interaction with the Ethics Committee & Authorities			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Deadline for submission to the second approval authority	New	-	Deadline of 2 years for submission to the second approval authority after approval has been issued by the first such authority. A request for a deadline extension will be regarded as a substantial modification to the clinical trial (see below). In the event of non-compliance with this deadline, the initial approval will lapse (*ClinO Art. 23 para. 1bis-1^{quater}, Art. 50*)
Submission of the application to the ethics committee	Change	The application documents had be co-signed by the investigator, if instead of him the sponsor submitted the application to the ethics committee.	If instead of the investigator the sponsor submits the application to the ethics committee, the application documents no longer have to be co-signed by the investigator (*ClinO Art. 24, Art. 51, Art. 62 let. a*)
Application documents to be reviewed by the ethics committee	New	-	The responsible ethics committee shall review: …, d^{bis}. If applicable, compliance with the requirements for consent in electronic form, … e^{bis}. The considerations concerning the right of the potential participants to receive information, … (*ClinO Art. 25, Art. 51, Art. 62 let. a*)
Deadline for enrolment of the first participant/ the start of the trial	New	-	Deadline of 2 years for the enrolment of the first trial participant/ the start of the trial after issue of the last approval required (possibly longer for rare disease trials). A request for a deadline extension will be regarded as a substantial modification to the clinical trial. In the event of non-compliance with this deadline, the trial will be regarded as interrupted. (*ClinO Art. 23a, Art. 51, Ar. 62 let. a^{bis}*)
Submission of substantial modifications to the ethics committee	New	-	The following are considered to be substantial modifications: …, e. The extension of the 2-year-deadline concerning the application with the 2 different approval authorities (see above) as well as the deadline for the enrolment of the first trial participant (see above); the investigator shall indicate to the ethics committee whether the application documents are still up-to-date; if

			this is not the case, the investigator shall submit updated application documents. (*ClinO Art. 29 para 3 let. e, Art. 50, Art. 62 let. a*)
Submission of substantial modifications to Swissmedic or FOPH	New	-	The following are considered to be substantial modifications: …, d. The extension of the 2-year-deadline concerning the application with the 2 different approval authorities (see above) as well as the deadline for the enrolment of the first trial participant (see above); the sponsor shall indicate to Swissmedic or FOPH whether the application documents are still up-to-date; if this is not the case, the sponsor shall submit updated application documents. (*ClinO Art. 34 para 3 let. d, Art. 50, Art. 55 para 3 let. d*)
Notification and reporting to the ethics committee	Change	Instead of the investigator, the sponsor could overtake the notification and reporting obligations vis-à-vis the ethics committee, but only if he also submitted the application dossier to the ethics committee.	Instead of the investigator, the sponsor can overtake all notification and reporting obligations vis-à-vis the ethics committee. This must be stated for in the application dossier. (*ClinO Art. 44a, Art. 57*) ***Note:*** Newly this is also possible, if the sponsor has not submitted the application dossier to the ethics committee.

Use of accompanying Examinations involving Ionising Radiation			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Procedure	Change	FOPH had to review only studies including accompanying examinations with ionizing radiation from non-authorized drugs or non-CE-marked medical devices that in addition involved an actual radiation dose of more than 5mSv.	FOPH will newly review all studies including accompanying examinations with ionizing radiation using non-authorized drugs or non-CE-marked medical devices. (*ClinO Art 36a para. 2, Art. 51, Art. 62 let. a*) ***Note:*** The dose of more than 5mSv is not a criterion anymore, if the FOPH is involved in the approval procedure and has to provide an opinion to the ethics committee.

Liability Coverage and Data Retention			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Exemption from liability	Change	Exempt from liability were damages that were in line with current scientific knowledge and a. Similar harm could have happened with standard treatment, or b. No standard treatment exists for the life-threatening condition.	Exempt from liability is anyone who proves similar harm could have happened with standard treatment. (*ClinO Art. 10 para. 2*) ***Note:*** The extent of the damage and the criterion of acutely life-threatening disease are no longer relevant to liability exemption considerations, and have both been deleted.
Liability coverage	Change	The liability coverage had to cover damage occurring up to 10 years after the completion of the clinical trial.	The liability coverage must newly cover damage occurring up to 20 years after the completion of the clinical trial. (*ClinO Art. 13 para. 3*) ***Note:*** This change brings this legislation into line with the relevant new provisions of the Swiss Code of Obligations. (*CO Art. 60 para. 1bis*)
Data retention	Change	Clinical trial data and requisite documentation had to be retained for at least 10 years.	Clinical trial data and requisite documentation must be newly retained for at least 20 years. (*ClinO Art 45 paras. 1 and 2, 62 let. e*) ***Note:*** Data retention periods for clinical trials of transplant products and blood / blood products (according to *TPA Art. 40 para. 1)* as well as on transplantation (according to *Transplantation Act Art. 35*) remain unchanged.

Start, Completion, Premature Termination, Interruption, or Resumption of a Clinical Trial			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
First Participant First Visit (FPFV)	New	-	Ethics committee notification of the first visit of the first participant in the clinical trial in Switzerland within 30 days. (*ClinO Art. 38 para. 1 let. a, Art. 51, Art. 57 para. 1, Art. 62 let. c*)
Trial completion (Last Participant Last Visit (LPLV)) in Switzerland	Change	Ethics committee notification of completion of the clinical trial in Switzerland within 90 days.	Ethics committee notification of completion of the clinical trial in Switzerland within 30 days. (*ClinO Art. 38 para. 1 let. b, Art. 57 para. 1, Art. 62 let. c*)
Global trial completion	New	-	Ethics committee notification of global completion of a multinational clinical trial within 90 days. (*ClinO Art. 38 para. 1bis, Art. 57 para. 1, Art. 62 let. c*)
Premature trial termination, interruption and resumption	Change	Ethics committee notification of the discontinuation or interruption of the clinical trial within 15 days.	Ethics committee notification of the premature termination, interruption or resumption of the clinical trial within 15 days. An interruption lasting for more than 2 years is considered to be a premature termination. (*ClinO Art. 38 para. 2, Art. 57 para. 1, Art. 62 let. c*)
Final report	Change	Ethics committee submission of a final report within 1 year after completion or discontinuation of the clinical trial.	Ethics committee submission of a summary final report within 1 year after completion or premature termination of the clinical trial. (*ClinO Art. 38 para. 3, Art. 57 para. 1, Art. 62 let. c*)

Registration and Publication			
Topic	**New/ Change**	**ClinO before 01Mar2025**	**ClinO after 01Mar2025**
Registration	Change	Registration of the clinical trial in a primary registry recognized by the WHO or ClinicalTrials.gov and in SNCTP using a Swiss national language after approval and before the start of the clinical trial.	Registration of the clinical trial in a primary registry recognized by the WHO or ClinicalTrials.gov and in the Swiss registry HumRes in the national languages for the regions in which participant recruitment is envisaged. The registration must be regularly updated. Registration must take place before the conduct of the clinical trial, and within 6 months after approval has been granted. (*ClinO Art. 64, Art. 67, Annex 5*)
Registration of Phase I clinical trials	Change	Phase I clinical trials on medicinal products must be registered no later than 1 year after the completion of the clinical trial.	For Phase I clinical trials on medicinal products, certain registration details must also newly be published before the trial begins. The publication of certain business-relevant details may continue to be delayed up to 30 months after completion or early termination of the trial. (*ClinO Art. 64 para. 2bis, Annex 5*)
Publication of summary of results	New	-	Publication of summary of results in an international registry within 1 year (up to 30 months after completion or early termination of Phase I clinical trials). If a clinical trial is interrupted for more than 2 years, it is considered prematurely terminated and results must also be published. (*ClinO Art. 65a para. 1 and 3, Annex 5*)
Publication of lay summary	New	-	Publication of a lay summary in the Swiss registry HumRes in the national languages for the regions in which trial participants were recruited. This must also be done within 1 year of the trial's completion or premature termination. (*ClinO Art. 65a para. 2, Art. 67, Annex 5*)

Clincial Trials with Medicinal Products

Categorisation			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Category A	Change	Clinical trials fall under *Category A* if: 1. The medicinal product is authorised in Switzerland and 2. Its use: a. Follows the approved prescribing information, b. Used for a related condition (same ICD disease group) or at a lower dose for a self-limiting disease, or c. Is standard practice per international guidelines.	Clinical trials fall under *Category A* if: 1. The medicinal product is authorised in Switzerland, 2. It hasn't been modified, and 3. Its use meets one of the following: a. Follows the approved prescribing information, b. Used for a related condition (same ICD disease group) or at a lower dose for a self-limiting disease, or c. Is standard practice per international guidelines. (*ClinO Art. 19 para. 1*)
Category B	Change	Clinical trials fall under *Category B* if the medicinal product: 1. Is authorised in Switzerland but not used as per Category A …	Clinical trials fall under *Category B* if the medicinal product: 1. Is authorised in Switzerland but not used as per Category A, or has undergone a low-risk modification (see below), 2. Is authorised in a country with equivalent medicinal product control and is unmodified or low-risk modified, or 3. Is a placebo made for the clinical trial. (*ClinO Art. 19 para. 2*) ***Note:*** Low-risk modification means: 1. Modification to the secondary packaging, as long as it is not damaged, 2. Modification to the primary packaging (unless the product is a sterile medicinal product or an immunological product, and if the shelf life is not impaired),

			3. Modification by over-encapsulation of an otherwise unchanged solid product, as long as this does not affect absorption and shelf life is not impaired. (*ClinO Annex 2bis*)
Category C	Change	Clinical trials are Category C if the medicinal product is not authorised in Switzerland.	Clinical trials are Category C if the medicinal product contains an active substance and: 1. Is authorised in Switzerland or a country with equivalent medicinal product control but has been more than low-risk modified, or 2. Is not authorised in Switzerland or any country with equivalent medicinal product controls. (*ClinO Art. 19 para. 3*)

Safety Documentation, Notifications and Reporting			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Waived AEs in category C trials	New	-	In category C trials, the sponsor may, in justified exceptional cases, waive documentation of adverse events identified as not critical to the safety evaluation. (*ClinO Art. 39 para. 1bis*)
Documentation of AEs that are critical for safety evaluation	New	-	Terms 'critical / not critical to the safety evaluation' newly introduced for Category B and C clinical trials. Adverse events critical to the safety evaluation must always be documented in a standardised manner for Category B and C clinical trials. (*ClinO Art. 39 paras. 1bis and 2*)
Notification of fatal SAEs	Change	Ethics committee notification of a fatal serious adverse event occurring at a trial site in Switzerland within 7 days.	A fatal serious adverse event occurring at a trial site in Switzerland no longer needs to be reported to the ethics committee (*ClinO Art. 40*), unless it constitutes a SUSAR (see below).

Notification of SUSARs	Change	Ethics committee (and Swissmedic, if applicable) notification of a fatal suspected unexpected serious adverse reaction (SUSAR) occurring at a trial site in Switzerland within 7 days and any other SUSAR within 15 days.	Not only SUSARs with fatal consequences but also life-threatening SUSARs must be reported to the ethics committee (and Swissmedic, if applicable) within 7 days and any other SUSAR within 15 days. (*ClinO Art. 41 para. 2*)
Notification of SUSARs after trial completion	New	-	The SUSAR reporting requirements newly also apply to any SUSAR which occurs or is learned of after the completion of the clinical trial in Switzerland. (*ClinO Art.41 para. 4bis*)
Annual safety and progress report	Change	Submission of an annual safety report (ASR) to the ethics committee (and Swissmedic, if applicable)	Submission of an annual safety and progress report to the ethics committee (and Swissmedic, if applicable). (*ClinO Art. 43 para. 1*)

Clinical Trials on Transplantation of Human Organs, Tissues and Cells

Safety Documentation, Notifications and Reporting			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Waived AEs in category C trials	New	-	In category C trials, the sponsor may, in justified exceptional cases, waive documentation of adverse events identified as not critical to the safety evaluation. (*ClinO Art. 39 para. 1bis, Art. 57*)
Notification of SAEs	Change	Ethics notification of fatal serious adverse events (SAEs) occuring in Switzerland within 7 days and any other SAE within 15 days. Ethics as well as FOPH notification of fatal suspected unexpected serious adverse reactions (SUSARs) occuring in Switzerland within 7 days and any other SUSAR within 15 days.	Ethics committee (and FOPH, if applicable) notification of fatal and life-threatening serious adverse events (SAEs) occurring in Switzerland within 7 days and any other SAE within 15 days. (*ClinO Art. 57a para. 2*) ***Note:*** The term SUSAR does not play a role anymore in safety management and reporting for clinical trials on transplantation.
Notification of SAEs after trial completion	New	-	The SAE reporting requirements also apply to any SAE which occurs or is learned of after the completion of the clinical trial in Switzerland. (*ClinO Art.57a para. 5*)
Annual safety and progress report	Change	Submission of an annual safety report (ASR) to the ethics committee.	Submission of an annual safety and progress report to the ethics committee (and FOPH, if applicable). (*ClinO Art. 57b*)

Other Clinical Trials

Safety Documentation, Notifications and Reporting			
Topic	**New/ Change**	**ClinO before 01Nov2024**	**ClinO after 01Nov2024**
Annual safety and progress report	Change	Submission of an annual safety report (ASR) to the ethics committee.	Submission of an annual safety and progress report to the ethics committee. (*ClinO Art. 43 para. 1, Art. 62 let. d*)

2 Ordinance on Clinical Trials of Medical Devices (ClinO-MD)

General provisions applying to all clinical trials under the ClinO-MD

Terminology/ Wording			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Application for a research project	Change	«authorisation» «authorisation procedure»	«approval» «approval procedure»
Scientific integrity	Change	«Principles and Procedures for Integrity in Scientific Research»	«code of conduct for scientific integrity»
Notification and reporting	Change	«reported», «reporting»	«notified», «notification» (changed where «reported» or «reporting» was used instead of «notified» or «notification»)
Consent	Change	«withdrawal»	«revocation»
Liability	Change	«indemnification»	«coverage»
Trial milestones	Change	«end of the clinical trial»	«completion of the clinical trial»
Discontinuation	Change	«early termination»	«premature termination»

Investigator Qualification			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Professional qualification	New	-	The clinical trial investigator must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure compliance by calling in appropriate expertise. (*ClinO-MD Art. 5 para. 1 let. d*)

Design & Planning			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Inclusion of relevant groups of persons	New	**-**	Inclusion of groups of persons that are relevant for answering the scientific question, particularly regarding sex and age, must be ensured. Any exclusion or deliberate underrepresentation of relevant groups must be declared and justified. (*ClinO-MD Art. 3 para. 1 let. a, ClinO Art. 4a*)

Information and Consent			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024/01Mar2025**
Information of the trial participant	New	-	The trial participant must be informed about: - The chance that surplus information may appear, and how important it is - both the discovery itself and the choice to know or not know about it. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 7 para. 1 let. e^{bis})* - When the lay summary of the trial results is expected to be published and under what HumRes-number (or old SNCTP-number) it can be found. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 7 para. 1 let. h^{bis}*)
Information in case of genetic testing	New	-	1. If genetic testing is done for presymptomatic, prenatal, or family planning reasons and reveals health-related results, the person must be informed about: a. The test's purpose, method, and meaning b. The disorder's type and frequency c. Possible medical, psychological, and social effects d. What the results could mean for them and their family, and their right not to know. 2. In presymptomatic testing, they must also be told when insurers may request genetic data. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 7a; HGTA Art. 3 let. e, g, i, Art. 43-44*)
Information in case of prenatal risk assessment	New	-	If prenatal risk assessment is conducted, the pregnant woman must additionally be informed about: a. The test's purpose, nature, and meaning b. The possibility of an unexpected result c. Possible follow-up examinations d. Information and counseling centers e. Her rights regarding consent, information, and the right not to know. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 7b, HGTA Art. 3 let. h, Art. 23*)

Form of consent	Change	Consent had to be obtained exclusively in written form (handwritten signature).	Possibility of eConsent 1. Consent must be signed by hand or electronically. 2. It must: a. Be dated b. Remain readable for the full retention period. 3. Electronic consent is allowed if: a. The person is clearly identified b. The method avoids rushed decisions c. It's securely protected from changes d. The method is explained in the application. 4. The person can choose to receive the consent documents on paper or electronically. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 7c*) ***Note:*** See also swissethics guidelines on electronic study information (eIC)
Communication of results	New	-	1. People have the right to know - or not to know – their health-related results from tests that meet current medical standards. 2. Results must be shared with the person if: a. The results must be notified to authorities according to law b. It involves public health measures c. It is required to protect the person (in case he/ she lacks capacity) or others' life or health. (*ClinO-MD Art. 3 para. 1 let. b, ClinO Art. 8a)*

Communication and Interaction with the Ethics Committee & Authorities			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Submission of the application to the ethics committee	Change	The application documents had to be co-signed by the sponsor, if instead of him the investigator submitted the application to the ethics committee.	If instead of the sponsor the investigator submits the application to the ethics committee, the application documents no longer have to be co-signed by the sponsor. (*ClinO-MD Art. 10 para. 3*)
Application documents to be reviewed by the ethics committee	New	-	The responsible ethics committee shall review: …, d^{bis}. If applicable, compliance with the requirements for consent in electronic form, … e^{bis}. The considerations concerning the right of the potential participants to receive information, … (*ClinO-MD Art. 11, ClinO Art. 25*)

Use of accompanying Examinations involving Ionising Radiation			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Procedure	Change	FOPH had to review only studies including accompanying examinations with ionizing radiation from non-authorized radiopharmaceuticals that involved an actual radiation dose of more than 5mSv per person per year.	FOPH will newly review all studies including accompanying examinations with ionizing radiation using non-authorized radiopharmaceutical or non-CE-marked medical devices. (*ClinO-MD Art. 14 para. 2*) ***Note:*** The dose of more than 5mSv is not a criterion anymore, if the FOPH is involved in the approval procedure and has to provide an opinion to the ethics committee.
Assessment of compliance with the dose constraint	Change	Before, the sponsor was supposed to assess the compliance with the dose constraint.	The investigator shall assess compliance with the dose constraint. (*ClinO-MD Art. 39 para. 1*)

Reporting of exceedance of the permitted dose constraint	Change	So far only the sponsor could notify an exceedance of the permitted dose constraint within 7 days to the ethics committee.	Now, either the investigator or the sponsor can notify an exceedance of the permitted dose constraint within 7 working days to the ethics committee. (*ClinO-MD Art. 39 para. 2)*

Liability Coverage and Data Retention			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Exemption from liability	Change	Exempt from liability were damages that were in line with current scientific knowledge and a. similar harm could have happened with standard treatment, or b. no standard treatment exists for the life-threatening condition.	Exempt from liability is anyone who proves similar harm could have happened with standard treatment. (*ClinO-MD Art. 3 para. 1 let. c, ClinO Art. 10 para. 2*) ***Note:*** The extent of the damage and the criterion of acutely life-threatening disease are no longer relevant to liability exemption considerations, and have both been deleted).
Liability coverage	Change	The liability coverage had to cover damage occurring up to 10 years after the completion of the clinical trial.	The liability coverage must newly cover damage occurring up to 20 years after the completion of the clinical trial. (*ClinO-MD Art. 3 para. 1 let. c, ClinO Art. 13 para. 3*) ***Note:*** This change brings this legislation into line with the relevant new provisions of the Swiss Code of Obligations. (*CO Art. 60 para. 1bis*)
Data retention			***Note:*** The data retention requirement for medical devices remains unchanged at 10 years, or 15 years for implantable devices even though the liability coverage was extended up to 20 years. (*ClinO-MD Art. 40)*

Safety Documentation, Notifications and Reporting			
Topic	**New/ Change**	**ClinO-MD before 01Nov2024**	**ClinO-MD after 01Nov2024**
Annual safety and progress report	Change	Submission of an annual safety report (ASR) to the ethics committee (and Swissmedic, if applicable)	Submission of an annual safety and progress report to the ethics committee (and Siwssmedic, if applicable). (*ClinO-MD Art. 35 para. 1*)

Registration and Publication			
Topic	**New/ Change**	**ClinO-MD before 01Mar2025**	**ClinO-MD after 01Mar2025**
Registration	Change	Registration of the clinical trial in a primary registry recognized by the WHO or ClinicalTrials.gov and in SNCTP using a Swiss national language after approval and before the start of the clinical trial.	Registration of the clinical trial in a primary registry recognized by the WHO or ClinicalTrials.gov and in the Swiss registry HumRes in the national languages for the regions in which participant recruitment is envisaged. The registration must be regularly updated. Registration must take place before the conduct of the clinical trial, and within 6 months after approval has been granted. (*ClinO-MD Art. 41*, *ClinO Art. 64, Art. 67, Annex 5*)
Publication of summary of results	Change	The sponsor had to publish the results of clinical trials with medical devices in a recognised register.	The sponsor must ensure that a summary of the trial results is entered and published in a recognised registry. (*ClinO-MD Art. 42 para. 1*)
Publication of lay summary	New	-	Publication of a lay summary in the Swiss registry HumRes in the national languages for the regions in which trial participants were recruited. (*ClinO-MD Art. 42 para.2*)

Extension of publication period	New	-	The deadlines for publishing the results may be modified. But such modifications must be requested by the sponsor (with appropriate reasons) in the trial's application documentation, including the intended publication date. (*ClinO-MD Art. 42 para. 3*)

3 Ordinance on Human Research with the Exception of Clinical Trials (HRO)

General provisions applying to all HRO research projects

Terminology/ Wording			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Application for a research project	Change	«authorisation» «authorisation procedure»	«approval» «approval procedure»
Scientific integrity	Change	«Principles and Procedures for Integrity in Scientific Research»	«code of conduct for scientific integrity»
Filing an objection	Change	«to dissent»	«to object»
Amendment	Change	«change» «significant»	«modification» «substantial»
Research project	Change	«proposed»	«intended» (in connection with «research», «further use», «anonymisation»)
Research project milestones	Change	«discontinuation»	«premature termination»

Definitions			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Surplus information	New	-	«surplus information means results relating to a specific person, in particular incidental findings, which arise in the course of a research project and which are not required either for the conduct thereof or to answer the scientific question» *(HRO Art. 1a)*
Minimal risks and burdens	Change	…means risks and burdens, ...: f. examinations using ionising radiation, provided that the effective dose is below 5 mSv per research project and per person concerned and: 1. The medicinal product used is authorised or exempt from authorisation, or 2. The medical devices bear a conformity mark and no contrast medium is used.	minimal risks and burdens mean risks and burdens, ...: f. accompanying examinations involving ionising radiation, provided that the effective dose is below 5 mSv per research project and per person concerned, no contrast medium is used, and: 1. the radiopharmaceuticals employed are used in accordance with the authorisation or are exempt from authorisation, or 2. the medical devices employed bear a conformity mark and are used in accordance with the instructions for use. *(HRO Art. 7 para 3 let. f)*
Anonymisation	Change	1. Biological material and health data must be anonymised so that no one can identify the person without unreasonable effort. This means especially removing or masking names, addresses, dates of birth, and ID numbers.	1. Biological material and health data must be anonymised so that identifying a person is impossible, or only possible with disproportionate effort. 2. Anonymisation must use current state of the art methods. Personal details that could reveal identity (e.g. name, address, date of birth, ID numbers) must be deleted or changed. The anonymisation method must be documented, including the remaining risk of re-identification. (*HRO Art. 25*)

Coding	Change	1. Biological material and health data are considered properly coded if, without access to the key, they appear anonymised. The key must be stored separately by a person named in the application who is not part of the research project.	1. Biological material and health data are correctly coded if linking them to a specific person is only possible with disproportionate effort, unless one has access to the key or source data. 2. Coding must use current state of the art methods. The key must be stored separately by a person or organizational unit named in the application who is not part of the research project. (*HRO Art. 26*)

Project Leader Qualification			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Professional qualification	New	-	The project leader must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure compliance by calling in appropriate expertise. (*HRO Art. 4 para. 1 let. d)*

Design & Planning			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Inclusion of relevant groups of persons	New	**-**	Inclusion of groups of persons that are relevant for answering the scientific question, particularly regarding sex and age, must be ensured. Any exclusion or deliberate underrepresentation of relevant groups must be declared and justified. (*HRO Art. 2 let. c, ClinO Art. 4a*)

Biological Material			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Storage	Change	Any person who stores biological material ensures that the technical requirements are met for appropriate storage of the biological material.	Any person who stores biological material ensures that the technical requirements are met for appropriate storage of the biological material according to national and international guidelines. (*HRO Art. 5 para. 2 let. b*)

Information and Consent			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Information of the research project participant	New	-	The research project participant must be informed about: - The chance that surplus information may appear, and how important it is - both the discovery itself and the choice to know or not know about it. (*HRO Art. 8 para. 1 let. d^{bis}*)
Information in case of genetic testing	New	-	1. If genetic testing is done for presymptomatic, prenatal, or family planning reasons and reveals health-related results, the person must be informed about: a. The test's purpose, method, and meaning b. The disorder's type and frequency c. Possible medical, psychological, and social effects d. What the results could mean for them and their family, and their right not to know. 2. In presymptomatic testing, they must also be told when insurers may request genetic data. (*HRO Art. 5a, Art.8a; HGTA Art. 3 lit. e, g, i, Art. 43-44*).

Information in case of prenatal risk assessment	New	-	If prenatal risk assessment is conducted, the pregnant woman must additionally be informed about: a. The test's purpose, nature, and meaning b. The possibility of an unexpected result c. Possible follow-up examinations d. Information and counseling centers e. Her rights regarding consent, information, and the right not to know. (*HRO Art. 8b, HGTA Art. 3 let. h, Art. 23*)
Form of consent	Change	Consent had to be obtained exclusively in written form (handwritten signature).	Possibility of eConsent 1. Consent must be signed by hand or electronically. 2. It must: a. Be dated b. Remain readable for the full retention period. 3. Electronic consent is allowed if: a. The person is clearly identified b. The method avoids rushed decisions c. It's securely protected from changes d. The method is explained in the application. 4. The person can choose to receive the consent documents on paper or electronically. (*HRO Art. 8c, Art. 28-29, Art. 31, 44 para. 3*) ***Note:*** See also swissethics guidelines on electronic study information (eIC)
Communication of results	New	-	1. People have the right to know - or not to know – their health-related results from tests that meet current medical standards. 2. Results must be shared with the person if: a. The results must be notified to authorities according to law b. It involves public health measures c. It is required to protect the person. (in case he/ she lacks capacity) or others' life or health. (*HRO Art. 9a*)

Research involving Measures for Sampling of Biological Material or Collection of Health-related Personal Data from Persons (HRO Chapter 2 projects)

Communication and Interaction with the Ethics Committee			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Application documents to be reviewed by the ethics committee	New	-	The responsible ethics committee shall review: …, c^{bis}. if applicable, compliance with the requirements for consent in electronic form, … d^{bis}. the considerations concerning the right of the potential participants to receive information, … (*HRO Art. 15*)
Application documents to be reviewed by the ethics committee	Change	Application documents: 1.1 Basic form, including a summary of the protocol in the national language of the research site and reasons for the requested categorization …	Application documents: 1.1 Administrative information, including a summary of the protocol and reasons for the requested categorization … (*HRO Annex 2*) ***Note:*** The application no longer needs to include a summary of the research plan in the national language of the project site.
Submission of substantial modifications to the ethics committee	Change	The following are considered to be significant changes: …, b. in the case of a Category B research project, changes to the protocol which concern the goal or the central topic of the research project …	The following are considered to be substantial modifications: …, b. modifications to the protocol which concern the goal or the central topic of the research project … (*HRO Art. 18 para. 3 let. b*) ***Note:*** Modifications to the protocol of Category A research projects that affect the goal or central topic of the project are now also considered substantial modifications.

Use of accompanying Examinations involving Ionising Radiation			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Procedure	Change	FOPH had to review only studies including accompanying examinations with ionizing radiation from non-authorized radiopharmaceutical that involved an actual radiation dose of more than 5mSv per person per year.	FOPH will newly review all studies including accompanying examinations with ionizing radiation using non-authorized radiopharmaceutical or non-CE-marked medical devices. (*HRO Art. 19 para. 2*) ***Note:*** The dose of more than 5mSv is not a criterion anymore, if the FOPH is involved in the approval procedure and has to provide an opinion to the ethics committee.

Liability Coverage and Data Retention			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Exemption from liability	Change	A person is not liable under HRA Art. 19 para. 1 if they can show that: 1. the damage is minor and temporary; and 2. the damage is no worse than what could reasonably be expected given current scientific knowledge.	There are no exemptions from liability anymore. HRO Art. 12 was abolished.
Data retention	New	-	The project leader must retain all the research project data for a period of at least 10 years after the completion or premature termination of the research project. (*HRO Art. 23a*)

Milestones of a Research Project			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Completion	New	-	A research project is completed when the last health-related personal data is collected or the last biological sample is taken, unless the protocol says otherwise. (*HRO Art. 6a*)

Further Use of Biological Material and Health-related Personal Data o (HRO Chapter 3 projects)

Communication and Interaction with the Ethics Committee			
Topic	**New/ Change**	**HRO before 01Nov2024**	**HRO after 01Nov2024**
Application documents to be reviewed by the ethics committee	New	-	The responsible ethics committee shall review: …, b^{bis}. the scientific quality, … (*HRO Art. 34*)