Schweizerische Eidgenossenschaft
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**Bundesamt für Gesundheit BAG**
**Office fédéral de la santé publique OFSP**
**Ufficio federale della sanità pubblica UFSP**
**Federal Office of Public Health FOPH**

swissethics

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# Partial revision of the HRA and StRA ordinances

Information for enforcement authorities
and researchers

Latest update: 30.07.2024

HRA: Human Research Act; StRA: Stem Cell Research Act

# Introductory remarks

This presentation has been jointly compiled by the Federal Office of Public Health (FOPH), swissethics and Swissmedic.

It is intended to provide comprehensive and understandable information on the modifications to the ordinances of the HRA of 7 June 2024.

Its content will be constantly updated to reflect the latest status of the publication and the entry into effect of the ordinances concerned.

Further detailed information on the individual modifications will be found in the explanatory report (available in German, French or Italian) on the partial revision.

# Contents

# Approval by the Federal Council, entry into effect, publications and links

- The Federal Council formally approved the modifications to the HRA's implementing legislation on 7 June 2024.
- The modifications enter into effect on 1 November 2024, with the exception of the new transparency provisions, which come into effect on 1 March 2025.
- Information on the modifications will be found on the following webpages:

Amendment of the HRA ordinances | Kofam

Current legislative project: Revision of Ordinances (admin.ch)

https://swissethics.ch/en/templates

Swissmedic: Clinical trials

# Publication of the revised ordinances

- The modified ordinances have been published in the Classified Compilation (SR):

  Human Research Ordinance (HRO)

  Clinical Trials Ordinance (ClinO)

  Ordinance on Clinical Trials with Medical Devices (ClinO-MD)

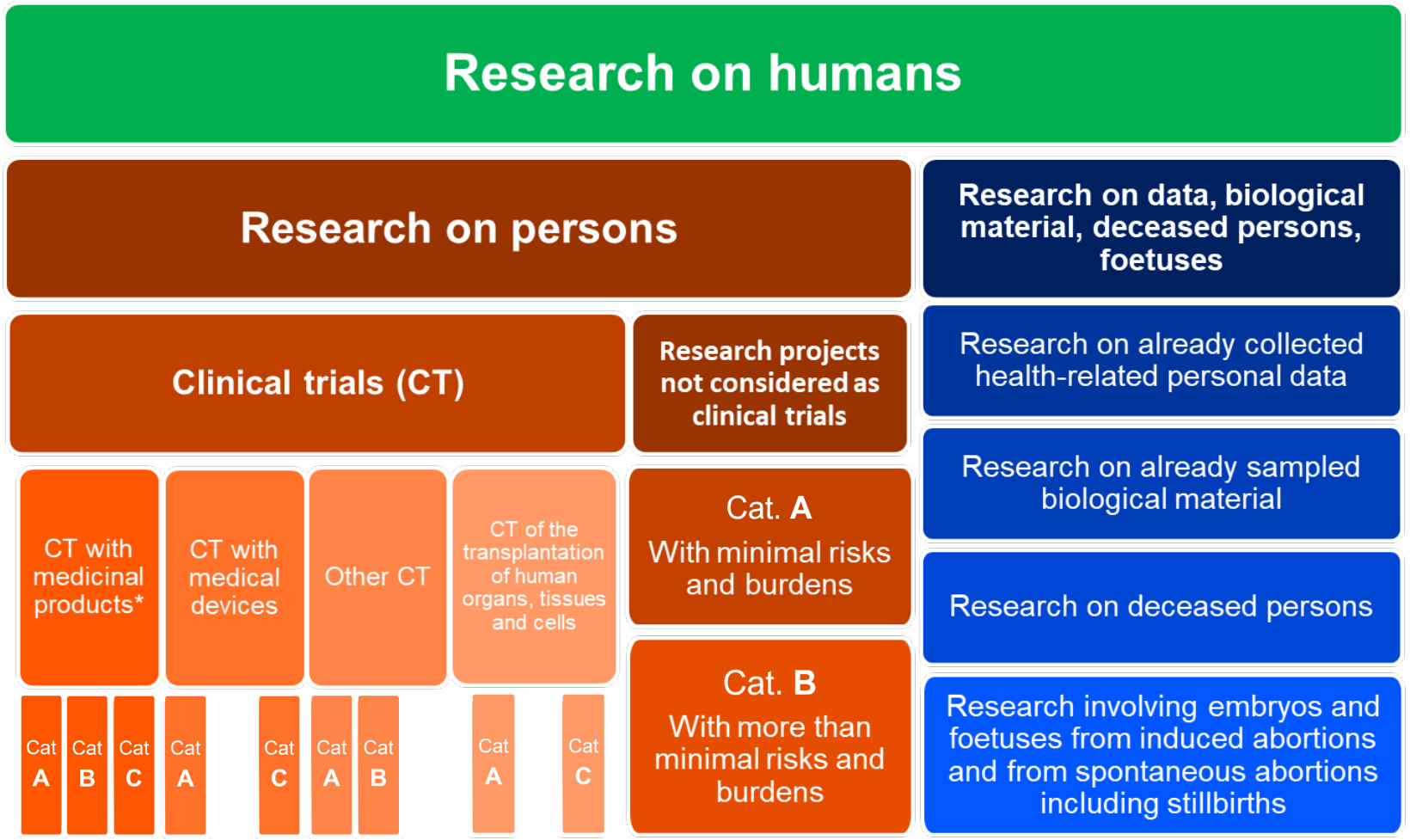
  HRA Organisation Ordinance (OrgO-HRA)

  Stem Cell Research Ordinance (SCRO)

- The ‘All versions of this law’ box on the left can be used to select the version(s) desired. The versions of the above ordinances which come into effect on 1 November 2024 (and on 1 March 2025 in the case of the ClinO and the ClinO-MD) will also be found here.
- The ordinances are available in the three national languages of German, French and Italian. English versions should also be available by October 2024.

# Overview of the provisions for human research in Switzerland

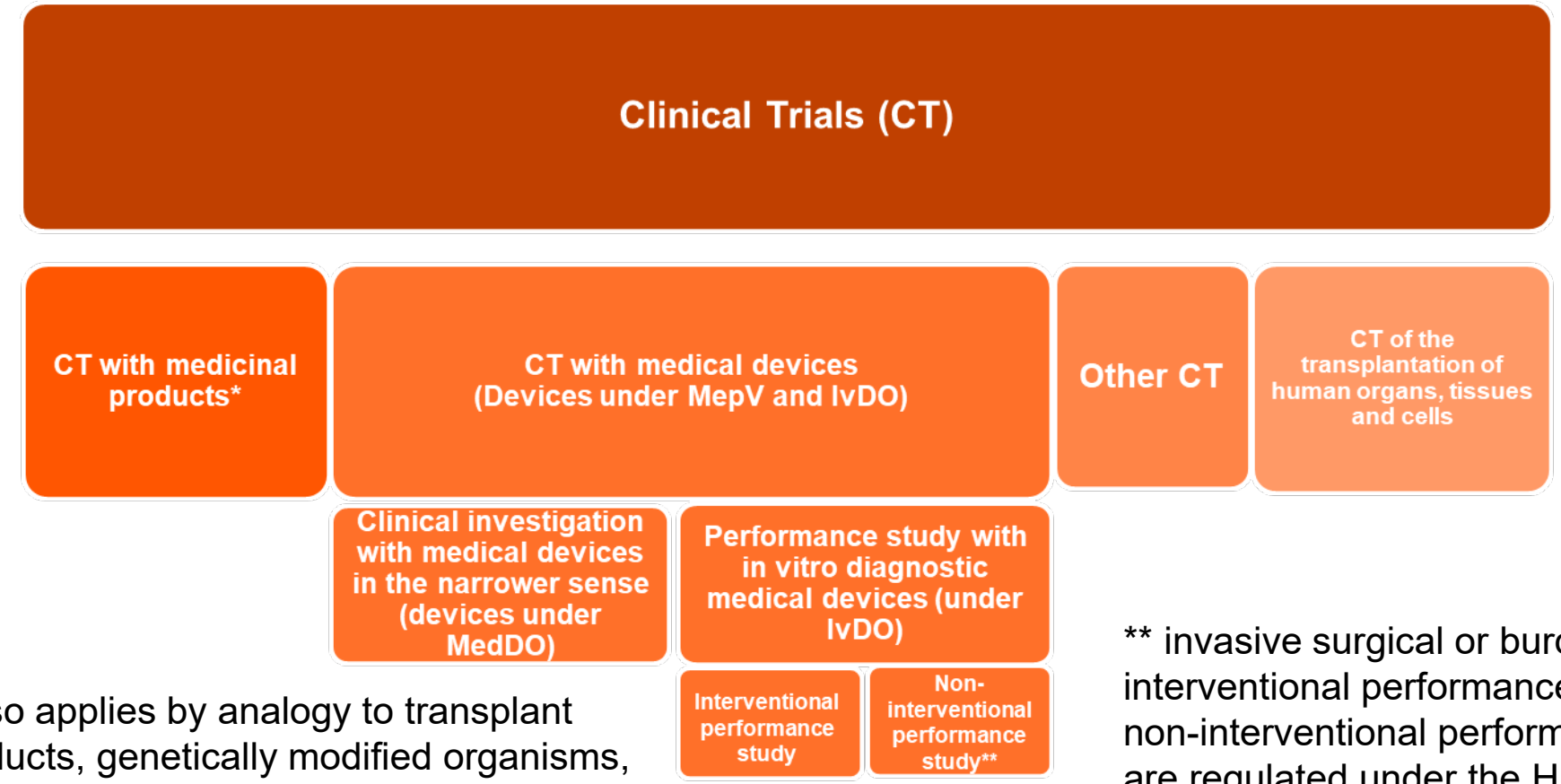
# Systematics of human research (HRA)




Cat. A

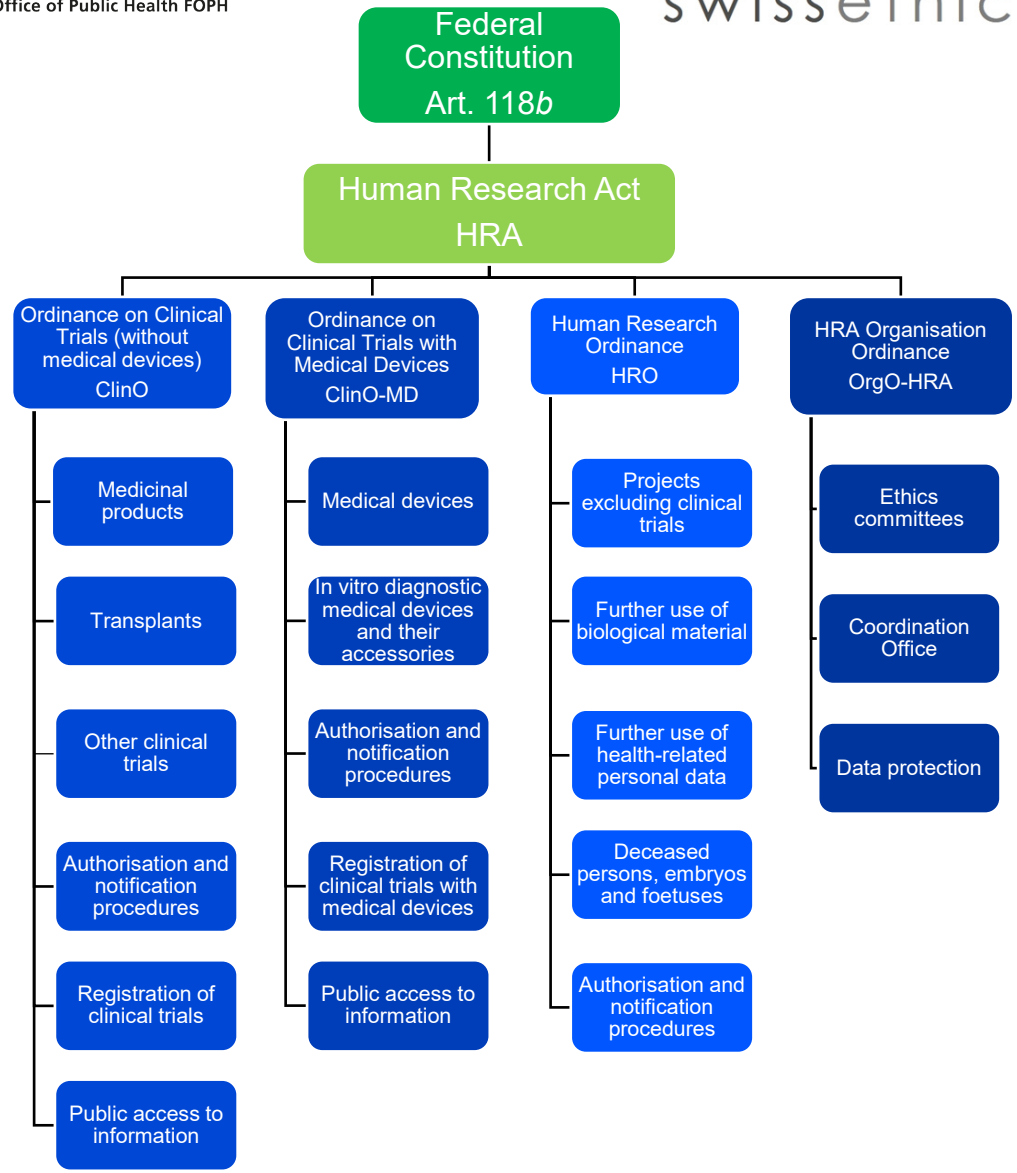
* also applies by analogy to transplant products, genetically modified organisms, pathogenic organisms and gene therapies

# Systematics of human research (HRA) – clinical trials



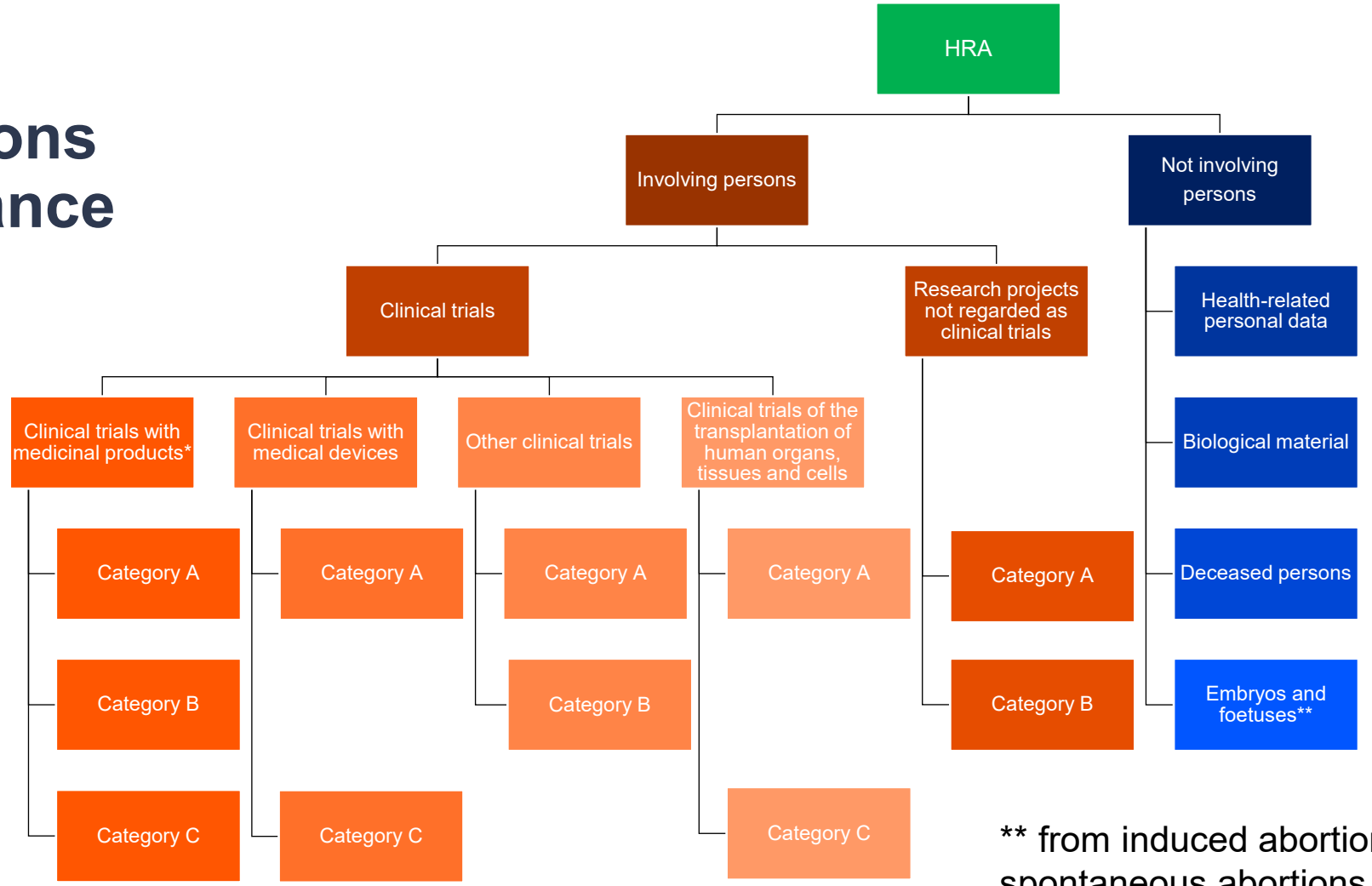

* also applies by analogy to transplant products, genetically modified organisms, pathogenic organisms and gene therapies

** invasive surgical or burdensome non-interventional performance studies; other non-interventional performance studies are regulated under the HRO




## Law and ordinance structure

# Categorisations under ordinance provisions




* also applies by analogy to transplant products, genetically modified organisms, pathogenic organisms and gene therapies

** from induced abortions and from spontaneous abortions including stillbirths

# The amendments in detail: OrgO-HRA, ClinO, ClinO-MD, HRO, SCRO

# Please note:

The following slides contain direct links to the corresponding articles.

Please note that these links are not to the full revised versions of the documents concerned (which will be found in the Classified Compilation [SR]), but to the corresponding German-language amending enactment (which will be found in the Official Compilation [AS]), which contains only the amendments concerned.

This is because links cannot be provided to articles in the SR version which have not yet come into effect.

The amending enactments are only available in German, French and Italian, but the full revised versions will also be available in English.

# OrgO-HRA

# Organisation of ethics committees

- Additional expertise in health information technology required in composition of ethics committees (Art. 1 para. 1).
- Requirements of persons working for the scientific secretariat (Art. 3 para. 1 lit. a): specification of type of degree required abolished => qualification requirement broadened.
- Projects involving the further use of existing biological material and/or health-related personal data which raise particular ethical, scientific or legal issues are newly subject to the simplified procedure (instead of decision by the chair) (Art. 6 para. 1).
- The duties of the FOPH and the Coordination Office for Human Research (kofam) are now more clearly separated (Art. 10).
- The Swiss Association of Research Ethics Committees (swissethics) is formally tasked with coordination between ethics committees (new Art. 10*a*).
- Data transmissions from the BASEC to the FOPH are now prescribed for public information purposes, for the evaluation of human research legislation and for the operation of the Swiss National Clinical Trials Portal (SNCTP) (new Art. 11*a*).

# ClinO

# Terms and definitions

- Definition of ‘clinical trial’ amended: an intervention need no longer be health-related -> “health-related” deleted (Art. 2 lit. a).
- Definition of ‘intervention’ amended: the listing of the types of measure concerned (preventive, diagnostic, therapeutic, palliative or rehabilitative) is deleted to broaden the term (Art. 2 lit. b). An intervention is now any measure to which the participant is subjected and whose effects on this person are to be investigated.
- The terms ‘investigational medicinal product’ and ‘placebo’ are now defined => placebos and other comparator products are now also considered for the categorisation of clinical trials on medical products (Art. 2 lit. g and h).

# Terms and definitions

- Minimal risks and burdens with regard to protection from radiation redefined (Art. 2 lit. c no. 6; see separate slide on protection from radiation).
- ‘Surplus information’ including ‘incidental findings’ newly defined (Art. 2 lit. f): surplus information is personal results which arise without being sought in the course of a clinical trial and which are not required either for the conducting thereof or to answer the scientific question.
- Incidental findings are a form of surplus information (for a full definition see the Swissethics guidelines on handling incidental findings, available in German, French and Italian) .

# Reference to ‘scientific integrity’

- The specifications for scientific integrity have been updated, with a new reference to the Code of conduct for scientific integrity issued by the Swiss Academies of Arts and Sciences **in its May 2021 version** (Art. 3 para. 2 in combination with Annex 1 no. 1).

# Requirements of application documents for clinical trials

- New requirements for the information of the trial participants:
  - Surplus information and incidental findings and the consequences thereof (Art. 7 para. 1 lit. e$^{bis}$)
  - Information in certain cases of genetic testing, including possible ramifications with regard to insurance providers (Art. 7a in combination with Art.18a and Art. 7b)
  - Details of the expected time of publication of the lay summary of the trial results and under what registration number on the SNCTP this will be found (Art. 7 para. 1 lit. h$^{bis}$).
- A description of how the requirements for electronic consent (Art. 7c in combination with Art. 25 lit. d$^{bis}$) should be met: see also the Swissethics guidelines on electronic study information (eIC).
- Due regard for the individual's right to be informed: the procedure for communicating results must now be described (Art. 8a in combination with Art. 25 lit. e$^{bis}$).
- Inclusion of relevant groups of persons: any exclusion or deliberate underrepresentation of relevant groups must be declared and justified (Art. 4a).

# Liability coverage

- Liability coverage must newly extend to damage occurring up to **20 years** after the completion of the clinical trial (Art. 13 para. 3), instead of the previous 10 years. This change brings this legislation into line with the relevant new provisions of the Swiss Code of Obligations (CO Art. 60 para. 1bis).
- Clinical trial data and requisite documentation must be newly retained for 20 years (Art. 45 paras. 1 and 2).
- Exemption from liability: 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 (Art. 10 para. 2).

# Categorisation of clinical trials on medicinal products (Art. 19)

- Certain clinical trials on medicinal products have been reclassified from Category C to Category B. The trials concerned are those involving:
  - investigational medicinal products authorised in other countries with equivalent medicinal product control
  - investigational medicinal products that have undergone low-risk modifications (particularly in connection with the blinding of authorised medicinal products); see also Annex 2bis.

# Deadlines for clinical trials

- Deadline of **two years for submission to the second approval authority** after approval has been issued by the first such authority (Art. 23 para. 1$^{bis}$ – 1$^{quater}$).
  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 initial approval will lapse.
- Deadline of **two years for the enrolment of the first trial participant** after issue of the last approval required (Art. 23a).
  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.

# Documentation, notifications and (adverse event) reporting for clinical trials: general remarks

- The provisions regarding (adverse event) reporting and notifications (Articles 38-41, 43 and 44a) have been amended to align with the EU regulation on clinical trials on medicinal products for human use -> simplification of cross-border clinical trials.
- **Non-safety-critical** notifications: the new provisions apply to **all** the clinical trials covered by the ClinO, i.e. to clinical trials on medicinal products, on transplant products and on products as specified under TPA Art. 2*a* para. 2, to transplants and to other clinical trials.
- The new provisions regarding **safety-critical** reporting vary depending on the type of clinical trial concerned.

# Documentation, notifications and reporting

## Clinical trials on medicinal and transplant products and on TPA Art. 2a para. 2 products

- Notification of the ethics committee:
  - within **30 days**: the first visit of the first participant and the completion of a clinical trial in Switzerland (Art. 38 para. 1)
  - within **90 days**: the global completion of a multinational clinical trial (Art. 38 para. 1$^{bis}$)
  - within **15 days**: the premature termination, interruption or resumption of a clinical trial (Art. 38 para. 2).
- Summary final report to be submitted to the ethics committee within **one year** of the completion or premature termination of the trial concerned (Art. 38 para. 3).
- For Category B and C clinical trials, such notifications and reports must also be submitted to Swissmedic (Art. 38 para. 5).

# Documentation, notifications and reporting

## Clinical trials on medicinal and transplant products and on TPA Art. 2a para. 2 products

### Documentation of adverse events (AE)

- In justified exceptional cases, the standardised documentation of some adverse events may be waived for Category C clinical trials (Art. 39 para. 1$^{bis}$).
- Terms “critical / not critical to the safety evaluation” newly introduced for Category B and C clinical trials (Art. 39 paras. 1$^{bis}$ and 2).
- Adverse events critical to the safety evaluation must always be documented in a standardised manner for Category B and C clinical trials (Art. 39 paras. 1$^{bis}$ and 2).

# Documentation, notifications and reporting

## Clinical trials on medicinal and transplant products and on TPA Art. 2a para. 2 products

### Reporting of serious adverse events (SAE)

- New: a fatal serious adverse event occurring at a trial site in Switzerland need no longer be reported to the ethics committee (Art. 40) unless it constitutes a SUSAR (see below).

### Reporting of a suspected unexpected serious adverse reaction (SUSAR)

- New: not only SUSARs with fatal consequences but also life-threatening SUSARs must be reported to the ethics committee (and possibly also to Swissmedic) **within 7 days** (Art. 41 para. 2).
- These reporting requirements newly also apply to any SUSAR which occurs after the completion of the clinical trial in Switzerland or is learned of after the completion of the clinical trial concerned (Art. 41 para. 4$^{bis}$).

# Documentation, notifications and reporting

## Clinical trials on medicinal and transplant products and on TPA Art. 2a para. 2 products

### Reporting on the safety of participants

- The safety report must be supplemented by a statement on the trial's general progress (Art. 43 para. 1).

# Documentation, notifications and reporting

## Clinical trials on transplantation

- **Notifications:** the amended Article 38 is applicable *mutatis mutandis* to clinical trials on transplantation (Art. 57), with the same notification deadlines with regard to first visits, completion, premature termination, interruption and resumption.
- **Documentation of adverse events (AE):** the amended Article 39 is applicable *mutatis mutandis* to clinical trials on transplantation (Art. 57).

# Documentation, notifications and reporting

## Clinical trials on transplantation

### SAE and SUSAR reporting:

- The new Article 57*a* applies specifically to clinical trials on transplantation, drawing on the amended Article 41.
- Serious adverse events occurring in Switzerland with fatal or life-threatening consequences: reporting to the ethics committee **within 7 days** (Art. 57a para. 2).
- Other serious adverse events occurring in Switzerland: reporting to the ethics committee **within 15 days** (Art. 57a para. 2); for Category C clinical trials, additional reporting to the FOPH.
- These reporting requirements newly also apply to any such event which occurs after the completion of the clinical trial in Switzerland or is learned of after the completion of the clinical trial concerned (Art. 57a para. 5).

# Documentation, notifications and reporting for clinical trials: clinical trials on transplantation

## Reporting on the safety of participants

- New Article 57b on safety reporting for clinical trials on transplantation: replaces the previous reference in Article 57 to Article 43; content remains unchanged.
- The safety report must be supplemented by a statement on the trial's general progress (Art. 57b para. 1).

# Documentation, notifications and reporting

## Other clinical trials

- **Notifications:** the amended Article 38 is applicable *mutatis mutandis* to other clinical trials (Art. 62 lit. c), with the same notification deadlines with regard to first visits, completion, premature termination, interruption and resumption.
- **Documentation and reporting of serious adverse events in other clinical trials:** remains unchanged (Article 63).
- **Reporting on the safety of participants in other clinical trials**: Art. 62 lit. d continues to refer to the now-amended Art. 43 paras. 1 and 2 -> the safety report must be supplemented by a statement on the trial's general progress.

# Sponsor's and investigator's responsibilities

- The clinical trial investigator must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure the corresponding compliance by other means (Art. 6 para. 1).
- If the clinical trial application is submitted to the ethics committee by the sponsor, it need no longer be co-signed by the investigator (Art. 24 para. 3).
- The sponsor may newly assume a clinical trial's notification and reporting obligations, even if the trial application is submitted by the investigator. Any such assumption must be specified, however, in the application documents (Art. 44a).
- The clinical trial application need no longer include a summary of the protocol in the national language of the trial site (Annex 3 and associated explanations).

# Innovations in clinical trials in the radiological protection field

- Stricter definition of minimal risks and burdens: in the event of accompanying examinations involving ionising radiation, the radiopharmaceuticals and/or medical devices employed must not only be authorised and bear conformity markings, but must also be **used in accordance with the relevant instructions** (Art. 2 lit. c no. 6).
- The FOPH's Radiation Protection Division will newly study **all** accompanying examinations using non-authorised or non CE-marked applications, and not only those involving an actual radiation dose of more than 5 mSv (Art. 36a para. 2).
- The documentation of the information of relevance for radiological protection will no longer be provided separately but will be included in the final report required under Article 38. If the FOPH has also provided its own opinion with regard to the trial concerned, the investigator shall also send this report to the FOPH (Art. 44 paras. 5 and 8).

# Innovations in clinical trials involving gene therapies, genetically modified organisms and pathogenic organisms (ClinO Section 4)

- Approval limits abolished: five-year maximum validity of approval deleted (Art. 35 para. 6 removed).

# Registration and publication

- Certain information on the clinical trial must be published in BASEC in the national languages for the regions in which participant recruitment is envisaged (Art. 64 para. 2).
- The sponsor must publish a summary of the results of the trial in an international registry within one year of the trial's completion or premature termination (Art. 65a para. 1).
- A lay summary of the results of the trial must also be published in BASEC in the national languages for the regions in which trial participants were recruited. This must also be done within one year of the trial's completion or premature termination (Art. 65a para. 2).
- 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 (Art. 64 para. 2$^{bis}$).

# ClinO-MD

# Requirements of application documents for clinical trials (Art. 3 para. 1 in combination with Art. 11)

The following new and amended articles of **ClinO** also apply to ClinO-MD:

- New requirements for the information of the trial participants:
  - Surplus information and incidental findings and the consequences thereof (ClinO Art. 7 para. 1 lit. $e^{bis}$)
  - Information in certain cases of genetic testing, including possible ramifications with regard to insurance providers (ClinO Art. 7a in combination with Art.18a and Art. 7b)
  - Details of the expected time of publication of the lay summary of the trial results and under what registration number on the SNCTP this will be found (ClinO Art. 7 para. 1 lit. $h^{bis}$).
- A description of how the requirements for electronic consent should be met (ClinO Art. 7c in combination with Art. 25 lit. $d^{bis}$).
- Due regard for the individual's right to be informed: the procedure for communicating results must now be described (ClinO Art. 8a in combination with Art. 25 lit. $e^{bis}$).
- Inclusion of relevant groups of persons: any exclusion or deliberate underrepresentation of relevant groups must be declared and justified (ClinO Art. 4a).

# Liability

- In line with the corresponding amendment to ClinO, liability coverage must newly extend to damage occurring up to **20 years** after the completion of the clinical trial instead of the previous 10 years (Art. 3 para. 1 lit. c of ClinO-MD in combination with ClinO Art. 13 para. 3).
- This change brings this legislation into line with the relevant new provisions of the Swiss Code of Obligations, in which an absolute statute of limitations of 20 years has applied to entitlement to damages in the event of death or injury or to compensatory damages for pain and suffering since January 2020 (CO Art. 60 para. $1^{bis}$).
- The **data retention requirement** under Article 40 remains **unchanged** at 10 years, or 15 years for implantable devices.

# Sponsor's and investigator's responsibilities

- The clinical trial investigator must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure the corresponding compliance by other means (Art. 5 para. 1).
- If the clinical trial application is submitted to the ethics committee by the investigator, it need no longer be co-signed by the sponsor (Art. 10 para. 3).

# Innovations in clinical trials in the radiological protection field

- The FOPH's Radiation Protection Division will newly study **all** accompanying examinations using non-authorised or non CE-marked applications, and not only those involving an actual radiation dose of more than 5 mSv (Art. 14 para. 2).
- In a further innovation, either the investigator or the sponsor (previously only the sponsor) may report an exceedance of the guideline maximum dosages permitted to the ethics committee (and for Category C trials also to Swissmedic) within 7 working days (Art. 39 para. 2).

# Reporting

**Annual reporting on the safety of participants:**

- The safety report must be supplemented by a statement on the general progress of the clinical trial concerned (Art. 35 para. 1).

# Registration and publication

- Certain information on the clinical trial must be published in BASEC in the national languages for the regions in which participant recruitment is envisaged (Art. 41 para. 1 in combination with ClinO Art. 64 para. 2).
- The sponsor must newly only ensure that a summary of the clinical trial results is published in an international registry by the deadlines specified (i.e. they need no longer take such action themselves) (Art. 42 para. 1).
- A lay summary of the results of the trial must also be published in BASEC in the national languages for the regions in which trial participants were recruited within one year of the trial's completion or premature termination (Art. 42 para. 2).
- The deadlines for publishing the results of a clinical trial may be modified. But any such modification must be requested by the sponsor (with appropriate reasons) in the trial's application documentation, which must also include the new intended publication date (Art. 42 para. 3).

# HRO

# Terms and definitions

- ‘Surplus information’ including ‘incidental findings’ newly defined (Art. 1a): surplus information is personal results which arise without being sought in the course of a clinical trial and which are not required either for the conducting thereof or to answer the scientific question.
- Incidental findings are a form of surplus information (for a full definition see the Swissethics guidelines on handling incidental findings).
- The completion of a research project has been redefined as the last collection of health-related personal data or the last obtainment of biological material (Art. 6a).
- Minimal risks and burdens in the radiological protection field have been redefined (Art. 7 para. 3 lit. f): see ‘Innovations in clinical trials in the radiological protection field’ below.

# Inclusion of relevant groups of persons

- The sponsor and the project manager must now ensure that the groups of persons who are of relevance to the answering of the scientific question are adequately represented (Art. 2 lit. C in combination with ClinO Art. 4a).

# Storage and retention

- The provisions regarding the storage of biological material for research purposes have been realigned to pay due regard to national and international guidelines (Art. 5 para. 2 lit. b).
- For research projects involving persons (Chapter 2), the project's management must newly retain all data for **at least 10 years** after the project's completion or premature termination (Art. 23a).

# Requirements of application documents for research projects

- New requirements for the information of the research project participants:
  - Surplus information and incidental findings and the consequences thereof (Art. 8 para. 1 lit. $d^{bis}$)
  - Information in certain cases of genetic testing, including possible ramifications with regard to insurance providers (Art. 8a in combination with Art.5a and Art. 8b).
- A description of how the requirements for electronic consent should be met (Art. 8c in combination with Art. 15 lit. $c^{bis}$).
- Due regard for the individual's right to be informed: the procedure for communicating results must now be described (Art. 8a in combination with Art. 15 lit. $d^{bis}$).
- Inclusion of relevant groups of persons: any exclusion or deliberate underrepresentation of relevant groups must be declared and justified (Art. 2 in combination with ClinO Art. 4a).

# Requirements of application documents for research projects

- For anonymisations of data and biological material: a description is required of the anonymisation methodology and the risk of re-identification (Art. 25 para. 3).
- For coding of data and biological material: details must be provided of the person or the organisational unit in possession of the key (Art. 26 para. 2).

# Liability in research projects involving persons (Chapter 2)

- There are now no exceptions from liability: the former Article 12 has been abolished.
- In contrast to ClinO, the liability coverage remains unchanged and must extend to damage which may occur up to **10 years** after a research project's completion (Art. 13 para. 3 lit. c of the presently valid HRO).

# Sponsor's and investigator's responsibilities

- The investigator must have appropriate knowledge and skills in the areas of data protection and data security or be able to ensure the corresponding compliance by other means (Art. 4 para. 1).
- The application need no longer include a summary of the research plan in the national language of the project site (Annex 2 and associated explanations).

# Innovations in clinical trials in the radiological protection field

- Stricter definition of minimal risks and burdens: in the event of accompanying examinations involving ionising radiation, the radiopharmaceuticals and/or medical devices employed must not only be authorised and bear conformity markings, but must also be used in accordance with the relevant instructions (Art. 7 para. 3 lit. f).
- The FOPH's Radiation Protection Division will newly study all accompanying examinations using non-authorised or non CE-marked applications, and not only those involving an actual radiation dose of more than 5 mSv (Art. 19 para. 2).

# Substantial modifications

- For all (Category A and Category B) research projects involving persons, any modifications to the research plan which relate to the project's objectives and/or its central research question will be newly regarded as substantial modifications (Art. 18 para. 3 lit. b).

# Adjustments to the anonymisation provisions in the light of technological advances (Art. 25)

- Any attribution of any data or material to a particular person must be rendered impossible or must be hindered to such a degree that the restoration of any such attribution could only be achieved with disproportionately high effort.
- All anonymisations must be effected using a methodological approach which is based on the latest appropriate technologies, and any data which might permit the restoration of their attribution to a particular person must be modified or deleted.
- The methodologies used must be documented, and the remaining re-identification risk must be described.

# Adjustments to the coding provisions in the light of technological advances (Art. 26)

- Data and biological material must be effectively coded so that without the key thereto or access to the source data concerned, it would only be possible with disproportionately high effort to attribute such data or biological material to a particular person.
- Coding must be effected using a methodological approach which is based on the latest appropriate technologies.
- The coding key must be kept – separate from the data and the biological material concerned – by a person or an organisational unit not involved in the research project. This person or unit must also be specified in the project application.

# SCRO

# Information and consent of the couple concerned

- The provisions for giving the couple concerned an appropriate period of reflection on their consent decision are now anchored in the corresponding article on consent (Art. 3 para. 2). These were previously included under the article on information (Art. 2 of the presently valid SCRO).
- The wording in the event of refusal or revocation of consent has been modified to reflect societal trends, with “couple” and (couple) “member” replacing “woman” and “man” (Art. 4).

# Licensing of research projects

- Wording in the provisions for licensing research projects has been refined. E.g., the application to the FOPH now requires a description of the 'process' and not the 'project' (Art. 5 lit. a); and instead of the 'approval of the research project granted by the competent ethics committee', the 'decision of the competent ethics committee' must now be submitted (Art. 5 lit. c).
- An application for the derivation of human embryonic stem cells (hESC) must be submitted to the FOPH; in order to be able to submit such an application, a research project must be submitted to the EC in accordance with Art. 17 SCRO or the HRA. In view of this, Article 5 lit. b now also includes a corresponding reference to the HRA.
- The provisions for applications for research projects to improve stem cell derivation procedures are being realigned to in-practice developments. Reasons must now be provided why equivalent findings could not be obtained via other means, *in particular via research projects using induced pluripotent stem cells (iPSCs)* (and no longer via 'experiments involving animal embryos') (Art. 8 lit. c).

# Approvals of the import/export of human embryonic stem cells

- Applications to import embryonic stem cells must be submitted to the FOPH; in order to apply to import, a research project must have been submitted to the EC in accordance with Art. 17 SCRO or the HRA; in view of this, Art.13 lit. a now also refers to the HRA.
- The application to import embryonic stem cells must now be submitted to the FOPH together with a “decision by the competent ethics committee” instead of the previous “approval […] granted by the competent ethics committee” (Art. 13 lit. b).
- Any import of embryonic stem cells must include proof that the stem cells concerned have been derived from surplus embryos, that the couple concerned has freely given their informed consent to the use of the embryo(s) for research purposes and that they have received no remuneration for the same. It is now left open, however, how and from where such proof needs to be provided, i.e. the previous reference to the “authority designated as competent […] or recognised” has been deleted (Art. 13 lit. d).
- The same applies to stem cell exports. Here, too, it is now left open who should provide the proof required that the research project should yield important findings and that it has the ethical approval of an authority independent of the project manager (Art. 15 lit. d).

# Approval procedure for the competent ethics committee (Section 7)

- The provisions here have been realigned to reflect current practice: for the justification why equivalent findings could not be obtained via other means, explicit reference is now made to iPSCs (Art. 17 lit. b).
- The relevant articles now talk of the “approval” of the competent ethics committee instead of its “assessment” (Art. 18 para. 2, Art. 20 para. 1 lit. b, Art. 21, Art. 22 para. 5).
- Review period: the competent ethics committee now issues its “decision” instead of its “assessment” (Art. 19 para. 1).
- Final report: a summary of the results achieved must be submitted, but these results need no longer be classified as “positive” or “negative” (Art. 25 para. 3 lit. c and para. 4).

# Data protection

- In line with current practice, the clinic which conducted the in vitro fertilisation must *pseudonymise* (not anonymize) the data relating to the surplus embryo (Art. 27 para. 2).

# Content of the public registry

- The FOPH must now be provided with the name and the address of the holder of the licence concerned (instead of the details of the project manager which were previously required) (Art. 29 para. 1 lit. a no. 3).

# Transitional provisions

# Transitional provisions for research projects approved before 1 November 2024 (ClinO Art. 72, ClinO-MD Art. 48b, HRO Art. 48a)

- The **liability, documentation and data and material retention obligations** of **research projects conducted under the ClinO, ClinO-MD and HRO** will continue to be subject to the present legal provisions.

# Transitional provisions for clinical trials under ClinO which were approved before 1 November 2024 (ClinO Art. 72)

- The new **notification, reporting and documentation obligations** basically apply from 1 November 2024. But if necessary, researchers may continue to meet such obligations as stipulated under present law until 31 October 2025.
- The **two-year deadline for submitting an application** to the second approval authority and the two-year deadline for **enrolling the first trial participant** will only come into effect on 1 November 2024, and will thus initially run until 31 October 2026.
- The new provisions for **categorising a clinical trial on medicinal products** can also be applied to trials which have been approved under present law. The researchers concerned may, if they wish, apply between now and 31 October 2025 to have their trial re-categorised under the new legal provisions.
- The obligation to **publish a summary of the clinical trial's results** within a year of its completion applies from 1 March 2025 to all trials completed on or after this date. It does not apply to trials which are completed before 1 March 2025.

# SCRO

- The amendments to the SCRO enter into effect on **1 November 2024**.
- There are **no transitional provisions**.

# End

# Annex / Reserve

- The following slides provide more detailed information on the documentation, notification and reporting provisions for clinical trials on transplantation and other clinical trials.

# Documentation, notifications and reporting for clinical trials: clinical trials on transplantation

## Notifications

The amended ClinO Article 38 is applicable *mutatis mutandis* to clinical trials on transplantation (see ClinO Art. 57):

- Notifications of the ethics committee:
  - The first visit of the first trial participant and the completion of a clinical trial on transplantation in Switzerland must be communicated to the ethics committee within **30 days** (Art. 38 para. 1).
  - The global completion of a clinical trial on transplantation must be communicated to the ethics committee within **90 days** (Art. 38 para. 1$^{bis}$).
  - The premature termination, interruption or resumption of a clinical trial on transplantation must be communicated to the ethics committee within **15 days** (Art. 38 para. 2)

# Documentation, notifications and reporting for clinical trials: clinical trials on transplantation

**Documentation of adverse events:**

The amended ClinO Article 39 is applicable *mutatis mutandis* to clinical trials on transplantation (see ClinO Art. 57):

- Documentation of adverse events: in justified exceptional cases, the standardised documentation of some adverse events may newly be waived for Category C clinical trials (Art. 39 para. 1$^{bis}$).
- Introduction of the terms “critical / not critical to the safety evaluation” for Category C clinical trials (Art. 39 paras. 1$^{bis}$ and 2)
- Adverse events critical to the safety evaluation must always be documented in a standardised manner for Category C clinical trials (Art. 39 paras. 1$^{bis}$ and 2).

# Documentation, notifications and reporting for clinical trials: other clinical trials

## Notifications

The amended ClinO Article 38 is applicable *mutatis mutandis* to other clinical trials (see ClinO Art. 62 lit. c):

- Notifications of the ethics committee:
  - The first visit of the first trial participant and the completion of a clinical trial in Switzerland must be communicated to the ethics committee within **30 days** (Art. 38 para. 1).
  - The global completion of a clinical trial must be communicated to the ethics committee within **90 days** (Art. 38 para. 1$^{bis}$).
  - The premature termination, interruption or resumption of a clinical trial must be communicated to the ethics committee within **15 days** (Art. 38 para. 2).

# Documentation, notifications and reporting for clinical trials: other clinical trials

**Documentation and reporting of serious adverse events for other clinical trials:**

- The documentation and reporting provisions remain unchanged (Article 63 of the current ClinO).

**Reporting on the safety of participants in other clinical trials:**

- The existing reference to ClinO Article 43 remains. In view of the amendment to the same, the safety report must now also be supplemented by a statement on the general progress of the clinical trial (Art. 43 para. 1).