University of Basel
Department of Clinical Research

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Guidelines for researchers on the revision of the ordinances of the Human Research Act in Switzerland

1. What is the reason?

The ordinances of the Human Research Act (HRA) have been revised and include numerous adjustments. In the four ordinances of the HRA, some improvements and requirements have been made to the technological, scientific and social changes, and they have also been adapted to international developments.

The revised ordinances will enter into force on **1 November 2024**, with the exception of the provisions on transparency in clinical trials, which will enter into force on 1 March 2025.

2. What are the most important changes for researchers?

For clinical trials according to ClinO und ClinO-MD and Research projects according to HRO:

(Art.7c, ClinO, Art.3 ClinO-MD, Art.8c HRO; Art.4a ClinO, Art.3 ClinO-MD, Art.2 HRO; Art.45 Abs.1 und 2 ClinO, Art.23a HRO; Art.13 ClinO, Art. 3c ClinO-MD, Art.13 HRO; Art.7, Art. 8a ClinO, Art.3 ClinO-MD, Art.9a HRO)

- Researchers can now obtain the consent of research participants electronically (so-called e-consent).
- Researchers are explicitly encouraged to include in their research project groups of persons who are relevant to the scientific issue; in particular, gender and age groups.
- The retention obligation for clinical trials of medicinal products is extended to a total of 20 years (with the exception of clinical trials of transplant products and clinical trials of blood and blood products), and for research projects to 10 years.
- An insurance certificate must be provided that covers for damages that occur up to 20 years after the clinical trial has ended and 10 years after the research project has ended.
- Researchers must comply with specific requirements that contribute to the comprehensible information of participants, with a focus on possible incidental findings.

For clinical trials according to ClinO and ClinO-MD:

(Art. 19 und Annex 2until, ClinO; Art. 38-41 ClinO; Art.64, 65 und Annex 5 ClinO, ClinO-MD Art. 41, 42)

- There will be a less stringent categorization, since, for example, the authorization status in countries with comparable medicinal product control will now also be taken into account and the term ‘low-risk change’ has been introduced. This list is not completed.
- Fatal SAEs in clinical trials no longer have to be reported within a short time frame, but only listed in the annual safety listing.
- Researchers must now publish a summary of the results in lay language and in the national language.

3. What are the transitional regulations for studies that have already been approved?

(Art. 72 ClinO, Art. 48b ClinO-MD and Art. 48a HRO)

The following transitional regulations apply to clinical trials and research projects that were approved before 1 November 2024:

- The liability, security and retention obligations for clinical trials according to ClinO, ClinO-MD and research projects according to HRO will continue as based on the current applicable law also after 1 November 2024.

- The new notification, reporting and documentation requirements for ongoing clinical trials in accordance with ClinO will apply from 1 November 2024. However, researchers may continue to fulfil these obligations under the current law as needed until 31 October 2025. After that date, however, they must have submitted an amendment to the study documents to the EC and Swissmedic.

- The new regulations for categorizing a clinical trial can also be applied to trials that have already been approved. Researchers can request a category adjustment under the new legislation until 31 October 2025 if they want.

- The two-year period for submitting the application to the second authorizing authority and the two-year period for including the first participant in clinical trials in accordance with ClinO will begin on 1 November 2024.

Publication of the summary of clinical trial results in accordance with ClinO

(Art. 65a ClinO)

This regulation applies from 1 March 2025 to all trials completed after 1 March 2025 and must be fulfilled within one year of completion of the clinical trial in accordance with ClinO. It does not apply to trials completed before 1 March 2025.

4. How should researchers proceed when preparing new applications?

Researchers are required to adapt the study documents for ongoing studies to the new templates and to submit them with the next amendment or by 31 October 2025 at the latest. For prospective studies, the currently valid templates and forms from swissethics and Swissmedic must be used.

5. Who you can contact:

DKF will be happy to support you in implementing changes and submissions. Regardless of whether we have previously submitted for you or you did the submission by yourself, we offer you a revision-specific regulatory check of your study documents and are also happy to submit for you the amendment.

We can check study-relevant documents such as the study protocol, ICF, contracts and insurance certificates, but can also help you to redefine the risk category of an existing study.
Of course, we are also available as usual for new studies and will carry out a complete check.

For all enquiries, you can contact us directly via regulatorik.dkf@usb.ch. If you have previously submitted the study yourself, it is best to fill out the contact form and upload the previous documents there.