

Analysis of the regulation of damage and liability in human research in Switzerland, focusing on insurers

June 2018 update to the report of 30 November 2015

Executive Summary

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Abstract:

The protection of persons participating in medical research projects is a key element of the legal regulation of research. The survey for the period 2014–2017, updating an earlier one covering the period 2011–2014, also shows only a small number of cases of potential damage reported to insurers under the Human Research Act (HRA). This survey provides a rough overview, as standardised case reporting has not been established. According to the stakeholder groups, patient organisations and liability insurers interviewed, action is required primarily with regard to the provision of information for trial subjects and investigators. This is also particularly important in the light of Federal Supreme Court jurisprudence, since study participants must be aware of the exclusion of liability based on the exemptions specified in Art. 10 of the Clinical Trials Ordinance (ClinO). This exclusion of liability limits the scope of protection under the HRA in practice.

Keywords:

Human Research Act liability, cases of damage, provision of information in medical research projects, exemptions specified in ClinO, limitation of liability in medical research projects

1. Aim and background

The present study is concerned with the question whether the regulation of liability under the new Swiss Human Research Act adequately ensures the protection of trial subjects. It updates the survey already undertaken in 2015 by the Swiss Academy of Insurance Medicine (asim) at Basel University Hospital as departmental research commissioned by the Federal Office of Public Health (FOPH).

2. Methods

As in the initial study, a simple written survey was used to assess – this time for the period from January 2014 to December 2017 – the number of reported cases of potential damage and liability, the processing thereof, and the HRA-related experience gained as a result. Included in the survey were all insurers offering coverage for trials conducted in accordance with the HRA in Switzerland and all the Swiss Disability Insurance (IV) recourse services.

In supplementary interviews with the five largest insurers, procedural questions, the amount of damages, action required and developments were discussed. Three telephone interviews were conducted to determine the experience and views of patient organisations.

This streamlined procedure, supplementing the fundamental report of 2015, was designed primarily to document the quantitative development of liability cases and the most important practical experience. As a contextual aspect, an assessment is given of the Federal Supreme Court Decision 4A_549/2015 of 27 June 2016 on liability in human research.

3. Results and interpretation

It should first be noted that comprehensive statistics on liability cases arising from research projects are not systematically recorded and collated by all insurers. The figures are thus partly based on estimates. However, since all the insurers (response rate = 100%) took part in the survey, the overall picture can be assumed to be reliable.

Written survey:

- For the four-year period (2014–2017), the survey shows a somewhat lower number of cases – overall, the insurers report 40–48 cases of potential damage registered (also as a precautionary measure), compared with 52–68 in the initial survey, which only covered a period of 3.5 years.
- Around 60–70% of cases are purely precautionary notifications, for which a claim is not subsequently pursued. Compensation was paid in approx. 20–25% of cases, and approx. 8–10% were rejected. Around 15–20% of cases have yet to be resolved.
- The compensation payments concerned minor cases, with CHF 3000 being reported as the maximum payment. Among the pending potential liability cases, one is classified as a case of major damage.
- Rejections are attributed in some cases to severe underlying conditions (exemption from liability or questionable evidence of causality).
- The IV recourse services virtually never submit claims based on HRA liability. One case is pending; in an estimated 0–3 cases a recourse claim has not been pursued following an initial examination.

Oral survey:

- Insurers and patient organisations do not see any substantial changes as a result of the HRA; however, they emphasise the short period of experience, which, with a small number of cases, does not permit a reliable assessment. The HRA has not led to a rise in premiums.
- Both groups identify a need for the provision of information concerning the risks and benefits of study participation including the liability aspects and, in particular, the right to claim directly against insurers, which is not yet used in practice. Here, they emphasise the differing interests of patients/subjects on the one hand and investigators/industry on the other.
- Both groups see a need for optimisation with regard to transparency and systematic information on research in accordance with the HRA – particularly concerning the number of projects, persons involved, events and consequences of events potentially involving liability aspects.
- Conflicting views are expressed concerning the provisions on exemption specified in Art. 10 ClinO: for the insurers, they create clarity and legal certainty; for the patient organisations, they undermine the protection of patients.

Contextual aspect:

In Decision 4A_549/2015 of 27 June 2016, the Federal Supreme Court (still under the previous legal regulations, but with interpretative relevance for the HRA) ruled that it must always be clear to the subject that only additional research-related risks are covered by the liability assured by the CHUV *in casu*, classifying the previous legal provisions under the Therapeutic Products Act primarily as fault-based liability.

Interpretation:

The update shows a picture essentially similar to that of the initial survey conducted in 2015. Cases of damage and liability under the HRA are rare, and major-damage events even more so. In the absence of complete, systematic records of relevant parameters, the study can only be considered to provide a rough overview. The downward trend observed in the number of cases compared to the initial survey may be a chance variation or may also be associated with a possible general downward trend for studies in the period under review. The published data on the number of studies registered does not permit comparison, as the data for the current study period is presented differently than in the initial survey. From a systemic perspective, it is striking, as already noted in the initial survey, that a combined overall view and overall monitoring of ongoing studies is lacking, also in relation to potential liability cases. In the assessment of all three perspectives (protection of patients and subjects, legal requirements, favourable research conditions), primary importance is attached to the provision of information. To date, inadequate attention has been paid to the provision of comprehensive, readily intelligible information – also on liability aspects – for study participants.

The exemption provisions serve as a defence against liability. Here, the study conditions do not permit any material evaluation. The Federal Supreme Court decision of June 2016 indicates the need for action with regard to clear communication and information, and the fundamental issue of exemptions.

4. Recommendations

The comprehensive options for action and recommendations from the 2015 report retain their validity, particularly the considerations concerning the regulation of exemptions. Focusing on the results of the update, the following action areas are **now** recommended:

- **Development of systematic monitoring** – introduction of systematic recording of (potential) damage cases under the HRA. Proposals for implementation are:
 - introduction of standardised reporting (ethics committees, investigators/institutions)
 - mandatory notification of insurers' HRA damage cases.
- Ensuring in-depth **provision of information for subjects and patients** on HRA protection (scope, limits, procedure), together with training of investigators. Proposals for implementation are:
 - development of a standard training tool for communication on liability and insurance, including the right to claim directly
 - development of an information sheet on these topics for subjects and patients
 - appropriate revision of the Informed Consent Template
 - focusing on provision of neutral information on risks and benefits of study participation.
- Development of **Best Practice for cases of damage** by:
 - elaboration of a consensus paper by stakeholders
 - establishment of standard operating procedures (SOP) for cases of damage
 - training of investigators on management of cases of damage.