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Process flow diagram for the planning and performance of scientific animal experiments

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Process Flow Diagram for the Planning and Performance of Scientific Animal Experiments

February 2002

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1. Preface

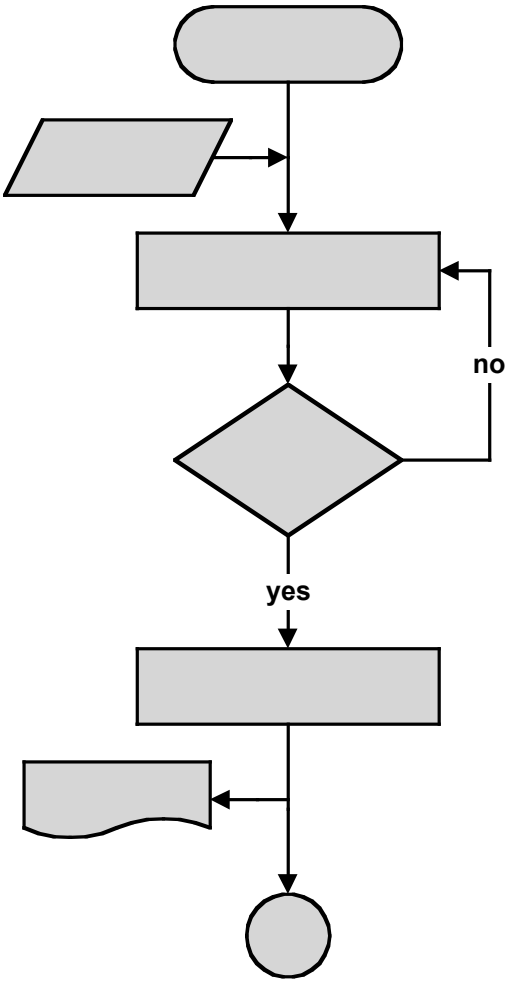
Scientific questions and extensive regulations (laws and decrees; scientific, health-authority and ethical requirements and guidelines) govern the planning, approval and performance of an animal experiment. It is the primary task of the study directors to observe these regulations, and it is the task of the bodies involved in the approval process (e.g. bodies responsible for animal protection, Cantonal Veterinary Office, animal experiment committees, Swiss Federal Veterinary Department), to check the corresponding applications. The individual steps, starting with the planning and continuing up to the conclusion of the animal experiment, follow a regulated process-flow plan.

The Ethical Committee for Scientific Animal Experiments of the SANS/SAMS has assumed the task of elucidating this process from the scientific, legal and ethical points of view and to present it in the form of a clearly arranged process-flow diagram, with the aim (a) of making the individual steps of the process and the responsibilities transparent for all interested parties and for all those involved in the animal experiment, and (b) of contributing to the training and further instruction of persons who direct, carry out and assess animal experiments.

The study directors are as a rule well equipped to establish the scientific procedures and to meet the legal requirements. It is more difficult, however, to arrive at an ethical balance between the interests of man and the interests of the animal. Neither the relevant literature on ethical questions nor the Ethical Principles and Guidelines (SANS / SAMS, 1995) define a procedure for ethical justification of animal experiments.

In order to meet this need, the Ethical Committee for Scientific Animal Experiments will pay special attention to this part of the process flow diagram and in 2002 will develop and publish guidelines on the ethical justification of animal experiments, in the sense of a self-assessment procedure for study directors.

2. Explanation of Process Flow Symbols



Start / End of a process

Input

Process step / activity

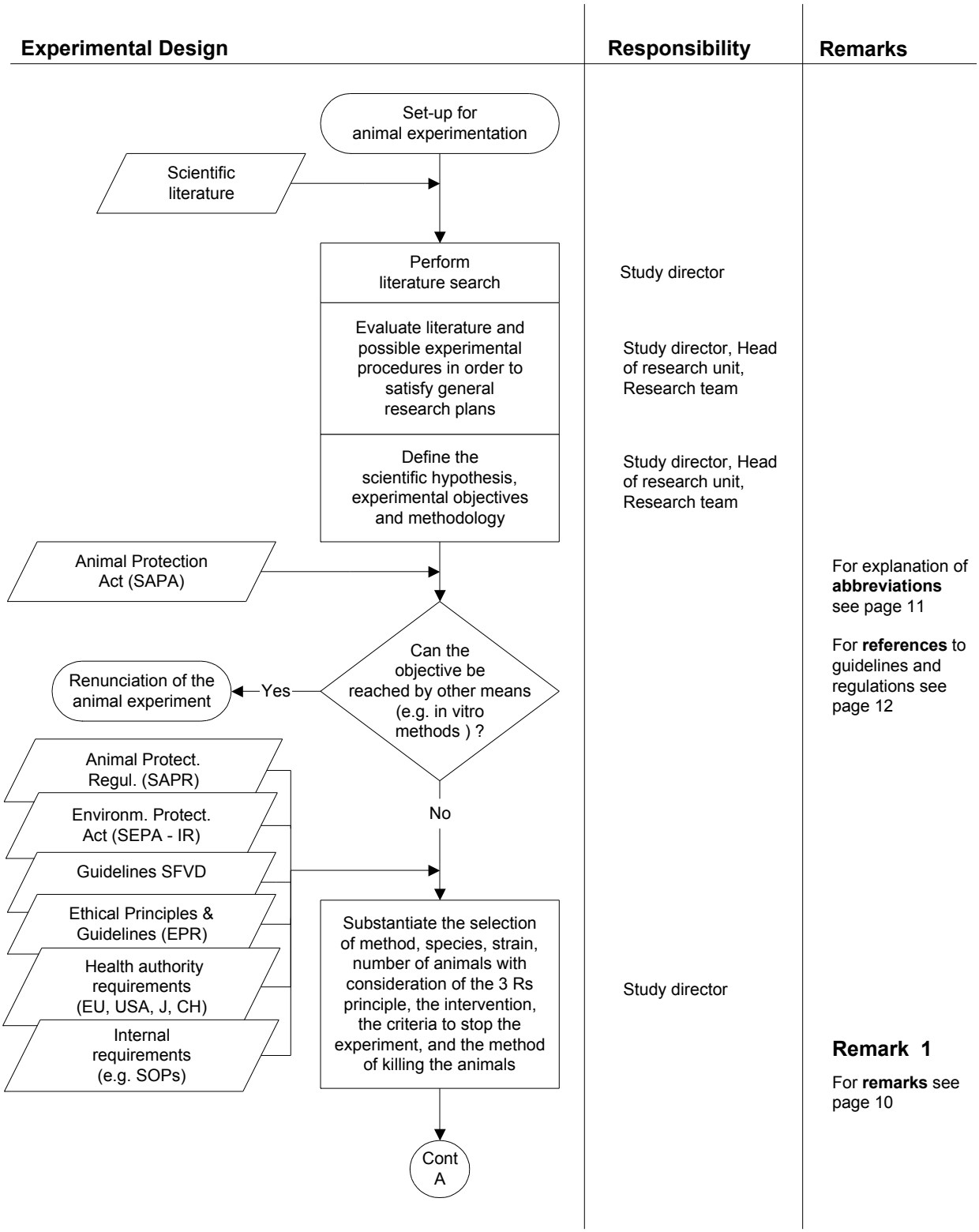
Decision

Process step / activity

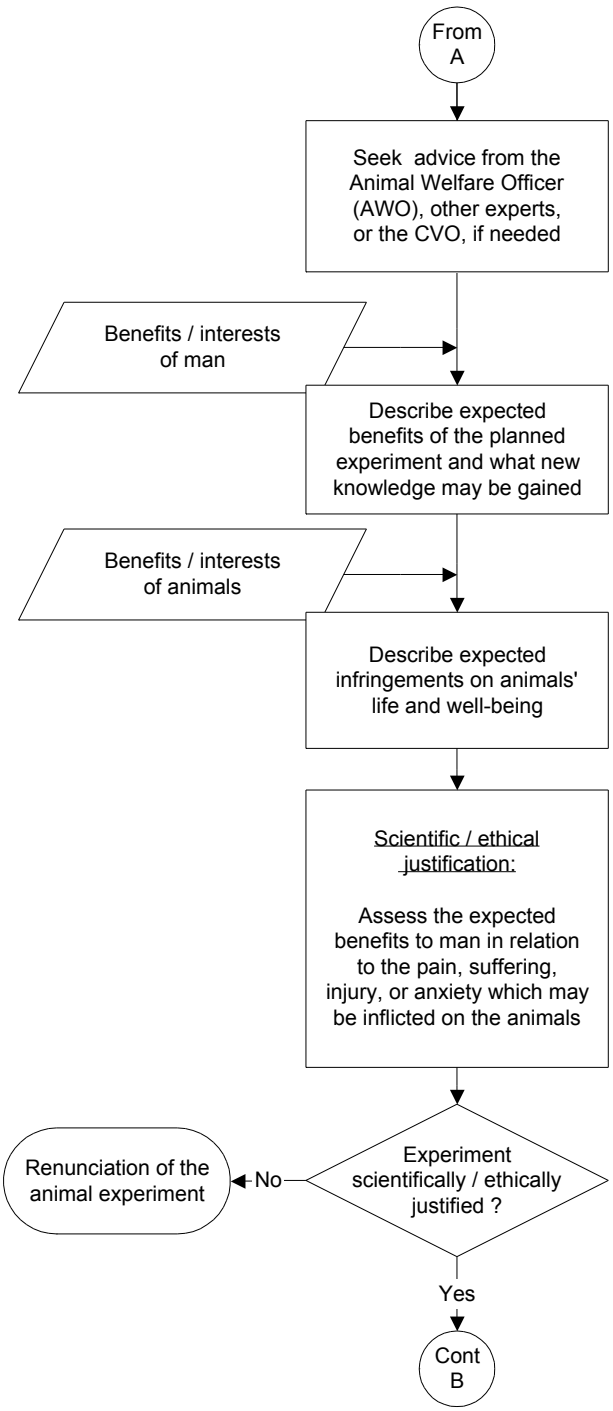
Output

Connector; connects pages

3. Process Flow



Scientific and Ethical Justification	Responsibility	Remarks



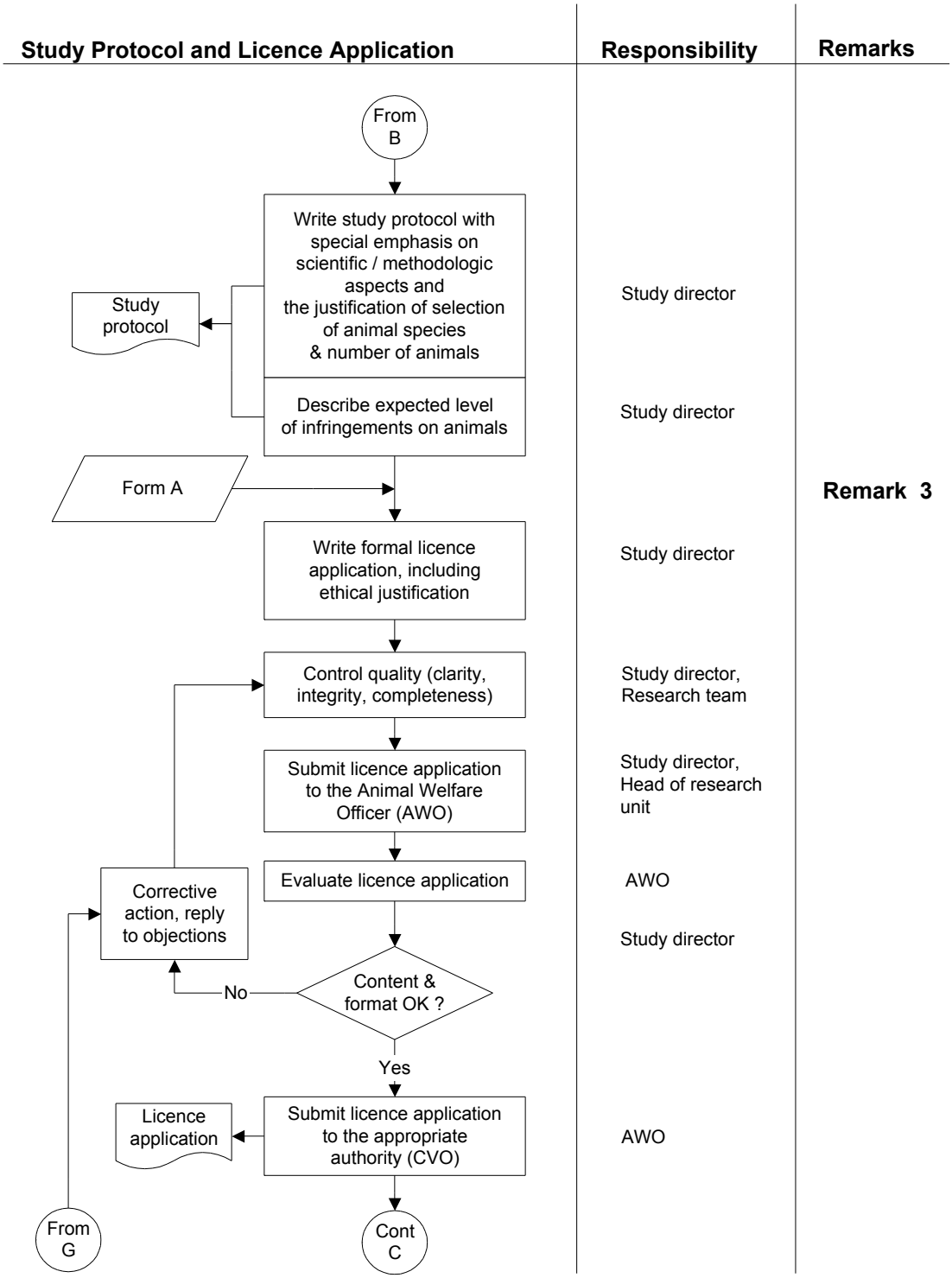
Study director

Study director

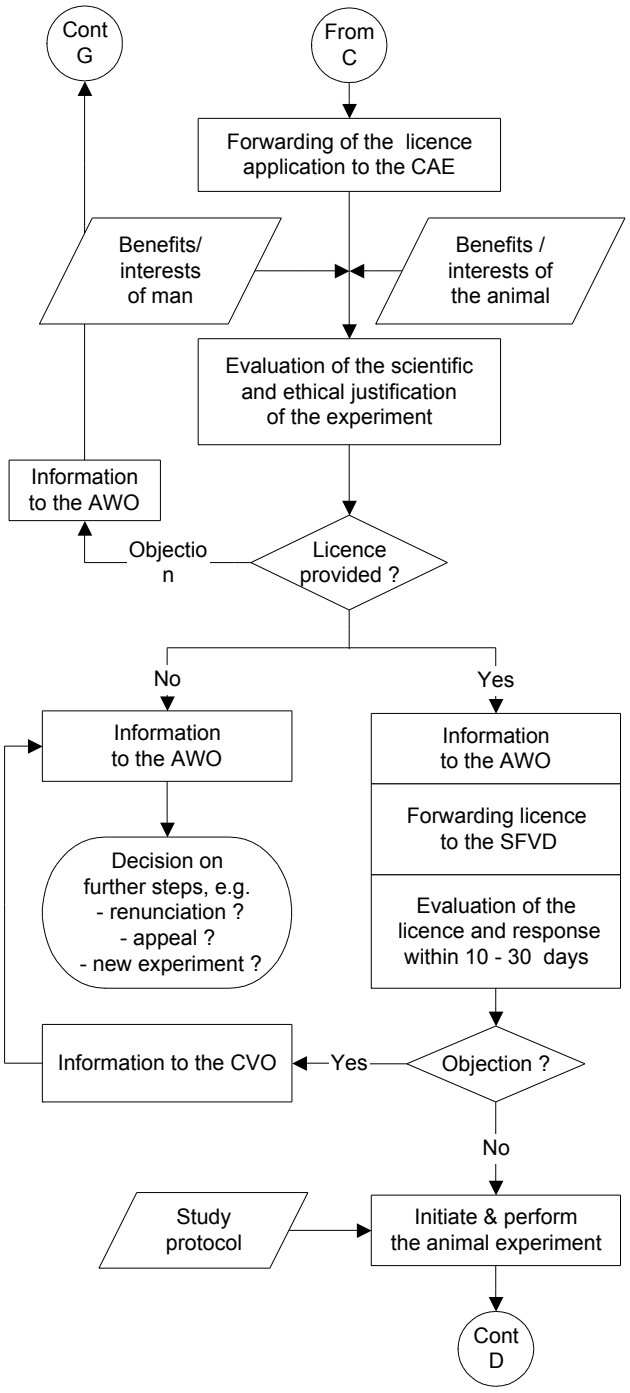
Remark 2

Study director

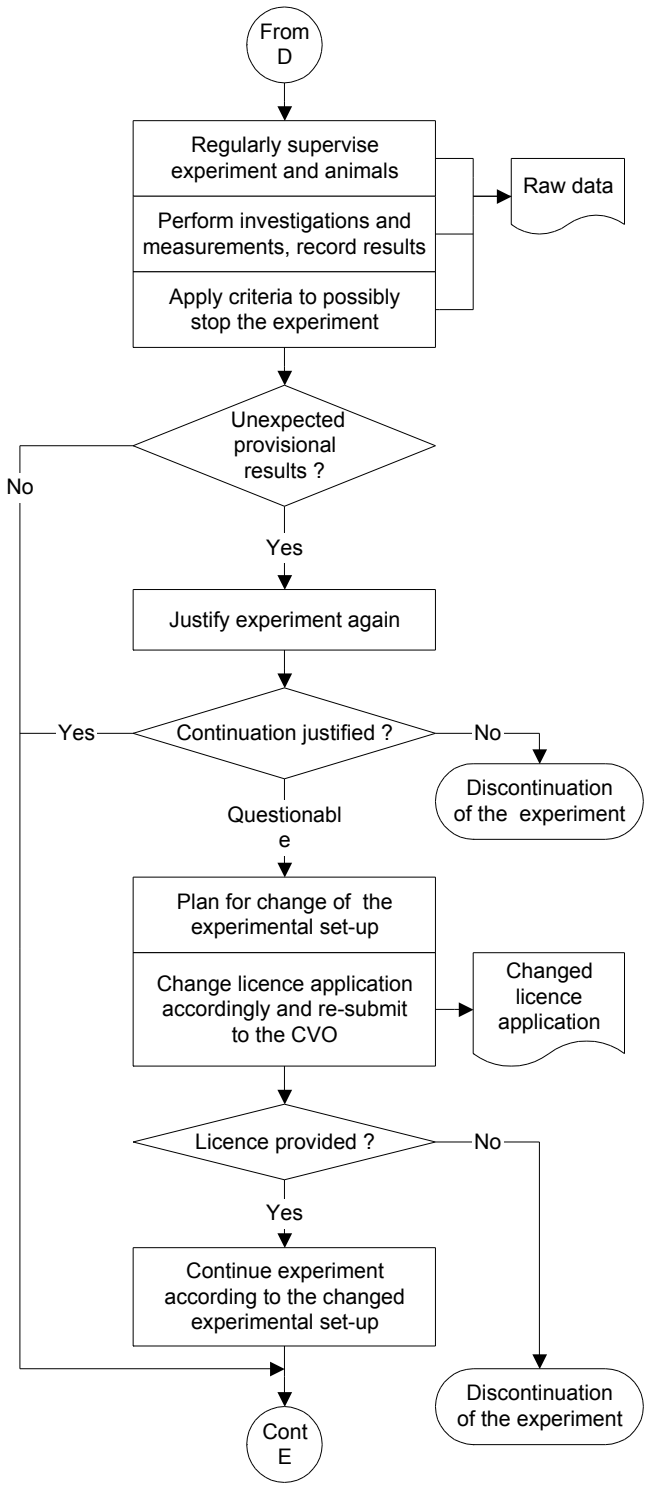
Study director, Head of research unit, Research team


Study Protocol and Licence Application
Responsibility
Remarks
From B
Write study protocol with special emphasis on scientific / methodologic aspects and the justification of selection of animal species & number of animals
Study director
Study protocol
Describe expected level of infringements on animals
Study director
Form A
Remark 3
Write formal licence application, including ethical justification
Study director
Control quality (clarity, integrity, completeness)
Study director, Research team
Submit licence application to the Animal Welfare Officer (AWO)
Study director, Head of research unit
Evaluate licence application
AWO
Corrective action, reply to objections
Study director
No
Content & format OK ?
Yes
Licence application
Submit licence application to the appropriate authority (CVO)
AWO
From G
Cont C

Provision of Licence and Start of Experiment	Responsibility	Remarks



Experimentation	Responsibility	Remarks



Research team, Study director

Research team, Study director

Research team, Study director

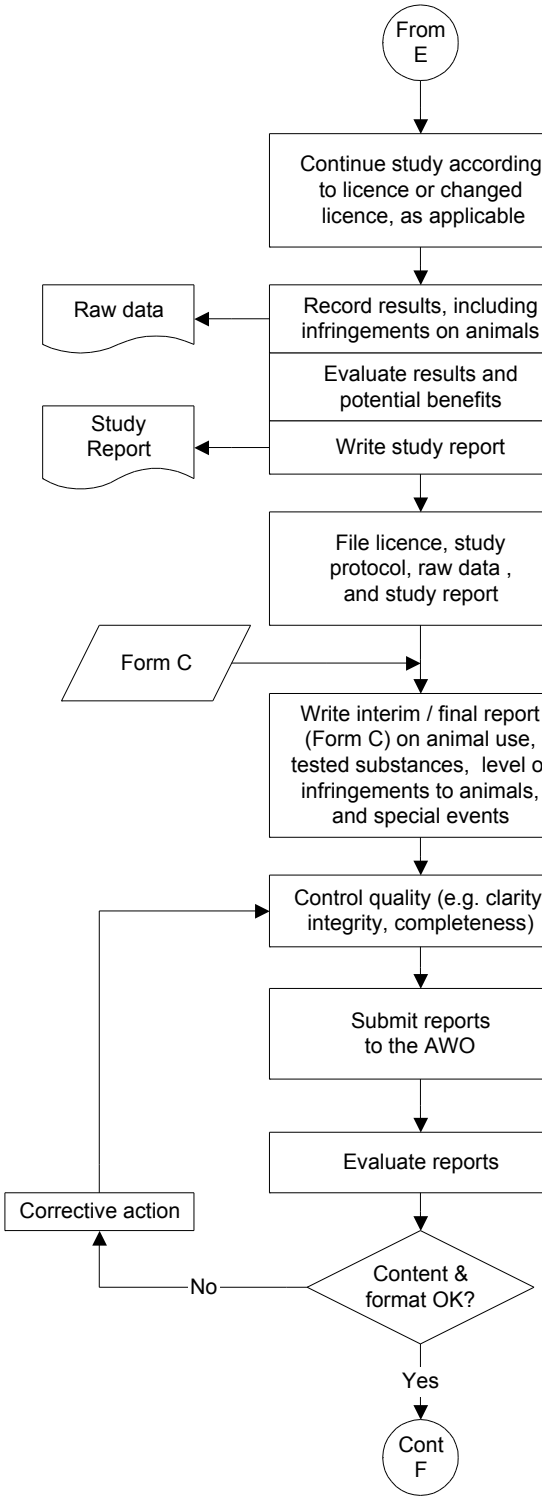
Study director, Head of research unit, Research team

Study director, Research team

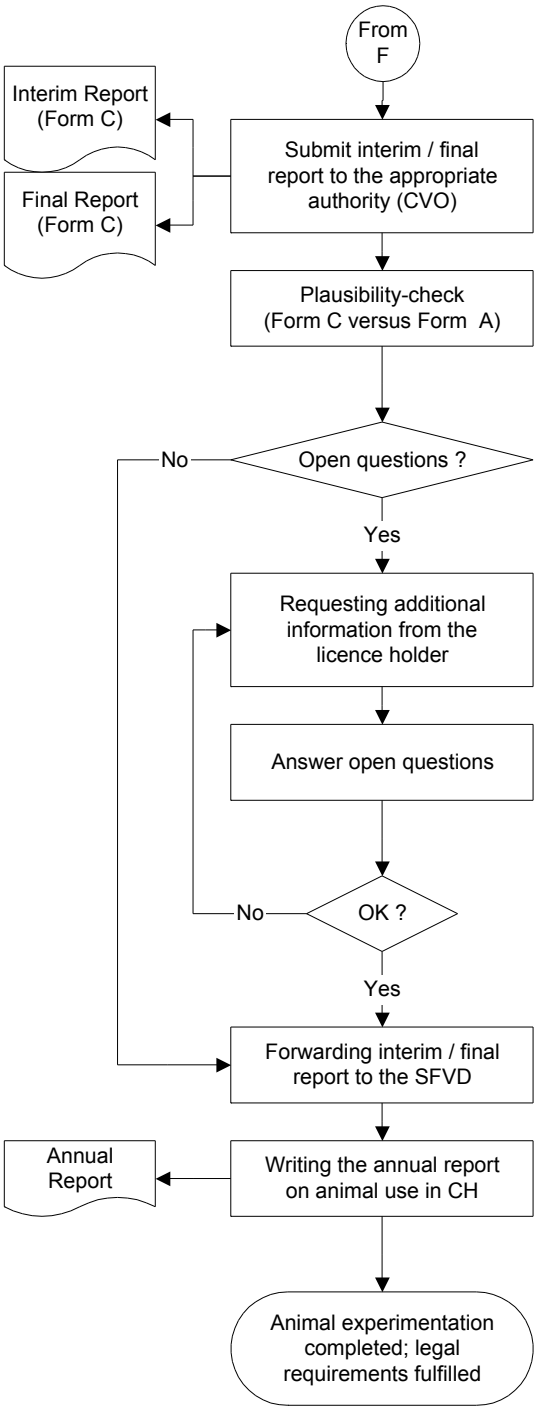
Study director, Head of research unit, AWO

CVO

Research team, Study director

End of Experimentation; Reporting	Responsibility	Remarks
		
	Study director, Research team	
	Study director, Research team	
	Study director, Research team	
	Study director	
	Archivist, Study director	**Remark 6**
	Study director	**Remark 7**
	Study director	
	Study director	
	AWO	
	Study director	

Animal Use Statistics	Responsibility	Remarks



4. Remarks

Remark 1: With animal experiments, SOPs are required in the area of GLP (safety studies of pharmaceutical and chemical substances).

Remark 2: A guideline for determining the ethical balance between the interests of man and the interests of the animal is in preparation (Ethical Committee for Scientific Animal Experiments of the SANS/SAMS).

Remark 3: The same experimental submission (Form A) is used for animal experiments that have to be reported as is used for animal experiments that require official approval. It is the task of the Cantonal Veterinary Office (CVO) to decide in which category the experiment falls.

Remark 4: The CVO is authorised to make decisions; the Committee for Animal Experiments (CAE) is always available, but only in a consultant capacity. If specific animal experiments are required by the health authorities (e.g. for safety studies of substances and products, in accordance with the guidelines of national and international authorities), in certain Cantons the CVO makes decisions without involvement of the CAE (limited ethical balance between the interests of man and the interests of the animal).

The CVO approves experiments, refuses them or rejects them. The purpose of rejection of an experiment is to provide the opportunity to again check the choice of method, the aspects regarding the "refine, reduce, replace" (3R) principle or the planned course of the experiment.

Remark 5: It is the duty of the CVO and the CAE to inspect the mode of housing and maintenance of the animals, as well as selected animal experiments.

Remark 6: According to the Swiss Animal Protection Act (SAPA), data must be kept on file for 3 years. However, according to the requirements of national and supra-national health authorities, for animal experiments involving study of the efficacy and safety of pharmaceutical and chemical substances, which are approved by health authorities and have been introduced onto the market, data must as a rule be kept on file for up to 20 years.

Remark 7: Interim reports are drawn up annually and concluding reports are drawn up after the completion of a research project. These reports are used by the SFVD, among other things as the basis for the

preparation of the annual statistics on animal experiments in Switzerland.

5. Abbreviations

AWO	Animal Welfare Officer (in industry and large research institutions; In smaller research units this functions is to be assumed by the unit head or the study director)
CAE	Committee for Animal Experiments (here understood to mean the Cantonal CAE). The Federal Committee for Animal Experiments (not mentioned in the process flow diagram) advises the SFVD on all questions connected with the housing and maintenance of experimental animals and with animal experiments and is available to the CVOs for consultation concerning basic questions and disputed cases
CVO	Cantonal Veterinary Office (Kantonales Veterinäramt)
EPR	Ethical Principles and Guidelines for Research on Animals (Ethische Grundsätze und Richtlinien für wissenschaftliche Tierversuche der SANW / SAMW)
GLP	Good Laboratory Practice (quality principles to be applied to all non-clinical [e.g. animal] studies performed to obtain data on the safety of chemical substances with respect to animal and human health or the environment, and to be presented to a regulatory authority)
3R	Principles „*Refine, Reduce, Replace*“
SAMS	Swiss Academy of Medical Sciences
SANS	Swiss Academy of Sciences
SAPA	Swiss Animal Protection Act (Tierschutzgesetz)
SAPR	Swiss Animal Protection Regulations (Tierschutzverordnung)
SEPA-IR	Swiss Environmental Protection Act - Inclusion Regulations
SFVD	Swiss Federal Veterinary Department (Bundesamt für Veterinärwesen)
SOP	Standard Operating Procedure (GLP)

6. References

- Swiss Federal Act on Animal Protection / Swiss Animal Protection Act (SAPA); No. 455, March 9, 1978

- Animal Protection Regulations (SAPR); No. 455.1 , May 27, 1981

- Ordinance 455. 171. 2 on the Training of Specialist Personnel involved in Animal Experimentation; July 1, 1999

- Swiss Environmental Protection Act (SEPA); No. 814.01 October 7, 1983 / Inclusion Regulations (IR) No. 814.912, August 25, 1999

- Guidelines and Information Sheets issued by the Swiss Federal Veterinary Department (SFVD):

  1.02 Licence Application and Notification of Animal Experiments: Explanatory Notes for Form A

  1.03 Interim and Final Reports on Animal Experiments: Explanatory Notes for Form C

  1.04 Classification of Animal Experiments according to Grades of Severity prior to the Experiment (Stress Categories)

  1.05 Retrospective Classification of Animal Experiments according to Degrees of Severity (Stress Categories)

  1.07 Appointment of Animal Welfare Officers in Companies and Institutions which conduct Animal Experiments

  4.01 Guidelines for the Filing of Applications and Approval of Experiments in Animals to test the Safety of Substances and Products (Toxicity Guidelines)

  4.02 Animal Experiments in the Training of Specialist Personnel; Training of Biology Laboratory Technicians

  4.05 Transgenic Vertebrates: Application of the Animal Protection Legislation on the production, breeding, holding and use of Transgenic Animals for Experimental Purposes

- Ethical Principles and Guidelines for Research on Animals (SAMS und SANS), Edition 2, 1995

- International Rules on Registration Requirements for Chemicals and Products (e.g. OECD Guidelines, Pharmacopoeia Monographs)

- National and Supranational Registration Requirements for Application of Pharmaceutical and Chemical Substances in CH, EU, USA, Japan etc.

- Ordinance 813.016.5 on Good Laboratory Practice (GLP) of February 2, 2000; Chapter 7 on SOPs