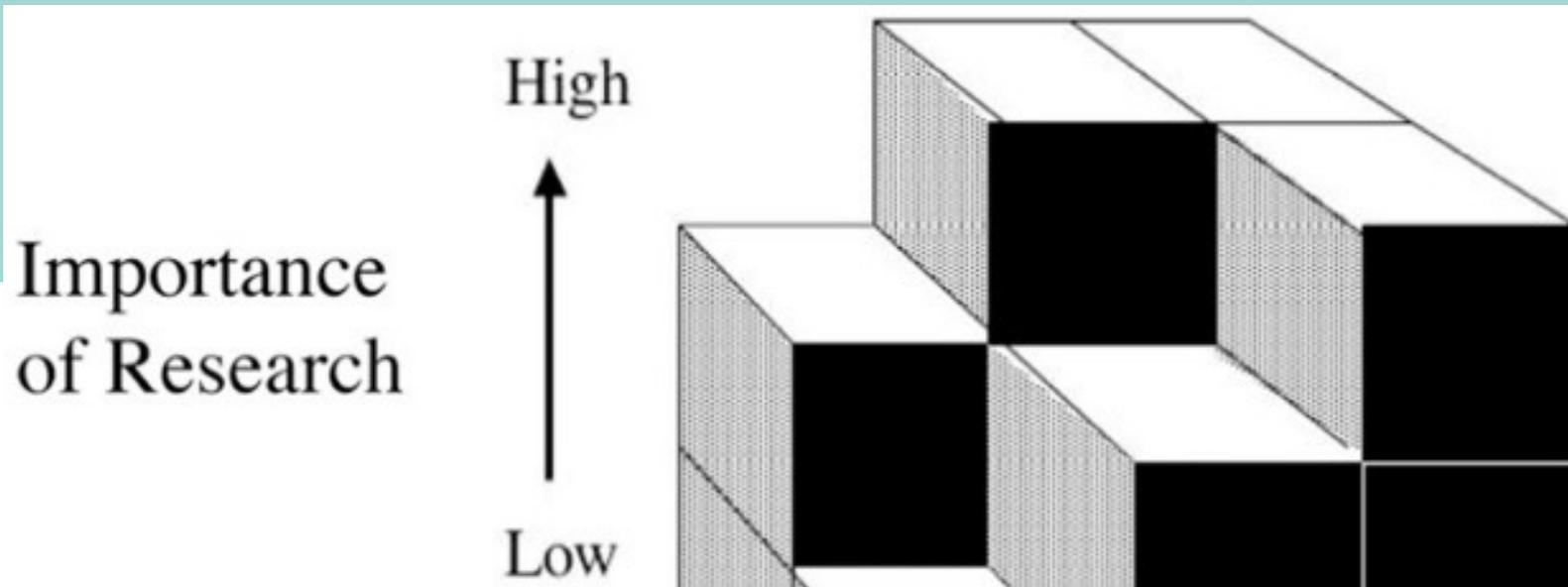


Universität  
Basel

# Decision Support Tools for the Conduct of Harm-Benefit Analysis

David Mawufemor Azilagbetor  
December 8, 2025

David Shaw  
Jens Gaab  
Rosa Maria Cajiga Morales  
Bernice Simone Elger  
Lester Darryl Geneviève



# Agenda.

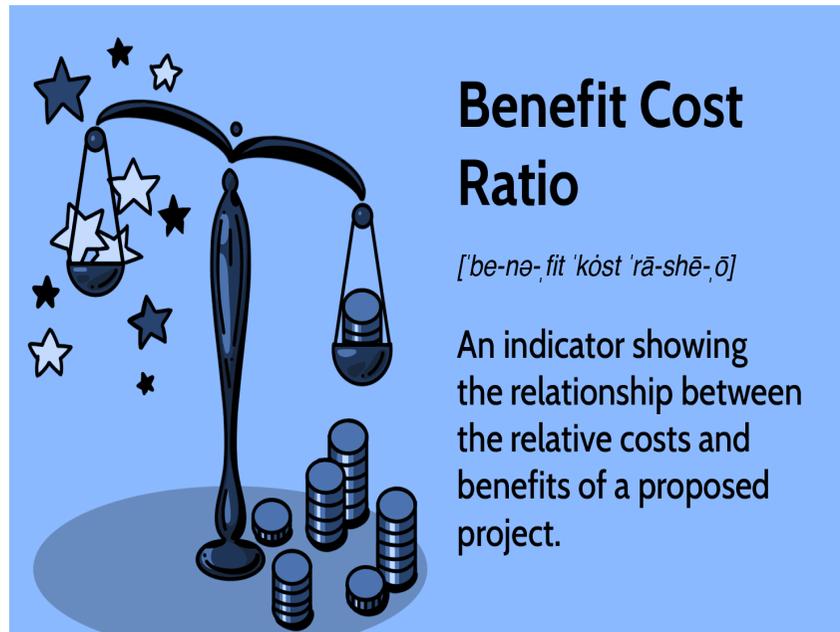
- 1 Animal research ethics and the 3Rs
- 2 The Harm-Benefit Analysis
- 3 Decision support tools
- 4 Strengths, Limitations and Conclusions
- 5 Approval rates

# The Harm-Benefit Analysis

Cost/risk-benefit analysis: a common decision theory

applied in several domains; economics, medicine:

- Cost-effectiveness analysis
- Risk-benefit ratio
- Cost-benefit ratio



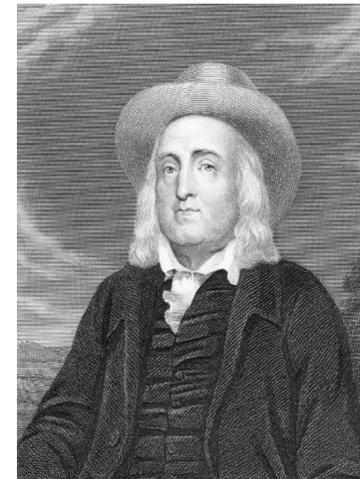
# The Harm-Benefit Analysis

Originates from **utilitarianism** as conceived by Jeremy

Bentham:

- The ethics of an action should be controlled by the notion of the greatest benefit for the greatest number involved.
- **Consequentialism** (Jeremy Bentham 1780; Card and Smith 2020):

The *ethical justification* of an *intended action* is determined by its *consequences* and their *usefulness* in making *society better* (Mill 1871; Jeremy Bentham 1890; Niemi 2019).

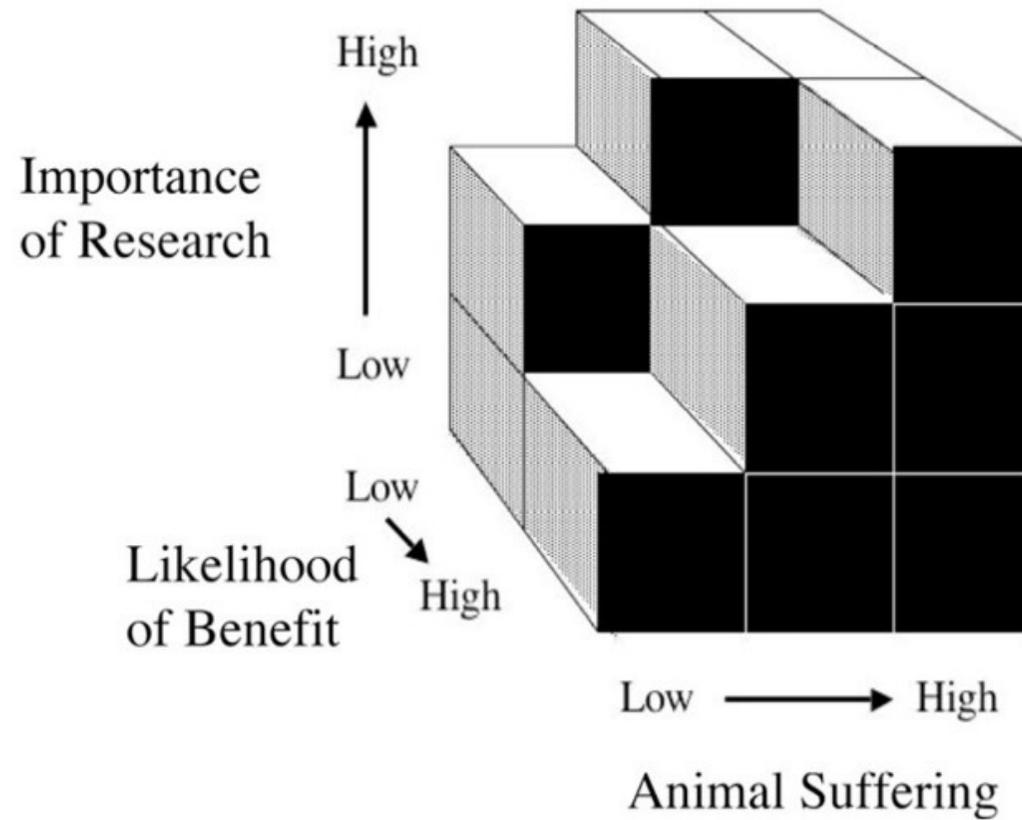


# The Harm-Benefit Analysis

- Research continuously documents challenges: difficulties in assessing harm and benefits; difficulties in comparing “apples with oranges”
- Researchers review HBA and propose tools to aid decision-making
- The extent to which such resources are currently available, their jurisdictions of applicability, and how they guide decision-making are not entirely clear.

# 1. Decision by Graphical representation– Bateson 1986

Bateson's Cube (1986)



# Scoping Review - Decision Support Tools for HBA

Pre-developed review protocol registered on **Open Science Framework**

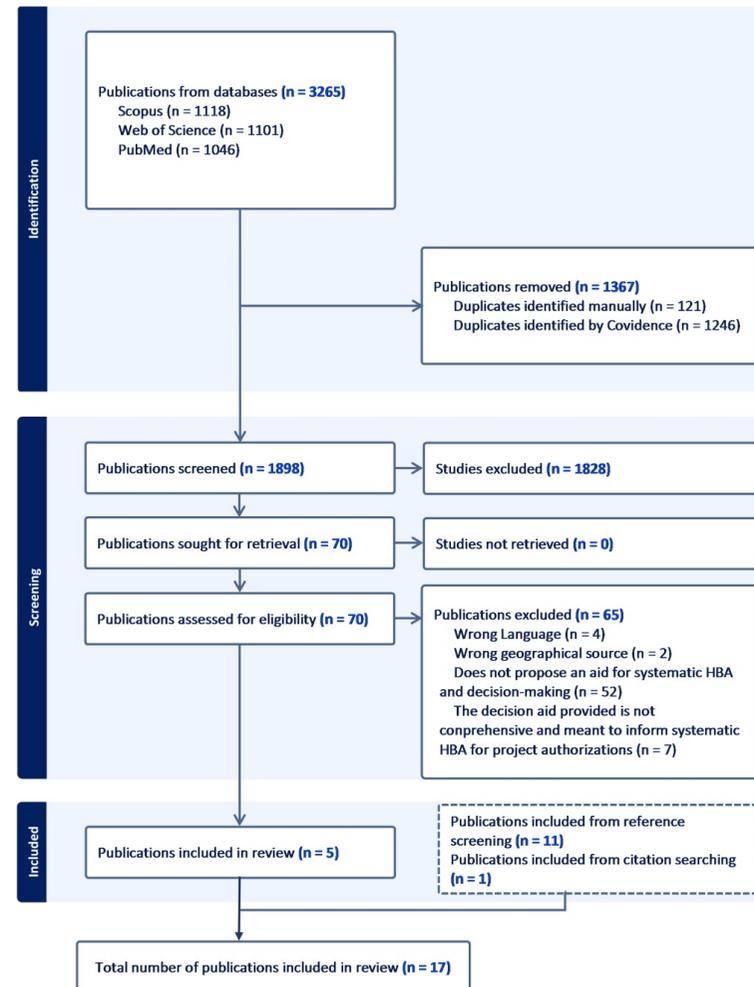
A systematic literature search on PubMed, Scopus and Web of Science

## Inclusion criteria:

- Publications in Europe and North America (USA and Canada)
- Period: 1985 to 2023.
- Publications proposing decision aids for systematic project evaluations.

## Results:

17 resources that can guide HBA and decision-making identified.



# Decision Support Tools for Harm-Benefit Analysis (HBA)

Decision Aid (Authors/Year)	Country (Author Affiliation /Legislation Referenced)	Region of Authorship	Country of Application
Bateson, 1986 [32]	UK	Europe	UK
Prentice et al., 1990 [53]	USA	North America	USA
Smith & Boyd, 1991 [56]	UK	Europe	Not specified
Porter, 1992 [47]	Canada	North America	Not stated
Boisvert & Porter, 1993 [57]	Canada	North America	Canada
de Cock Buning & Theune, 1994 [50] (Dutch model)	Netherlands	Europe	Netherlands
Animal Procedures Committee, 1994 [58]	UK	Europe	UK
Boisvert & Porter, 1995 [59]	Canada	North America	Canada

Delpire et al., 1998 [60]	Italy, UK	Europe	Not specified
Delpire et al., 1999[42]	Italy, UK	Europe	Not specified
Staffleu et al., 1999 [48]	Netherlands	Europe	Not stated
Voipio et al., 2004 [49]	Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Sweden and the Netherlands.	Europe	N/A
Lindl et al., 2012 [61]	Germany	Europe	Applicable in Germany; German laws were cited.
Bout et al., 2014 [25]	Netherlands	Europe	Not specified
Laber et al., 2016 [38]	USA, France, Spain and Norway	North America and Europe	Not stated
Liguori et al., 2017 [39]	Netherlands and Brazil	Europe and South America	Not stated
EU Expert Working Group, 2018 [33]	Europe	Europe	EU Member States where Directive 2010/63/EU is applicable

# Decision Support Tools – Approaches to HBA

Decision Aid (Authors/Year)	Approach to HBA	The Act of Harm-Benefit Balancing	Tools Provided
Bateson, 1986 [32]	<b>Graphic representation</b>	Use of a decision cube to assess quality of research, certainty of medical benefit and animal suffering. Projects falling within the opaque section are rejected.	A cube: (Bateson's cube)
Prentice et al., 1990 [53]	<b>Combined: Categories (protocol review guide) and Discourse (discussion)</b>	Protocol review instrument enables assessment of harm, benefit and the other. Final decision via committee discussion.	A protocol review guide.
Smith & Boyd, 1991 [56]	<b>Categories</b>	The decision aid provides items to evaluate. Final decision seems to be based on value judgements by decision-makers.	Two assessment schemes (for benefits and costs)
Porter, 1992 [47]	<b>Scoring/Metric</b>	By scoring the various (integrated) aspects (categories) of harm and benefits using the decision toolkit to arrive at a final score to make a decision.	Scoring system, from 8 to 40.

# Decision Support Tools – Approaches to HBA

Decision Aid (Authors/Year)	Approach to HBA	The Act of Harm-Benefit Balancing	Tools Provided
Boisvert & Porter, 1993 [57]	Scoring/Metric	By adding up the scores from the 10 categories.	A score sheet (via mathematical arithmetic)
de Cock Buning & Theune, 1994 [50]	Combined (Categories and Algorithm)	Detailed questions on quality of the experiment, discomfort, significance and credentials of the research group, help trace morally significant aspects of a proposal. The checklist offers a visual impression of the overall score. Harm and benefit are balanced using the matrix.	A checklist, decision-tree and balancing matrix (Table)
Animal Procedures Committee, 1994 [58]	<b>Algorithm/metric (Benefit divided by Cost)</b>	Justification is determined by dividing the benefits (importance and probability of achieving objectives) by the costs (adverse effects and coping strategies).	Mathematical formula for benefit-cost analysis
Boisvert & Porter, 1995 [59]	Discourse model (which can potentially lead to a score or value to benefit/cost)	Checklist with 10 categories, with 3 categories (A to C) attributed to the assessment of benefits and 7 (D to J) to the assessment of costs.	A checklist to guide cost-benefit balancing

# Decision Support Tools – Approaches to HBA

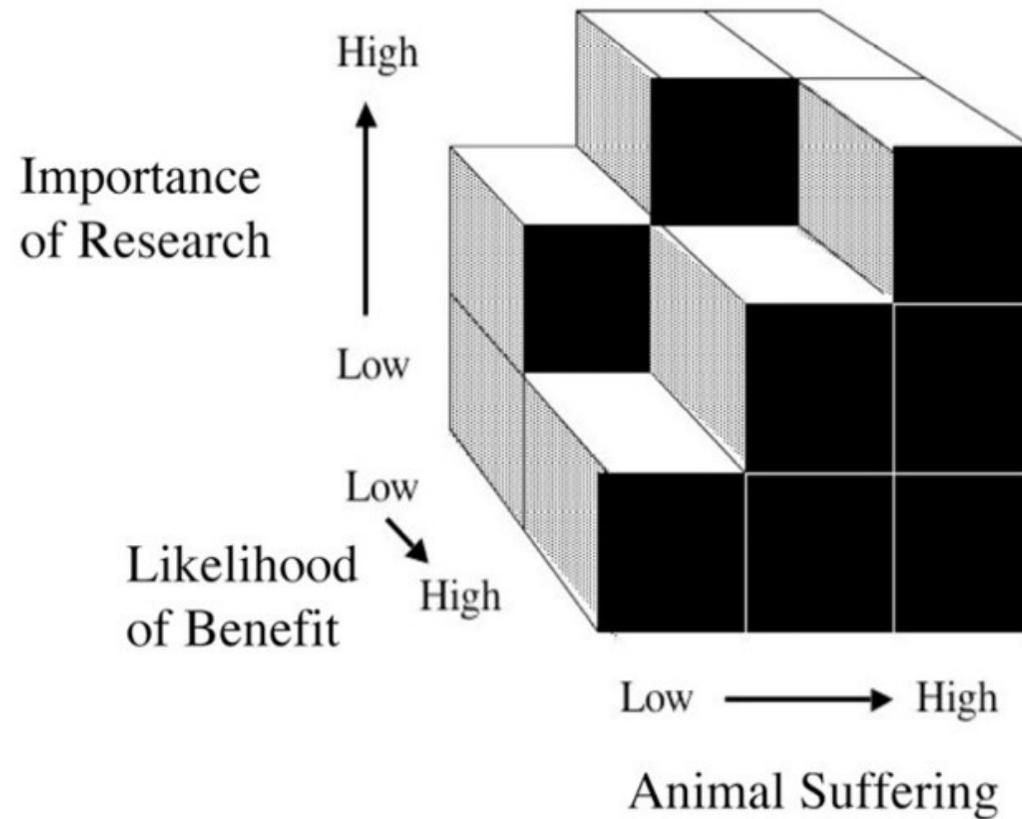
Decision Aid (Authors/Year)	Approach to HBA	The Act of Harm-Benefit Balancing	Tools Provided
Delpire et al., 1998 [60]	Scoring/Metric	Answering two entry-level questions followed by an ethical assessment of impacts on interest groups. The sink ensures that a single significant cost can lead to rejection, regardless of benefits.	A scheme
Delpire et al., 1999[42]	<b>Combined: Categories (Checklist) and decision-making matrix (Table)</b>	The table (matrix) is completed for the four criteria included in the application form by assigning a decision to each of the criterion.	1) Matrix; 2) Checklist; 3) Guidance notes; 4)Transgenic data sheet
Stafleu et al., 1999 [48]	Scoring system	By computing the final scores for human interests (health, knowledge and economic), ultimate aim; relevance experiment; and harm to the interests of the animal.	1) Scoring system with formulas; 2) Eight-step decision-making algorithm
Voipio et al., 2004 [49]	Combined: Graphic representation (Modified Bateson's cube); Categories (Harm and Benefits); and Discourse	Conducting a cost-benefit-means analysis. Evaluating means when costs are medium-severe, benefits are moderate-high, or when costs are higher than benefits. Severity degrees preferred over mathematical calculations.	Modified two-dimension Bateson cube.

## Decision Support Tools – Approaches to HBA

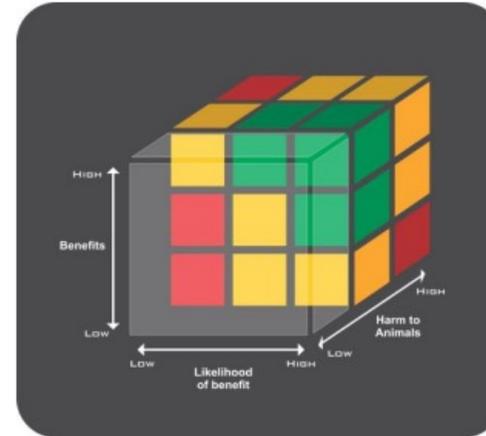
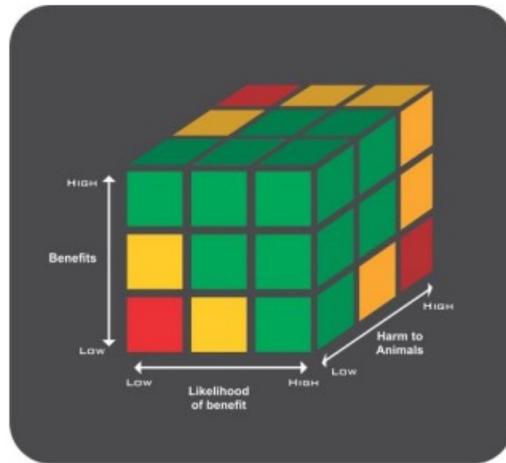
Decision Aid (Authors/Year)	Approach to HBA	The Act of Harm-Benefit Balancing	Tools Provided
Lindl et al., 2012 [61]	Discourse with Categories (Checklist)	Answering questions (in categories) stipulated in the application form.	An application form (checklist) with categories
Bout et al., 2014 [25]	Graphical representation with a discourse approach	The use of a graphical matrix showing the balance between different levels of harm and benefit.	A matrix
Laber et al., 2016 [38]	Combined: Scoring system (numeric) and Color scores (graphic representation)	The use of a template to assess benefits and harms, modulating factors (MF); and their mitigating and aggravating effects using a summary color and “plus” scores.	Template (table) used with “plus” and color codes.
Liguori et al., 2017 [39]	Combined: Algorithm (metric) and graphical representation	By grading human benefits versus animal harm while visualizing harm, benefits, and translational gap to reach a final score for a decision.	Algorithmic flowchart; Graphical tool; Scoring table.
EU Expert Working Group, 2018 [33]	Graphic representation (revised Bateson's cube)	Colored cubes depict links between the harms, benefits and likelihood of success: Green cubes depict a favorable HBA while detailed analyses are needed for amber and red cubes.	Revised Bateson's cube.

# 1. Decision by Graphical representation– Bateson 1986

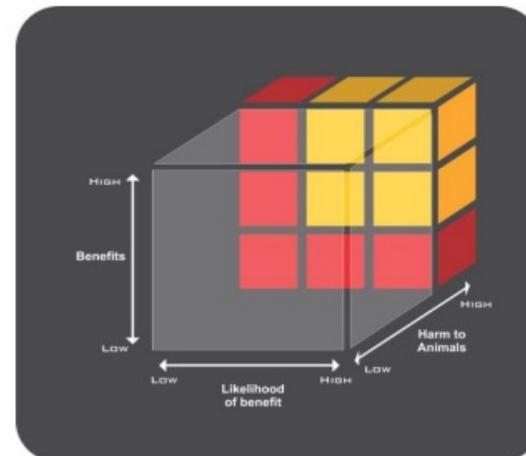
Bateson's Cube (1986)



# Modified Bateson's Cube



National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. Working document on Project Evaluation and Retrospective Assessment. Brussels, 18-19 September 2013



## 2. Decision by categorical groupings – Delpire et al 1999

**Table I: The check-list**

To be completed by applicants for all proposals.

---

<b>1</b>	<b>Justification</b>
1.1	Specification of the field of activity and description of the general purpose of the work.
1.2	Application of the Three Rs.

---

<b>2</b>	<b>Scientific relevance</b>
2.1	Demonstration of the scientific quality of the work.
2.2	Demonstration of the quality of workers and facilities.

---

<b>3</b>	<b>Animal suffering</b>
3.1	Establishment of the severity of procedures.
3.2	Description of the impact of transport and housing conditions.
3.3	Overall assessment of adverse effects.

---

<b>4</b>	<b>Wider social, economic and environmental impacts</b>
	Assessment of the general impact of the work on the various interest groups involved, i.e. animals used/animals in general, human patients/consumers, society (developed and developing), and the biota (animal and plant life of a region).

---

## 2. Decision by categorical groupings – Delpire et al 1999

**Figure 1: The decision-making system**

To be completed by the responsible authorities for all proposals

	Approval	Conditional approval	Provisional rejection	Rejection	Referral
Criterion 1					
Criterion 2					
Criterion 3					
Criterion 4					
Overall Assessment					

## 2. Decision by categorical groupings – Delpire et al 1999

**Table II: The guidance notes**

---

### **1 Justification**

*1.1 Specify the field of activity and describe the general purpose of the work*

*1.1.1 Examples of categories of work, which could also be considered as an exhaustive list of permissible purposes:*

- basic research (increasing scientific knowledge);
- applied medical/veterinary research (prevention, diagnosis or treatment of disease);
- product development and testing (regulatory toxicology and development, quality and safety testing of chemicals, agrochemicals, food additives, pharmaceuticals, cosmetic ingredients and biologicals);
- environmental protection (in the interests of human/animal health, as well as protection of the environment in general);
- education/training (specify);
- development of alternative methods; and
- breeding of animals for experimental purposes.

*1.1.2 In addition to a list of permissible purposes, it is suggested that the following procedures be considered ethically unacceptable under any circumstances:*

- use of Great Apes;
- development of transgenic primates;
- use of animals for the testing or development of offensive weapons or alcohol and tobacco products;
- safety testing of finished cosmetic products (alternatives exist); and
- production of monoclonal antibodies by the ascites procedure (alternatives exist).

## 2. Decision by categorical groupings – Delpire et al 1999

1.1.3 *When describing the purpose of the work, assess its significance according to the following parameters (select and apply those relevant for the type of activity involved):*

- scientific value (originality and interest of the work);
- social value (importance of the health problem to be solved/the product to be developed and/or tested);
- economic value (for example, impact on national or individual industry, potential contribution to employment, use and conservation of national resources); and
- educational value (training of future medical doctors, veterinary surgeons and animal care-takers).

1.2 *Show application of the Three Rs*

1.2.1 *Replacement*

- justify the need to use animals in the experiments and certify the lack of valid replacement alternative methods (provide evidence of consultation with adequate sources/authorities and relevant analysis of information).

1.2.2 *Reduction*

- indicate the number of animals to be used and certify that this is the minimum consistent with providing valid scientific results (statistical analysis);
  - indicate whether it is a case of repeating or closely simulating previous research and, if so, justify;
  - indicate whether there is planned collaboration with other groups working in the same field and whether animals or their organs are shared and, if so, how; and
  - indicate whether animals are re-used and, if so, under what conditions.
-

## 2. Decision by categorical groupings – Delpire et al 1999

Table II: continued

---

### 1.2.3 Refinement

- indicate the species of animals used, and show that use is made of the least sentient species able to provide valid scientific results; and
  - indicate how pain and discomfort are minimised relative to the scientific needs of the project (use of analgesia/anaesthesia, humane methods of euthanasia, choice of endpoints with minimum suffering, choice of adequate housing conditions, choice of best available equipment, choice of most experienced personnel).
- 

## 2 Scientific relevance

### 2.1 Parameters for the scientific quality of the work

- demonstrate the relevance of the proposed work in relation to current knowledge and the subject to be addressed;
- indicate how the scientific quality of the proposal is assessed (for example, by periodical independent peer review);
- demonstrate adequacy and security of funding in relation to time-scale of proposed work;
- demonstrate quality of experimental design, including statistical aspects;
- demonstrate validity of working hypotheses and suitability of protocols in relation to general purpose of the work (i.e. schedule of experiments, including protocols); and
- summarise the results of any pilot studies.

## 2. Decision by categorical groupings – Delpire et al 1999

### 2.2 *Parameters for quality of workers and facilities*

#### 2.2.1 *Workers*

- demonstrate that the team is multidisciplinary to ensure availability of all the necessary competences, to maximise both scientific quality and animal welfare; and
- demonstrate relevant experience and adequate training (for example, certification) of all workers in relation to the specific field of activity and to animal care requirements. Make reference to compliance with relevant legislative requirements.

#### 2.2.2 *Facilities*

- demonstrate adequacy of facilities for performing experiments (for example, standards of equipment, operating areas), and for housing and care of the animals (for example, standards for feeding and watering systems, cleanliness, veterinary supervision). Make reference to compliance with relevant legislative requirements.
- 

## 3 **Animal suffering**

### 3.1 *List all procedures and assess their severity according to the following guidance*

- mild, for example, insertion of hypodermic needle, laparoscopy under anaesthesia, simple vascular cannulation, rectal examination, administration of innocuous substances by gavage;
  - moderate, for example, most surgical procedures under anaesthesia with recovery, toxicity tests avoiding lethal endpoints;
  - severe, for example, interventions which compromise the well-being of animals in a significant way, which involve major surgery, or which may cause acute pain, significant morbidity, or death;
  - unclassified, i.e. experiments which are performed under general anaesthesia without recovery, or on decerebrate animals.
-

## 2. Decision by categorical groupings – Delpire et al 1999

**Table II: continued**

- 
- 3.2 *Assess the impact of transport and housing conditions in terms of mild, moderate and severe, taking the following parameters into account*
- capture (animals taken from the wild);
  - transport duration and conditions (distance and packaging);
  - quarantine (if appropriate); and
  - laboratory environment (for example, single/group caging).
- 3.3 *Make an overall assessment of adverse effects in terms of mild, moderate and severe in relation to species-specific characteristics*
- in order to achieve a fair assessment of animal suffering, it is not sufficient to consider only the criteria listed above under 3.1 and 3.2. It is argued that severity is truly determined by an animal's capacity to experience pain, distress or discomfort. This means that factors such as the choice of species used and the skilled recognition of adverse effects, in order to manage and possibly avoid them by the choice of specific endpoints, are also essential for an acceptable assessment of the overall severity of the proposed work.
-

## 2. Decision by categorical groupings – Delpire et al 1999

---

### 4 Wider social, economic and environmental impacts

The assessment of the wider social, economic and environmental impacts of the work proposed should be made in terms of the various interest groups involved, i.e. animals used/animals in general; human patients/consumers; society (developed and developing); and the biota (the animal and plant life of a region).

The information provided for criteria 1–3 of the check-list enables the identification of the wider bioethical issues listed below. These should be addressed individually, and should lead to a positive/negative assessment of the work with respect to this particular criterion:

- a) quality of human relationships to the community of animals (animals used/animals in general), in terms of respect for their welfare and their own interests;
  - b) attitudes toward intended patients/consumers, in terms of respect for their quality of life, their safety, their freedom to make informed choices of therapy/product (and the availability of alternatives), and their fair treatment in terms of economic accessibility of therapy/product (and the availability of alternatives);
  - c) societal concerns (including those in developed and developing countries), in terms of standard of living, democratic and transparent decision-making processes, and fair distribution of resources; and
  - d) protection of the biota (the animal and plant life of a region), in terms of its conservation, maintenance of biodiversity, and existing safety regulations.
-

## 2. Decision by categorical groupings – Delpire et al 1999

### ***Recommended procedure for use of the decision-making system***

*Step 1: Individual assessment of information provided for criteria 1–4 in the check-list and assignment of one of the following decisions for each criterion:*

<i>Approval</i>	<i>Information provided is acceptable</i>
<i>Conditional approval</i>	<i>Approved, if specific recommendations are followed</i>
<i>Provisional rejection</i>	<i>Substantial modifications are required before further consideration</i>
<i>Rejection</i>	<i>Information provided is unacceptable</i>
<i>Referral</i>	<i>Insufficient information is provided for a decision to be made</i>

*Only for proposals involving the use of transgenic animals: correlation of the information gained from the transgenic data sheet with criteria 1–4 of the check-list (as appropriate), before assigning an individual decision for each criterion.*

*Step 2: Overall assessment of the proposal on the basis of individual decisions assigned in Step 1:*

<i>Approval</i>	<i>Approval has been assigned for each criterion, therefore the proposal is approved (subject to existing legal requirements), but will be submitted to periodical and specific reappraisal</i>
<i>Conditional approval</i>	<i>Specific recommendations must be implemented for one or more criteria, while approval has been assigned for the remaining criteria</i>
<i>Provisional rejection</i>	<i>Substantial modification is needed for one or more criteria, while approval or conditional approval has been assigned for the remaining criteria. The work is rejected until a further proposal is received</i>
<i>Rejection</i>	<i>Rejection has been assigned for one or more criteria and the proposal is therefore categorically refused</i>
<i>Referral</i>	<i>Insufficient information is provided for one or more criteria to be dealt with satisfactorily</i>

## 2. Decision by categorical groupings – Delpire et al 1999

**Figure 1: The decision-making system**

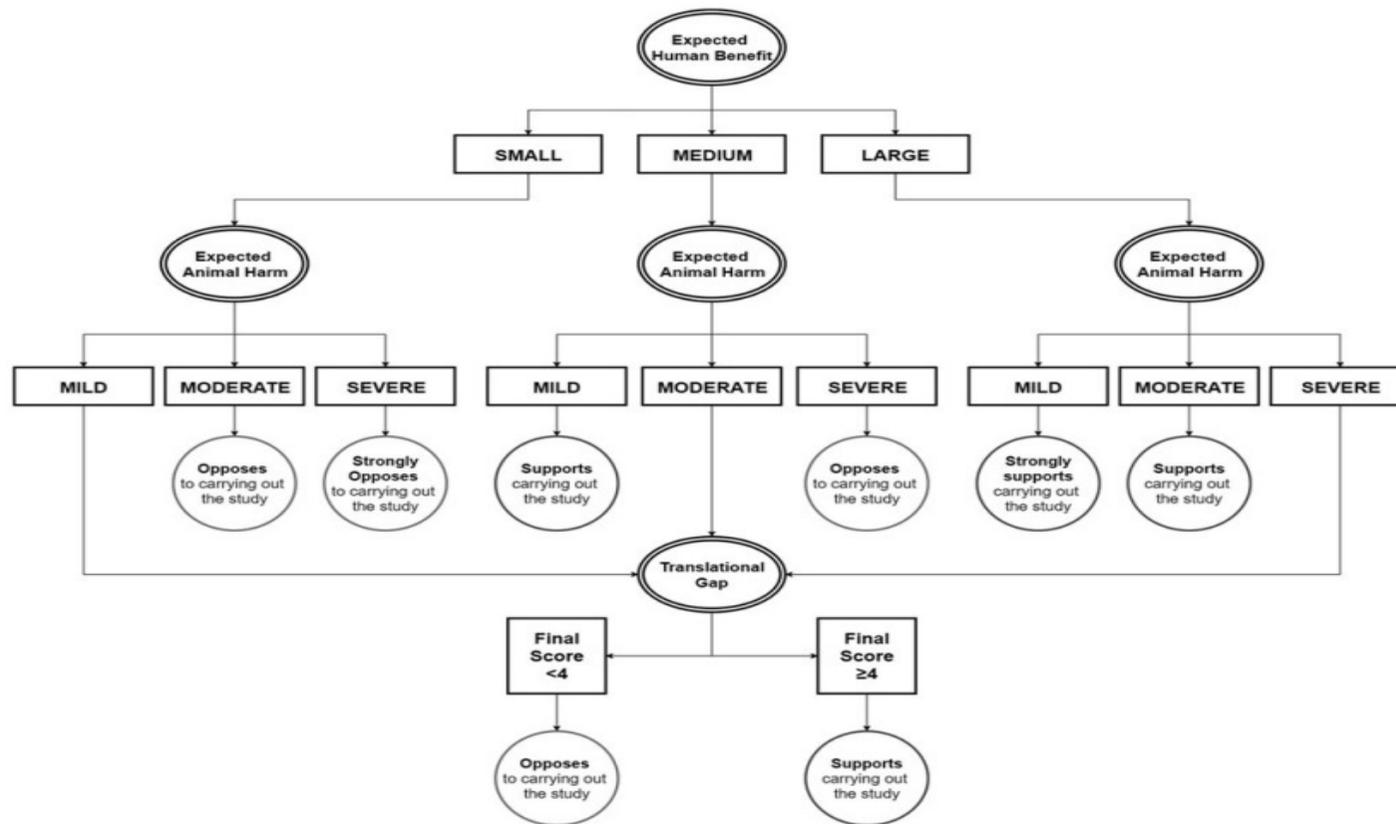
To be completed by the responsible authorities for all proposals

	Approval	Conditional approval	Provisional rejection	Rejection	Referral
Criterion 1					
Criterion 2					
Criterion 3					
Criterion 4					
Overall Assessment					

### 3. Decision matrix (graphical) – Bout et al. 2014

			Harm			
Benefit	Scientific	Societal	Mild	Moderate	Severe	
	Low	Low	Low	Red	Red	Red
		Moderate	Low	Green	Red	Red
		High	Low	Green	Green	Red
	Moderate	Low	Low	Green	Red	Red
		Moderate	Low	Green	Green	Red
		High	Low	Green	Green	Red
	High	Low	Low	Green	Green	Red
		Moderate	Low	Green	Green	Red
		High	Low	Green	Green	Green

## 4. Decision by Algorithms – Liguori et al 2017



**FIG. 1.** Flowchart of the harm–benefit analysis algorithm. Definitions of the expected human benefit and expected animal harm categories can be found in Table 2. Translational gap evaluation questionnaire and score can be found in Table 3.

## 4. Decision by Algorithms – Liguori et al 2017

TABLE 2. DEFINITION OF THE GRADES OF EXPECTED HUMAN BENEFIT AND ANIMAL HARM

<i>Grade</i>	<i>Definition</i>
Expected human benefit	
Small	Increased basic biological knowledge or knowledge of a disease mechanism.
Medium	New or better treatment for a nonlife-threatening disease.
Large	New or better treatment for a life-threatening disease.
Expected animal harm	
Mild	Short-term mild pain, suffering, or distress with no significant impairment of the well-being or general condition.
Moderate	Short-term moderate pain, suffering, or distress, or long-lasting mild pain, suffering, or distress, likely to cause moderate impairment of the well-being or general condition.
Severe	Severe pain, suffering, or distress, or long-lasting moderate pain, suffering, or distress, likely to cause severe impairment of the well-being or general condition.

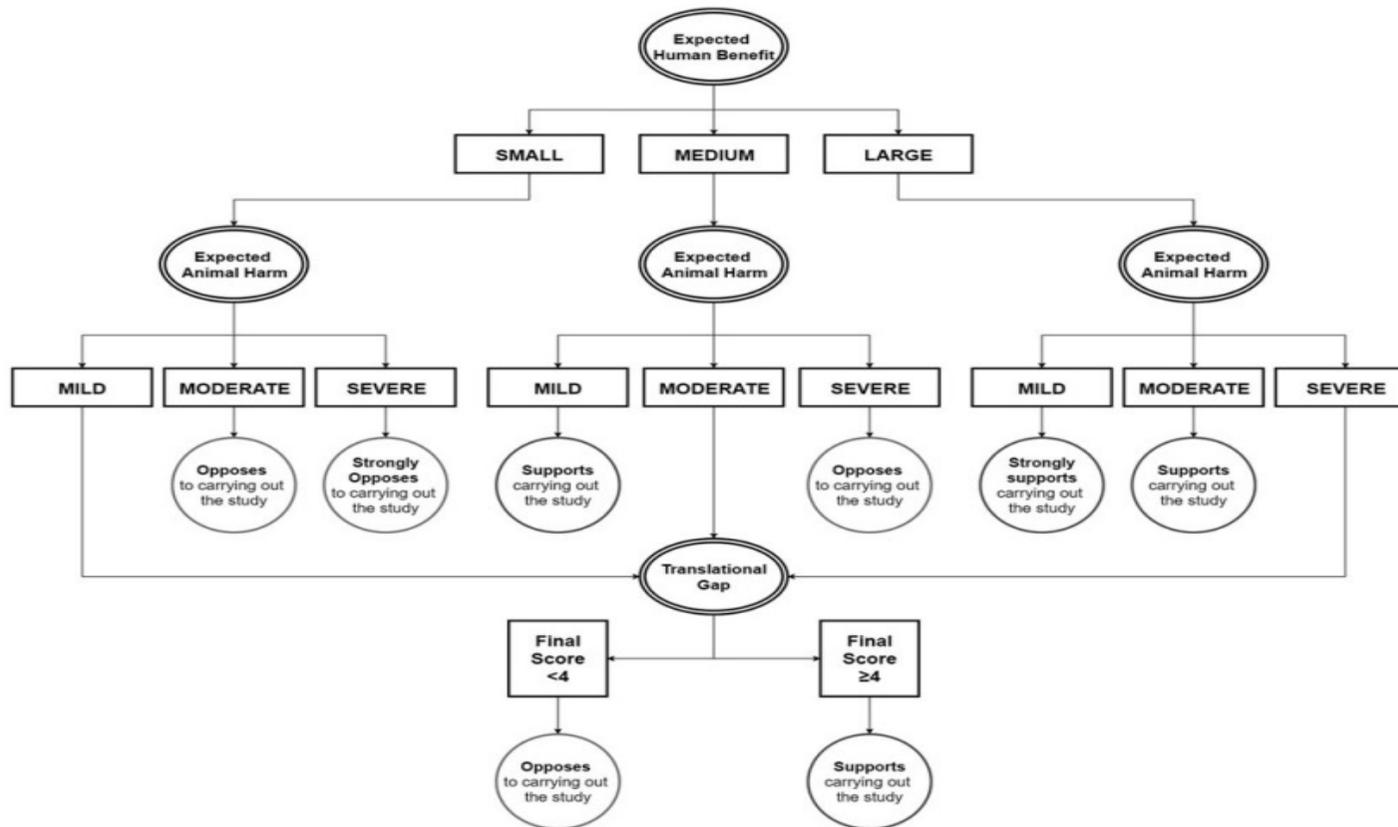
## 4. Decision by Algorithms – Liguori et al 2017

TABLE 3. GUIDE FOR THE TRANSLATIONAL GAP EVALUATION OF THE ANIMAL MODEL

<i>Characteristic</i>	<i>Questions to be answered (yes or no)</i>	<i>Score (if yes)</i>
Animal species	According to the literature, is the animal species representative of the human anatomy and pathophysiology for the studied organ/system? <sup>a</sup>	+1
Recovering status	Do untreated animals recover in the same manner as the natural history of disease in clinical presentation?	+1
Graft implantation site	Does the graft implantation site match type and anatomy to the clinical application?	+1
Gender and age	Do gender and age of the animal model match the clinical epidemiology of the disease?	+1
Disease pathophysiology	Is the animal model of the disease representative of the pathophysiology in clinical presentation?	+1
Previous evidence of translational potential	Was the animal model previously used in a preclinical study that resulted in successful clinical application? <sup>a</sup>	+2
	Total score	7

<sup>a</sup>Literature reference is necessary to support the answer.

## 4. Decision by Algorithms – Liguori et al 2017



**FIG. 1.** Flowchart of the harm–benefit analysis algorithm. Definitions of the expected human benefit and expected animal harm categories can be found in Table 2. Translational gap evaluation questionnaire and score can be found in Table 3.

## 5. Decision by Scoring – Porter 1992

---

PROPOSED SCORING SYSTEM TO MINIMIZE SUFFERING IN ANIMAL EXPERIMENTS

---

**A Aim of experiment**

1. Alleviation of substantial human or non-human pain
2. Alleviation of moderate human or non-human pain or suffering
3. Clear benefit to human or non-human health or welfare.
4. Some benefit to human or non-human health or welfare.
5. Fundamental research for the advancement of knowledge (no clear alleviation of pain or benefit to human or animal health)

**B Realistic potential of experiment to achieve objective**

1. Excellent
2. Very good
3. Average/fair
4. Limited
5. Very limited or impossible to assess

**C Species of animal**

1. Low sensibility/consciousness
2. Some sensibility
3. Sentient but possibly limited consciousness
4. Sentient and conscious
5. Sentient, highly intelligent and precognitive

**D Pain likely to be involved**

1. None
2. Minimal/slight
3. Moderate
4. Considerable
5. Severe

**E Duration of discomfort or distress**

1. None or very short
2. Short
3. Moderate
4. Long
5. Very long

**F Duration of experiment**

1. Extremely short  $10^{-5}$  LS
2. Short  $2 \times 10^{-4}$  LS
3. Moderate  $2 \times 10^{-2}$  LS
4. Long  $2 \times 10^{-2}$  LS
5. Very long  $> 2 \times 10^{-1}$  LS

**G Number of animals**

1. 1–5
2. 5–10
3. 10–20
4. 20–100
5. >100

**H Quality of animal care**

1. Excellent
2. Very good
3. Average
4. Good
5. Poor

## 6. Decision by Scoring – Stafleu et al. 1999

**Step one: formulation of the ultimate aim of the experiment**

**Step two: dermination of the weight of the human interest**

Score gains in health interest		Score gains in knowledge interest		Score gains in economical interest	
Item	Possible score	Item	Possible score	Item	Possible score
Suffering?	[ ] H (0 - 10)	Hypothesis?	[ ] K (0 - 5)	Effect industry?	[ ] E (0 - 5)
Mortality?		Originality?		Effect national economy?	
Morbidity?		Problem worth solving?		Effect human welfare?	

**Step three: computation of the total interest score of the ultimate aim (IUA)**

[ ] H = [ ] IUA (0 - 10)

[ ] H + [ ] K = [ ] IUA (0 - 10)

[ ] H + ([ ] K or [ ] E) x 2 = [ ] IUA (0 - 10)

[ ] H + [ ] K + [ ] E = [ ] IUA (0 - 10)

**Step four: assessment of the relevance of the animal experiment**

Replacement possible? Yes: score 0 No: score 10 [ ]

Methodological quality (general)? Score 7 - 10 score <7 = score 0 [ ]

Methodological quality (laboratory animal science)? Score 7 - 10 score <7 = score 0 [ ]

Necessity? Score 5 - 10 score <5 = score 0 [ ]

Probability? Score 0, 5 or 10 [ ]

Quality research group? Score 1 - 10 score <5 = score 0 [ ]

One or more "0" leads to relevance 0 => experiment unacceptable

Total relevance [ ] = [ ] R (0.65 - 1)

**Step five: calculation of the interest of the experiment for human beings (HI)**

[ ] IUA x [ ] R = [ ] HI (0 - 10)

**Step six: assessment and scoring of the harm to the interest of animals**

Actual discomfort	Duration of discomfort	Numbers of animals involved
No or positive 0	Short and/or once 0	<10 0
Slight 1	Medium and/or frequently 1	10 - 100 1
Medium 2	Long lasting and/or very frequently 2	>100 2
Severe 3		
Very severe 4		

Total discomfort [ ] A

Intrinsic value (fixed score) [ ] I

Psychological complexity [ ] P

Non human primates 2

Cold blooded -2

Other vertebrates 0

**Step seven: computation of the harm score for animals (A)**

[ ] T + [ ] I + [ ] P = [ ] A

**Step eight: Assessment of the ethical acceptability of the experiment**

If [ ] HI ≥ [ ] A Experiment acceptable

If [ ] HI < [ ] A Experiment unacceptable

## Decision Approaches – Strengths and Limitations

	Strengths	Weaknesses
Categories	Categories are useful for simplifying a complex picture. Identify severe categories and stimulate actions to avoid them.	The categories do not fit all cases.
Algorithms	Algorithms are helpful in guiding a decision.	Moral dilemmas cannot/shall not be solved by arithmetics.
Graphic representations	Graphic representations have pedagogic value in visualizing the concept and relationship between harm and benefit.	Depend on defined categories. Not operational.
Process-oriented models	Process-oriented models structure the HBA process, how to balance different opinions and question quality of the analysis. Generic.	Do not provide an answer on what models to use or provide solutions for conclusions.

Grimm H, Olsson IAS, Sandøe P. Harm–benefit analysis – what is the added value? A review of alternative strategies for weighing harms and benefits as part of the assessment of animal research. *Lab Anim* 2019;53:17–27

## Conclusions

- Decision aids can take different approaches to ethical evaluation due to the varying ethical perspectives of the authors or groups proposing them.
- Ethical ideologies are reflected in what is considered as harm to animals and what should count as benefit that justifies an animal research project.
- How a particular decision aid can be chosen to be used in oversight committees (which are generally composed of individuals with varying perspectives) can be challenging.
- Decision-making based on deliberation among committee members should be supported over the use of scoring approaches.
- Making ethical decisions on a case-by-case basis is preferable to accuracy, which may not be realistically practicable.

# References

1. Bout HJ, van Vlissingen JMF, Karssing ED. Evaluating the ethical acceptability of animal research. *Lab Animal* 2014 43:11 2014;43:411–4. <https://doi.org/10.1038/labam.572>.
2. Stafleu FR, Tramper R, Vorstenbosch J, Joles JA. The ethical acceptability of animal experiments: proposal for a system to support decision-making. *Lab Anim* 1999;33:295–303. <https://doi.org/10.1258/002367799780578255>.
3. Voipio H-M, Kaliste E, Hirsjärvi P, Nevalainen T, Ritskes-Hoitinga M. Nordic-European workshop on ethical evaluation of animal experiments. *Scandinavian Journal of Laboratory Animal Science* 2004;31:251–67
4. de Cock Buning T, Theune EP. A Comparison of Three Models for Ethical Evaluation of Proposed Animal Experiments. *Animal Welfare* 1994;3:107–28. <https://doi.org/10.1017/S0962728600016614>.
5. Prentice ED, Crouse DA, Rings RW, Prentice ED. Approaches to increasing the ethical consistency of prior review of animal research. *Invest Radiol* 1990;25:271–4. <https://doi.org/10.1097/00004424-199003000-00012>
6. Smith JA, Boyd KM. The assessment and “weighing” of costs and benefits. *Lives in the Balance: The Ethics of Using Animals in Biomedical Research: The report of a Working Party of the Institute of Medical Ethics*, New York: Oxford University Press; 1991.
7. Boisvert DP, Porter DG. Ethical scoring systems. In: Johnston NE, editor. *Animal Welfare Conference Proceedings*, Clayton, Victoria: Monash University; 1993, p. 23–7.
8. Delpire V, Shaw D, Crilly RE, Mephram TB, Combes RD, Balls M. A comprehensive evaluation of procedures involving the use of transgenic animals within the European Union. In: O'Donoghue PN, editor. *The Ethics of Animal Experimentation*, London: EBRA; 1998, p. 223–8.
9. Schuppli CA. Decisions about the use of animals in research: Ethical reflection by animal ethics committee members. *Anthrozoos* 2011;24:409–25. <https://doi.org/10.2752/175303711X13159027359980>.
10. Porter DG. Ethical scores for animal experiments. *Nature* 1992;356:101–2. <https://doi.org/10.1038/356101a0>.
11. Bateson P. When to experiment on animals. *New Sci* 1986;109:30–2.
12. Expert Working Group for Project Evaluation and Retrospective Assessment. *Caring for animals aiming for better science: Directive 2010/63/EU on protection of animals used for scientific purposes : project evaluation and retrospective assessment: Working document on Project Evaluation and Retrospective Assessment*. 2018. <https://doi.org/doi:10.2779/59814>
13. Laber K, Newcomer CE, Decelle T, Everitt JI, Guillen J, Brønstad A. Recommendations for addressing harm–benefit analysis and implementation in ethical evaluation – Report from the AALAS–FELASA working group on harm–benefit analysis – Part 2. *Lab Anim* 2016;50:21–42. <https://doi.org/10.1177/0023677216642397>.
14. Liguori GR, Jeronimus BF, De Aquinas Liguori TT, Moreira LFP, Harmsen MC. Ethical Issues in the Use of Animal Models for Tissue Engineering: Reflections on Legal Aspects, Moral Theory, Three Rs Strategies, and Harm/Benefit Analysis. *Tissue Eng Part C Methods* 2017;23:850–62. <https://doi.org/10.1089/TEN.TEC.2017.0189/ASSET/IMAGES/LARGE/FIGURE2.JPG>.
15. Smith JA, Van Den Broek FAR, Martorell JC, Hackbarth H, Ruksenas O, Zeller W. Principles and practice in ethical review of animal experiments across Europe: Summary of the report of a FELASA working group on ethical evaluation of animal experiments. *Lab Anim* 2007;41:143–60. [https://doi.org/10.1258/002367707780378212/SUPPL\\_FILE/FELASA\\_ETHICS.PDF](https://doi.org/10.1258/002367707780378212/SUPPL_FILE/FELASA_ETHICS.PDF).
16. Delpire VC, Mephram T Ben, Balls M. A Proposal for a New Ethical Scheme Addressing the Use of Laboratory Animals for Biomedical Purposes. <https://doi.org/10.1177/026119299902701s01> 1999;27:869–81. <https://doi.org/10.1177/026119299902701S01>.



Universität  
Basel

Thanks for your attention.

[Home](#) > [BMC Medical Ethics](#) > [Article](#)

# A scoping review of ethical decisions and decision tools for experimental animal protocols

Systematic Review | [Open access](#) | Published: 14 November 2025

Volume 26, article number 160, (2025) [Cite this article](#)



**BMC Medical Ethics**

