

**RESEARCH**

# The role of bioethics in animal ethics commissions

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**Abstract**

Guidelines for the use of animals as experimental models transposed bioethics area focusing on the legal area, which brought the benefit of standardization of physical and biological parameters, focused on animal welfare, but added bureaucratic and legal demands that occupied a reflection and discussion previously aimed at resolving ethical conflicts. This quantitative study aimed to characterize the opinion of members, coordinators and collaborators of ethics committees on how the use of Brazilian animals relates to those committees functioning. The 114 participants demonstrated adherence to the legislation but they pointed to an increase in potentially solving conflicts in the sphere of Bioethics. Although Bioethics has been identified as important for the proper functioning of committees, it has been defined in an unsatisfactory manner, evidencing the need to resume its role of guiding deliberations. This conclusion indicates the need to incorporate members with training in bioethics, invest in the frequent training of the collegiate and researchers involved in animal experimentation.

**Keywords:** Ethics committees. Animal experimentation. Deliberations.

**Resumo****O papel da bioética nas comissões de ética animal**

As diretrizes para usar animais como modelos experimentais transpuseram o campo bioético e chegaram ao âmbito jurídico. Se por um lado isso favoreceu a normatização de parâmetros físicos e biológicos voltados ao bem-estar animal, por outro, acrescentou demandas burocráticas que ocuparam a reflexão anteriormente destinada à resolução de conflitos éticos. Este estudo quantitativo objetivou analisar a opinião de membros, coordenadores e colaboradores brasileiros das comissões de ética no uso de animais sobre o funcionamento desses dispositivos legais. Os 114 participantes demonstraram aderir à legislação; contudo, apontaram aumento de conflitos potencialmente solucionáveis na esfera bioética. Embora importante para o bom funcionamento das comissões, a bioética foi definida como deficitária, precisando retomar seu papel norteador nas deliberações. Essa conclusão indica a necessidade de incorporar membros com formação em bioética, além de investir na capacitação frequente do colegiado e dos pesquisadores envolvidos em experimentação animal.

**Palavras-chave:** Comissão de ética. Experimentação animal. Deliberações.

**Resumen****El papel de la bioética en las comisiones de ética animal**

Las directrices para el uso de animales como modelos experimentales instrumentaron la orientación bioética incidiendo en el área legal, lo que trajo el beneficio de la normalización de parámetros físicos y biológicos, dirigidos al bienestar animal, pero incrementó las demandas burocráticas y legales que ocuparon la reflexión y discusión anteriormente destinadas a la resolución de conflictos éticos. Este estudio cuantitativo tuvo como objetivo caracterizar la opinión de miembros, coordinadores y colaboradores de las comisiones de ética en el uso de animales de Brasil sobre su funcionamiento. Los 114 participantes mostraron adhesión a la legislación, no obstante, señalaron un aumento de conflictos potencialmente solucionables en la esfera de la bioética. Aunque la bioética haya sido identificada como importante para el buen funcionamiento de las comisiones, fue definida de manera deficitaria, evidenciando la necesidad de retomar su papel de orientadora de las deliberaciones. Esta conclusión indica la necesidad de incorporar miembros con formación en bioética, invertir en la capacitación frecuente del colegiado y de los investigadores involucrados en la experimentación animal.

**Palabras clave:** Comités de ética. Experimentación animal. Deliberaciones.

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Declararam não haver conflito de interesse.

The questioning of limits on the use of animals as experimental models starts from the classical era and goes until the second phase of bioethics in the 1980s<sup>1,2</sup>. “institutional bioethics” was intended to protect human and non-human animal research participants. Following the discussions on standardization of human studies, animal ethics rested on the scientific advancement provided by the consolidation of animal welfare science<sup>3</sup> and benefited from regulations that have introduced guidelines for the use of animals supported by utilitarian values and in the ideas of replacement, reduction and refinement, the principles of the 3Rs<sup>4</sup> acronym in English.

In this way, any experimental animal intervention performed without legitimate justification and for which there was an alternative was considered immoral and illegal. This required the mobilization of moral agents to reduce the number of beings in studies, replacing them with less vulnerable beings or other alternatives. It was established that the refinement of the research should be done by innovative, less invasive and more effective methods, in order to avoid unnecessary pain and suffering<sup>2,5</sup>.

In Brazil, the first comissões de ética no uso de animais – Ceua (animal ethics commissions) were established in the 1990s and, even without legal obligation, sought to meet international expectations, mainly linked to the validation of the experimental protocol to disseminate research results in scientific journals<sup>1,6</sup>. During this period, Ceua’s establishment was based on bioethical principles to characterize reflections on the needs and limits of research, identifying vulnerabilities and seeking dialogue, education and consideration for consensus and fair solutions for all actors involved<sup>1,2,7,8</sup>.

The forms of original work of the Ceua varied, but all endeavoured to ensure that these beings under supervision were used in a humane manner. However, before assuring conscious use, the Ceua should deliberate on the justification of animal use, considering the scientific merit of the project and the suffering to be imposed on animals. In this way, ethical action would be carried out<sup>6,10</sup>, using sentience as a moral basis for applying the principle of equal consideration of interests<sup>11</sup>. The main conflict then would be the questioning of the commission’s competence to evaluate scientific merit and the need for the experiment<sup>6</sup>.

The Colégio Brasileiro de Experimentação Animal – Cobeia (Brazilian College of Animal Experimentation) started registering these initiatives in 2007<sup>12</sup>, and the Conselho Federal de Medicina

Veterinária – Federal Council of Veterinary Medicine (CFMV), in 2008<sup>13</sup>. This process culminated in Law 11794/2008, known as Lei Arouca<sup>5</sup> (Arouca law), which remained 13 years in processing in the National Congress. Thus, until 2008, the protection of fauna was supported by the Lei de Crimes Ambientais – Law 9.605/1998<sup>14</sup> (Law on Environmental Crimes), which criminalised and punished acts of abuse, mistreatment, injury or mutilation of wild, domestic or domesticated animals, native or exotic.

The Arouca Law, with 27 articles and 37 resolutions, provided an innovative perspective to protect animals used as experimental models, mainly in relation to other uses, and sought to meet specific normative needs for unrestricted application of the 3Rs principle<sup>5</sup>. The legislation focused initially in multidisciplinary ethics commissions, entrusting them to execute and enforce the norms through the judgment of suitability in the scientific use of animals. Five years were spent to adapt to the Arouca Law, with 2013 being the beginning of inspection and punishment.

These legal provisions affected the functioning of the Ceua, as the need to meet them gradually supplanted the bioethical essence of the commissions. For this, it contributed the administrative, civil and criminal co-responsibility of Ceua’s guild and researchers, in addition to the complex Brazilian guideline for care and use of animals in teaching or scientific research activities. Thus, it is important for each member of a Ceua to be aware of their responsibilities, so that the committees carry out their functions and are able to provide feedback to the community in general.

This study is based on the bioethical conception of the Ceua, highlighting its social, educational role as well as the role of promoter of reflections and dialogues on procedures and subsidies for the humanitarian management of animals. Consequently, the argument considers the intrinsic value of bioethics in recognising sentience as a factor to protect these beings and applying the principle of equal consideration of interests in verifying compliance with legal norms.

In view of the difficulty of interpreting laws, especially in view of the many specific recommendations, the impact of legislation on the generation of vulnerabilities in the Ceua’s action is questioned, as well as in the resolution of previous conflicts. Thus, the guiding question of this work was: did the insertion of the legal sphere into Ceua, with obligations and penalties attributed to the commissions, generate conflicts and distance from bioethics? The hypotheses tested were as follows:

- The legislation improved the conditions of production and manipulation of animals, offering technical base to evaluate projects and instigating the ethical reflection of the researchers when proposing protocol of submission based on the 3Rs principle. However, the focus on bureaucratic processes of adaptation to the law has reduced the space of bioethics, which demands a multidisciplinary vision to correctly apply the acquired scientific knowledge, uniting them with values such as beneficence, prudence, autonomy, justice and responsibility;
- It is believed that the perception of the coordinators is different from that of the members, because the former are given greater responsibility;
- it is hoped that the perception of members who experienced Ceua before the legal implementation is different from that of the current members, whose procedure is based more on technique than on ethics.

The analysis of the results considered that the commissions have given more value to the fulfilment of the bureaucracies than to the ethical instrumentalisation of the researcher. This reduces the awareness of these actors about their importance to promote changes in institutions instead of just registering technical opinions. Thus, the objective of this study was to analyse the opinion of members, coordinators and collaborators of the Brazilian Ceua on ethical conflicts in their institutions and how they perceive the influence of the legislation on the functioning of the commission.

## Material and method

In this quantitative and cross-sectional study, responses from coordinators, members and administrative employees of 410 Ceua were evaluated through an instrument composed of 22 questions distributed digitally by the Qualtrics software. The questions were elaborated based on an instrument validated in the I Workshop Sucessos e Vicissitudes das Ceua (First Successes and Vicissitudes of Ceua Workshop) promoted by the Pontifícia Universidade Católica do Paraná – Pontifical Catholic University of Paraná (PUCPR) in 2013<sup>15</sup>.

The questionnaire was organised in blocks, with six questions to characterise the participant and other open questions about strengths, weaknesses, conflicts, the role of bioethics and legislation. Within these issues were distributed several items (with a score of 1 to 9) on feelings, the functioning of Ceua,

supervision, communication with management bodies, practical classes and supervision.

The data were analysed considering null hypothesis of homogeneity in the resulting categories, confirmed by the non-parametric chi-square test in the categorical data. For the mean data the Anova parametric tests with post hoc Tukey test and Student's T test were used. In all situations, 95% confidence and 5% error were considered.

The research was carried out based on the ethical precepts of the Comissão Nacional de Ética em Pesquisa – Conep (National Commission for Research Ethics) registered by the Conselho Nacional de Saúde (National Health Council) in Resolutions CNS 466/2012 and CNS 510/2016. The research follows the guidelines of the Conep. The right to autonomy and confidentiality of research participants, as well as the confidentiality and integrity of the data, were respected.

## Results

### Characterisation of participants

The respondents were mainly women, with training in veterinary medicine and biology, coming from a public institution of higher education in the South and Southeast of Brazil and working in Ceuas consolidated after the establishment of the aforementioned legislation, corresponding to 27% of the invitations sent (Table 1).

Most of the respondents, regardless of the role, stated that they felt satisfied and fulfilled with their work in Ceua. However, there was more apprehension and discomfort after the establishment of the law. The composition of Ceua was mainly the result of technical training in all functions, the superior indication for members and administrative employees after the law, and personal interest in becoming a member after the law (Table 2).

The participants highlighted the respect for life, ethical integrity and responsibility for animal welfare, as well as for the work, education and training of members as strengths of their respective communities. These, particularly after the legislation, have also pointed to the democratic character evidenced in debates, common sense and respect for diversity. Regarding the weakest points, the highlights were the training of members by coordinators and others as well as the management, particularly after the legislation, and institutional support from the perspective of the coordinators.

**Table 1.** Relative frequency (%) of the characterisation variables of the respondents (%)

		Coordinator n=17	Member n=84	Administrative n=11	External n=2	Total 114
Origin	Public Institution	35%	58%	36%	-	54%
	Private Institution	35%	29%	54.5%	-	29.2%
	Company	30%	13%	9.5%	100%	16.8%
Ceua	Before 2008	17%	36	45%	-	35.8%
	2008-2013	41	33	45%	-	37.7%
	After 2013	41%	22.1	10%	100%	26.4%
Gênero	Female	59%	59%	90.1%	100%	62.3 <sup>(*)</sup> %
	Male	41%	41%	0.9%	-	37.7%
Region	South	29	51.4%	72.7%	50%	49.6 <sup>(*)</sup> %
	Southeast	53%	36.1%	18.2%	-	37.2 <sup>(*)</sup> %
	North	6%	2.8%	-	50%	3.5%
	Northeast	12%	5.5%	9.1%	-	6.2%
	Centre-west	-	4.2%	-	-	3.5%
University Course	Verterinary Medicine	82%	44%	9%	50%	48.7 <sup>(*)</sup> %
	Biology	18%	30%	9%	-	24.8 <sup>(*)</sup> %
	Others	-	26%	82%	50%	26.5%

\* The absolute values of each category were compared by the chi-square test. Significantly higher values ( $p < 0.05$ ) were accompanied by an asterisk (\*)

When asked to indicate low score for issues not yet resolved in Ceua and high scores for those resolved, participants did not demonstrate differences between their functions and the establishment of the law. It was agreed that none of the issues listed is fully resolved, with the most worrying being related to statistical design, training of members, certification of researchers, supervision and bioethics formation of agents (Table 2).

As for Ceua's relationship with the Conselho Nacional de Controle de Experimentação Animal – Concea (National Council for Control of Animal Experimentation), there was a low score in all the options, being more precarious the standardised online submission and the pressure to install a system of inspection of the research. Practical lessons also had low scores, especially in the certification of the authenticity of alternative methods to the use of animals as didactic resource. Considering control as a source of conflict, it was also seen as unsolvable, except in the management of formal complaints, only aspect with high scores (Table 2).

Almost half of the participants (48.7%) said they had already engaged in some conflict in the Ceua where they operate, but did not indicate which situation (42.1%), which conflict (60.9%) and how to mitigate them (69.4%). Regarding possible frictions between members' interests and the current management model, most responded that they did

not identify situations of this nature, especially in the case of administrative staff and members. As for the conflicts, difficulty was found mainly in mediating interests, yearnings and knowledge:

*"Ceua Members leaking information or defending projects with failures due to personal interest";*

*"Situations where common sense would limit the number of animals and / or research groups, but the statistician determines the 'x' using reliability as justification to support the work";*

*"When analysed by Ceua, studies of researchers linked to the university's board and containing impediments to achievement";*

*"The former coordinator signed project authorisations without going through Ceua";*

*"Several times the confusion is due to a lack of mutual understanding of Concea's regulations."*

Most of the respondents also did not report what they believed was the best way to mitigate differences, with the highest frequency of responses focused on the autonomy of Ceua (8.2%). Coordinators, members and commissions instituted after 2008 considered the implementation of the law to be a good thing, mainly because it increased the credibility of the Ceua (59.2%). However, the duality between law and bioethics was evident in the participants' expression:

**Table 2.** Conception of Ceua according to coordinators, members and administrative collaborators

Reason for	%	How to they feel	Average score	Integration with CONCEA	Average score
Competence	30.2%	Satisfied	7.8±1.5a	Representation	5.7±2.8a
Top indication	27.5%	Fulfilled	7±1.9 a	Communication	5.5±2.4a
Personal Interest	24.2%	Uneasy	4.5±2.2b	Training	5.3±2.5a
Bioethical formation	7.1%	Uncomfortable	3.4±2.2b	Online submission	5±3ab
Availability	3.8%			Pressure for inspection	4.3±2b
Others	7.2%				
Ceua's Strong Points	%	Matters already solved	Average score	Practical lessons	Average score
Respect for Life and integrity	39.5%	Communication with vivarium	7.6±2.2a	Completion of course work	6.8±2.7a
Members training	24%	Autonomy	7.4±1.9a	Student Complaints	5.6±3.3b
Democracy	18%	External member	7.4±3.3a	Students opposed	5.7±2ab
Management	14%	Inadequate protocols	7.3±2.8a	Surgical technique	5.6±3ab
Others	4.5%	Pressure for approval	7.3±3 a	Objection of consciousness	5.5±23b
		Members selection	7.2±1.9a	Certify Alternatives	4.5 ±2.8c
Fragile aspects of Ceua	%	Acceptance decisions:	7.1±1.9a	Inspection	Average score
Member's qualification	25%	Integration of other sectors	7±2.8a	Manage formalized reporting	5±3a
Management	20%	Technical and legal domain	7±2.7a	Embargoed in Surveillance	4.7±3ab
Institutional support	17.5%	Vivarium	6.8±2.3a	Manage informal complaints	3.8±2.8b
Commitment	8.5%	Institutional Support	6.7±2.8a	Monitoring project	3.6±2.7bc
Resistance	7%	Substitute methods	6.6±2.7a	Software monitoring	3.4±2.7c
Conflicts of interest	7%	Statistics	6.4±2.4b		
Others	15%	Training	6.4 6.4±2.4b		
		Inspection	6.3±2.7b		
		Certification Reserchers:	6±2.4b		
		Bioethical Formation	5.9±2.3b		

The means were compared between the variables by means of the Anova test, with values significantly different ( $P < 0.01$ ) accompanied by different letters

"[The law generates] a difference in ethics, legislation today speaks much louder than ethics itself";

"Legality gives guidance. On the other hand, the lack of common sense and interpretation of the law can hinder the processes";

"It used to depend on each member's point of view to assess animal discomfort and the level of pain. After the regulation everything was standardised for the best environmental conditions and animal welfare";

"After the regulation, the Ceua are much more concerned about being in compliance with the legislation";

"Today the members feel more secure and protected";

"The Ceua that I participate presents difficulties in interpreting the regulations".

However, 74.3% of the respondents consider the insertion of legislation to be good for the operation of Ceua. Coordinators and members of Ceua established after the law conceive of bioethics as an ethical and integrity guideline (60.5%):

"It is the great forum of interlocution, gathering the various knowledges, in search of precise ethical answers, for questions and situations in constant evolutionary process";

*"[It is up to bioethics] to make every animal user aware of the real importance and feasibility of the study proposed by him or her, in relation to the use of sentient beings";*

*"It is fundamental that the evaluation of the projects is not restricted solely to the technical and legal aspects, also considering the necessity or not of using animals in research and teaching";*

*"Bioethics is a principle that should govern the functioning and progress of Ceua's activities. All procedures should be adopted in accordance with the principle of animal welfare and minimising the unnecessary suffering of study organisms. "*

## Discussion

The data allowed to outline the conception and the relationship of coordinators, members and collaborators in the Ceua, mainly regarding the identification of conflicts in the action before and after the legislation. The study discussed feelings of Ceua members regarding the group, as well as about the practice and the role of each committee, seeking to know the perception of these subjects regarding the conflicts and protagonism in the suggestions to mitigate them.

The results refer to the contribution of a Ceua academic delegation established during the implementation of the legislation in Brazilian states of the South and Southeast, whose members are trained in biology and veterinary medicine. In view of the low adherence to research (27%), mainly of external members (only two), the group also stood out for showing interest and motivation in the subject, a fact that may have contributed to the results of this research.

The reduction obtained leads to reflection according to the original perspective of institutional bioethics, which proposes the multidisciplinary committees<sup>16</sup> aiming at the contribution of different visions, perceptions and interests in the deliberations of the group<sup>17</sup>. Thus, the low participation of industry committees (15.7%) and external members in this research compromises the vision of disparate segments and with different interventions. While academic research is motivated by social and scientific responsibilities, the economic bias of industry<sup>18</sup> and the inherent radicalism of animal protection<sup>6</sup> may lead to disagreements that end up compromising the socially consolidated

commitment of the committee to promote justifiable and thorough animal research.

The arguments against the Ceua are incipiently debated in the scientific environment, being identified in the argument of Fischer and collaborators, that even before the legislation mitigate the conflicts, it has not eliminated the main one that orbits between the justification of necessity and the right to the life of the animals<sup>8</sup>. Conflicts between incompatibility of the experimental model with human organism and desensitisation to animal suffering due to economic, industrial, and scientific interests, and how to evaluate each of the principles of the 3Rs principle with reliable sample size and the existence of pain and suffering were pointed out by Passion and Schramm<sup>19</sup> as unresolved issues. But, yes, silenced by the occupation of the space of debate by the application of the legislation, constituting one of the reasons of the disinterest of members of the animal protection in linking their names to the Ceua.

Although bioethics excels by multidisciplinary approaches aiming at the diversity of favourable and opposing arguments, presently veterinarians and biologists prevail, a fact that can influence legal requirements and mastery in technical evaluation<sup>8,15</sup>. This de-characterises the original intention of raising opposing perspectives and pursuing common interests.

The data of this research indicated a high degree of satisfaction and accomplishment of coordinators, members and collaborators in participating in Ceua, even after the implementation of the law. Probably this result stems from the nature of the function, aimed at reducing vulnerabilities and increasing the well-being of those involved, as well as the relative status in the academic environment. However, it is understandable and even expected that coordinators will point out more fears and discomforts after the legal determination, given the administrative, legal and criminal responsibilities established by the legislation<sup>5</sup>.

A significant part of the members sought to participate in the collegiate for personal interest. According to Fischer and collaborators<sup>15</sup>, 59% of the committees at the I Ceua Workshop stated that their members were appointed by managers, mainly because legal responsibilities require time and dedication for careful and prudent evaluation, resulting in little interest of researchers. However, the authors<sup>15</sup> warn that bioethics training and capability, as well as technical, environmental, biological and ecological knowledge in the manipulation of species

are fundamental for participation in Ceua to surpass personal opinion.

According to Zanetti and collaborators<sup>20</sup>, *the work in the Ceua demands collaboration with technical expertise, but the motivation to collaborate to improve integrity in research and BEA's conditions must also exceed legal requirements*. Respondents identified Ceua's ethical role, empowerment of members and the democratic aspect as positive points that motivated joining the group. On the other hand, they indicated management, institutional support and, again, training as fragile points, reinforcing the need for frequent improvement, once the system is inserted in a legislative complex.

These issues make up the Ceua agenda since its installation<sup>21</sup>, and even after 10 years still have to be overcome. Analyzing the problems raised in the First Workshop of Ceua<sup>15,22</sup>, it is verified that 50% of them received grades above 7, and 50% below; however, for the participants, none has been fully resolved. The selection of members and the communication with the vivarium, already classified as success points<sup>15</sup>, reflect the importance of forming the multidisciplinary team and incorporate the representative of the vivarium into it, favouring the broad conception of the subject and directly involving the person responsible for organizing the experimentation<sup>15</sup>.

On the other hand, problems to be solved in 2013 have already been satisfactorily overcome by respondents, such as integration with other sectors of the institution, pressure to approve projects, acceptance of peer decisions; autonomy of Ceua, protocol divergent from the guidelines, external member, functioning of the vivarium, legislation, institutional support, substitute methods and predominance of technique and law. It should be considered that this perception refers to the cut of this study and can be only an optimistic view of the participants who feel the support of the legislation to legitimise the competence of the Ceua.

According to Paixão<sup>6</sup>, the main conflict in the operation of the Ceua in the 1990s was the discredit of merit evaluation made by multidisciplinary collegiate. However, Oliveira and collaborators<sup>23</sup> recognised a significant increase in the acceptance of Ceua's recommendations by researchers and university students. This is mainly due to the idea that the commission knows the laws and protects the institution and the researchers in relation to the normative ones, which stimulates the passive attitude of the latter.

Fischer and collaborators<sup>15</sup> emphasised that institutional support is essential both to provide Ceua's operating structure and to support its decisions, even when they counteract economic interests involved in projects already approved by development agencies, for example. However, the legislative incongruity with regard to the use of experimental animals, the absence of standardisation for other uses, such as feeding or control, and the protection extended only to vertebrates, leaving out 95% of the fauna<sup>24</sup>, confuse the researcher and delay the understanding of why to be ethical with animals.

Members' bioethical training, certification of researchers, oversight and mastery of statistics are still problems to be overcome<sup>15</sup>. They may have become more evident after the legislation, since, in order to mark deliberations, it ended up limiting the sphere of bioethical performance as conceived by Paixão<sup>6</sup>. Fischer and collaborators<sup>15</sup> record that more than half of the participants of the event considered bioethical training an important criterion to compose the college of Ceua.

In addition, the concern to enable members to understand and apply legislation and established parameters, aiming at more effective action with the law, reduces the allocation of efforts in training in bioethics. The detachment of perspective in this field of knowledge has been felt even in human research ethics committees<sup>21</sup>. It is up to the Ceua to attest to the capacity of researchers to manipulate animals<sup>15</sup>. This responsibility has led to the elaboration of national courses offered by each institution.

According to Fischer and collaborators<sup>15</sup>, Ceua members still attribute credibility to the theoretical framework and statistical projections presented by the researchers, demanding the inclusion of a statistical professional in the commissions<sup>15</sup>. But statistics, which are primarily aimed at applying the principle of reduction, can lead to unpublishable data if they are insufficient to evidence the hypothesis tested, generating more losses than if the researcher had used the correct number.

Regarding the relationship between Ceua and Concea, the participants do not perceive many issues that need to be solved, except the need for an online submission system in accordance with the Brazilian platform for human research. The Ceua institution as a segment of the Concea within the institutions brings the expectation that communication between these two instances runs smoothly. In view of this excellence, Concea has promoted meetings, courses and support material.

Still, Ceua frequently complain about the difficulty of communicating with Concea, even suggesting in I Workshop the creation of official representation of commissions as a point of contact<sup>5</sup>. However, the positioning of respondents, especially members, regarding the demands of communication and Online submission does not reveal such discomfort. The detailed analysis of the questionnaires suggests that members do not understand the size of this demand as much as the coordinators and administrative staff, who are directly responsible and more responsive to daily problems and collections.

Regarding the practical classes, only the issue of the conclusion of the course involving animals was considered partially solved. The recommendation of the participants of the Ceua Workshop was to associate these studies with other larger projects, with the juniors being part of a small supervised part in animal manipulation. The other questions received low scores, as also confirmed by Passerino and collaborators<sup>25</sup>.

Dealing with opposing student positions, managing denunciations, and publicising the conscientious objection clause are practices associated with the expected educational role of the Ceua. This role should be exercised both in the training of students who disrespect animals and attribute them just utilitarian value, as in those who feel constrained in classes with animals. The conscientious objection clause is a legal prerogative that protects the student who does not wish to take practical classes involving the sacrifice of healthy animals to demonstrate known processes<sup>18</sup>.

It should be noted that Paraná<sup>26</sup> already has its own legislation in this respect, obliging any institution that uses animals to inform students and employees the right to objection to participation, as well as providing alternative means so as not to compromise the quality of teaching. It is also worth noting that the Concea<sup>5</sup> instituted the teaching obligation to provide alternative methods for students who are not interested in classes with animals, without prejudice to professional training. However, most of the students are unaware of this clause and, although they that it is unnecessary to interrupt the life of healthy animal to illustrate known processes, attributes credibility to the lecturer when he or she says that this is necessary for their formation<sup>27</sup>.

The access of pro-animal movement activists to traditionally limiting courses because they involve

animal manipulation has generated insecurity in the academic environment, with formal or informal denunciations, often through social networks, placing lecturers, institutions and Ceua in a condition of vulnerability. According to Passerino *et al*<sup>25</sup>, members of Ceua pointed out the difficulty of managing denunciations of students, but it is imperative to have mechanisms for administering formal and informal complaints and to establish crisis offices in order to solve problems in the institution itself, and not achieve judicial spheres without their consent, as has been the case.

Participants considered the certification of the effectiveness of alternative methods as a point of friction without many solutions, with emphasis on surgical technique classes. In 2014 this was attested by Passerino and collaborators<sup>25</sup>, who indicated that parsimony in the analysis of processes should prevail even the society demanding the definitive extinction of the use of animals as a didactic model<sup>28</sup>. The authors<sup>25</sup> recommended the animal manipulation in the final stages of the discipline, with students trained in alternative models, only to consolidate the technique required for subsequent surgical procedures.

There are several reports from international and national institutions that have replaced the animal model with computer simulation and virtual reality, obtaining more satisfactory results in the analysis of risks and decisions under pressure<sup>29</sup>. However, the lecturer has difficulty accessing this information and persuading the institution to invest in alternative methods whose existence makes it illegal the didactic use of animals<sup>28</sup>. Therefore, a specific instrument is necessary in order to have more possibilities, and Concea itself must mobilize to consolidate this instrument<sup>25</sup>.

At the 2016 meeting on alternative methods in education<sup>29</sup> it was pointed out that the method should be efficient to promote professional training, including technical and ethical training, but this decision was only consolidated in a normative resolution in 2018<sup>30</sup>. Due to the novelty of this requirement, it is still difficult for Ceua to certify the efficacy of methods that have not yet been validated<sup>25</sup>.

Respondents identified surveillance as a sensitive issue in Ceua's work<sup>5</sup>. Members even suggested that an outside consultant do this task<sup>22</sup>, claiming constraint in supervising peers and fear of causing discomfort with sudden onset. Since 2013<sup>22</sup> the Brazilian Ceua members indicate that the



inspection generates dissatisfaction and constraints. The group understood that this role would be in charge of Conceia, while Ceua would be responsible for monitoring and monitoring experiments, stating whether they are in accordance with the legal determination.

However, in practice this division of responsibilities gives rise to differences in how to monitor, inspect and supervise, requiring the *existence of individual journals and records for each animal accessible to all actors involved in experimentation*<sup>22</sup>. Another alternative would be to use standard software that automatically registers amount of animals, types of experiment, degrees of invasiveness, which would allow to direct the monitoring and to present partial and final reports.

Although Ceua is able to manage formal complaints, informal ones are more difficult, as discussed in the First Ceua Workshop, in the study by Oliveira and collaborators<sup>22</sup> and also detected in this study. Conceia does not accept anonymous complaint, but many times the complainant is intimidated in formalising the complaint, fearing retaliation from the institution. Although the law obliges Ceua to have ombudsmen<sup>5</sup>, other means are used, such as direct access to the Public Ministry. This makes the institution vulnerable, which can not solve the cases before taking on larger proportions<sup>22</sup>.

The low participation of external members in the study prevented the knowledge of their perception about the college of Ceua. It was hoped to prove that, being a minority, with small voting power, disparate values and without mastery of the scientific language, they would feel constrained to interfere in the evaluation before the academic arguments. The participation of the external member has always been relevant in ethics committees, since it authenticates deliberations<sup>6</sup>, but was considered a serious legal obstacle in Ceua<sup>15</sup>, since representatives of animal protection institutions seek to abolish their use in experimentation, not legitimizing academic justifications<sup>31</sup>.

The radical positioning of many activists has threatened institutions that are vulnerable to uncontrolled denunciations of people who often do not fully understand the research process. Thus, to solve this issue, it is necessary to improve the communication between academy, society and social movements – the role of Ceua, identifying and reducing vulnerabilities through dialogue<sup>32,33</sup>.

Conflict identification issues suggest that respondents came out after the legislation, which

provided questions on benchmarks, but emphasised those related to the pressure to approve projects or to agree with other researchers. Probably these disagreements are accentuated by the distance from bioethics, because in the deliberative sphere of ethical issues conflicts and pressures are expected that favor individual interests<sup>34</sup>.

Although the tool of the present research refrains from elements of reflection, it is still able in the dialogue to stimulate consensual, fair and vulnerability mitigating solutions, as it appears in the participants' speech. Oliveira and collaborators<sup>23</sup> identified that lecturers and students recognise improvement in the functioning of Ceua after the norm, standardising the elaboration and evaluation of protocols and highlighting the educational role. One respondent even claimed to have learned more about his experimental model to structure good argumentation.

Bonella<sup>33</sup> deposed as the coordinator of Ceua who experienced the legal transition, qualifying the Arouca Law as a retrocession for having generated ambiguities and embarrassment in members who had to abstain from ethical positioning, since the law often allows practices contrary to its very essence. Scientists continue to do what they have always done, satisfy the government by submitting to norms, and society continues to ascribe confidence to scientific processes, depriving itself of critical analysis<sup>32</sup>.

In opposition to this, the participants' speech of this research shows that they understand the legislation as support for their action. However, in view of the need to comply with legal requirements, they demonstrate a certain degree of accommodation in the deliberations, demanding regulations that meet all possible specificities in animal research.

An interesting point is that it prevails among the participants the conception of Ceua as the guiding force for deliberations, which reveals poor understanding of its real role. Bonella<sup>33</sup> suggests that the solution lies in attributing to animals the same human rights in research, condemning harmful procedures and stressing that in the inability to consent, this function is of the tutor. Most of the respondents abstained from proposing solutions to mitigate these conflicts, referring to the autonomy of Ceua and to external oversight.

Consequently, Ceua occupy a strategic position to monitor and guide ethically appropriate attitudes towards the use of animals in teaching and research, and to train new professionals sensitive to this issue

and respect all forms of life. It is incumbent upon these committees to promote scholarly debates, but to reach out to society in order to base answers regarding the use of animals as experimental models<sup>22</sup>.

### Final considerations

The data obtained from the sample of the present study allowed to outline the panorama of how coordinators, members and administrative collaborators perceive the performance of a Ceua. It was noted that the participants understand the legislation as a promoter of improvements to the BEA and of technical marks for project evaluation. However, it is also noted that the focus on bureaucratic processes to verify compliance with the law has reduced the scope for bioethical reflection, understood as important and necessary.

The analysis of the data showed that the coordinators' perception differs from that of the members, especially regarding the legal attributions of co-responsibility in the research. The former are more apprehensive about the consequences of their performance than the latter, but they show satisfaction in participating in the Ceua. The fact that the respondents were previously contacted to participate in this study suggests both affinity with the topic and empathy with the function itself, which may have led to the answers obtained.

The hypothesis of differences in conception of the members who worked for Ceua before and after the implementation of the law, defended in this paper, was not clearly evidenced, probably

because most of the respondents are part of Ceua implemented as a result of the regulations. However, the results showed that, although the legislation strengthened Ceua's credibility with the institution and its members, providing guidelines to direct deliberations, to a certain extent it imbedded the intervention of the commission, restricting it to the bureaucracy of conferring law.

This process of gradual decrease in bioethical reflection harms members of the Ceua in a situation of conflict, because they find themselves without the tools to intervene on the basis of a bioethical perspective, especially in matters that have not been clearly met by the legislation. Participants in the research understood bioethics as the guiding force for deliberations, identifying the need to resume it in Ceua. However, the training of the members of the committees is still incipient in this area, which demands, besides members with training in bioethics, frequent training of all those involved in animal experimentation.

To retake bioethics and its multidisciplinary character in Ceua's delegations must re-establish the channel of communication between the actors on ethical issues in order to mitigate the identified vulnerabilities, be them of animals, researchers, members, institution, pro-animal movements or society in general. Therefore, communication mechanisms must be developed to promote dialogue between these segments in order to understand their yearnings and interests to establish common values. In addition, formal and non-formal education programs need to be set up for higher, technical and basic education.

*We thank all participants who answered the questionnaire of this research.*

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#### Participation of the authors

Lilian Gauto Quintana Jankoski conceived the project, collected and tabulated the data and drafted the article, which is part of her master's dissertation. Marta Luciane Fischer participated in the conception of the project and the data collection, which she analysed, interpreted and discussed, preparing the results for the final writing.


#### Correspondência

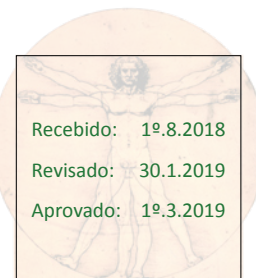
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## Annexes

You are being invited as a volunteer to participate in the study “The role of bioethics in the past, present and future of Ethics Committees on Animal Use”, which aims to contextualize historically ethical issues related to the management of Ceua, identifying their vulnerabilities and current weaknesses, as well as the problems already overcome by members, coordinators, researchers, secretaries and ecologists. We believe this research is important because it will help Ceua to identify and mitigate its vulnerabilities, recognising the role of bioethics.

**Participation in the study** – My participation in this study will be to answer an online questionnaire in the Qualtrics system, anywhere with internet access, which will take 15 minutes.

**Risks and benefits** – I have been advised that I can expect as a benefit of this study an ethical reflection on the guidelines for using animals in scientific research. I also received information about possible discomforts or risks, as embarrassment in responding to the questionnaire. To reduce them, you can immediately stop the response process.

**Confidentiality and privacy** – I am aware that my privacy will be respected, that is, my name and any data or elements that may identify me will be kept confidential. The researchers are responsible for the confidentiality of the data, as well as for the non-exposure of the research participants.

**Autonomy** – Assistance is ensured during all research, as well as free access to all the information and further clarification I wish about the study and its consequences, before, during and after my participation. I have also been informed that I may refuse to participate in the study or withdraw my consent at any time without justifying or suffering any prejudice to the assistance I have been receiving.

**Reimbursement and indemnification** – If I have any expenses resulting from participation in the research, such as transportation and food, the amounts spent will be reimbursed in the form of a deposit in a checking account. In the same way, in case of damage resulting from my participation in the study, I will be duly indemnified, as determined by law.

**Contact** – The researchers involved with this project are Lilian Gauto Quintana Jankoski and Marta Luciane Fischer, and with them I can keep in touch by calling (41) 9756-3372 and (41) 3271-2292. The Comitê de Ética em Pesquisa em Seres Humanos - CEP (Ethics Committee on Human Research) is composed of a group of people who are working to ensure that my rights as a research participant are respected. It has an obligation to evaluate whether the research was planned and is being performed ethically. If I believe that the research is not being carried out in the way I have imagined or that it is harming me in any way, I can contact the CEP of the Pontifícia Universidade Católica do Paraná - PUCPR (Pontifical Catholic University of Paraná) by telephone (41) 3271-2292, Monday to Friday from 08h00 to 17h30, or by e-mail to nep@pucpr.br.

**Statement** – I declare that I have read and understood all the information contained in this Free and Informed Consent Form and have had the opportunity to discuss this information. All my questions have been answered and I am satisfied with the answers. I will receive a signed and dated copy of this document and another signed and dated copy will be filed by the responsible researchers. Finally, having been guided as to the content of everything here mentioned and understood the nature and purpose of the study, I express my free consent to participate, being fully aware that there is no economic value to receive or pay for my participation.

**Image Usage** – No image, recording or audio will be used.

## Questionnaire

**1. About the Free and Informed Consent Form:**

- ( ) I read and I agree
- ( ) I read and I do not agree

**2. In which of the following categories do you fit:**

- ( ) Member or former member of a Board (1)
- ( ) Coordinator or former coordinator of a Ceua (2)
- ( ) Administrative staff of a Ceua (secretary) (3)
- ( ) External member (representative of civil society) (4)

**3. What is your gender?**

- ( ) Male
- ( ) Female

**4. What is your background?**

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**5. How long have you been a graduate?**

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**6. In which region of Brazil do you perform your function in Ceua?**

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**7. In what institution do you perform your function?**

- ( ) Institution of teaching and research (faculties and universities) public
- ( ) Institution of teaching and research (faculties and universities) private
- ( ) Research institution (laboratories or companies)

**8. What is the year of Ceua's implementation in your institution?**

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**9. For what reason have you been nominated to participate in the Ceua? You can choose more than one option**

- ( ) Personal Interest
- ( ) Technical capacitation
- ( ) Availability of hours
- ( ) Indication of managers
- ( ) Training in bioethics
- ( ) Others

**10. Score from 1 to 9 how much you feel comfortable about participating in the Ceua.**

	1	2	3	4	5	6	7	8	9
Satisfied									
Apprehensive									
Fulfilled									
Uncomfortable									

**11. What are the strengths you identify in the Ceua where you are a part of?**

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12. What are the fragile points you identify in the Ceua where you are a part of?

---

13. Have you ever felt conflicted about any situation experienced in your Ceua? Which?

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14. Score from 1 to 9 the following items regarding the performance of your Ceua, being 1 for an issue not yet resolved and 9 for a fully resolved question:

	1	2	3	4	5	6	7	8	9
Members selection									
Members' Bioethical training									
NGO representative (external member)									
Acceptance of Ceua's decisions by the faculty of the institution (research and practical classes)									
To whom to respond institutionally (Ceua autonomy)									
Ethical and technical certification of researchers (training course)									
Statistical evaluation of sample size									
Pressure to approve projects with funding									
Institutional support for training and improvement of members (participation in courses, workshops, congresses and events)									
Technical and legal adaptation of the vivarium									
Communication with vivarium									
Issue opinion for protocols that do not fit into the regulations (eg zootechnical practices, ecological field studies)									
Integration with other sectors of the institution (Pibic, TCC)									
To enable researchers to correctly fill out the form, especially with regard to the 3R principle									
Monitoring of researches and classes (supervision)									
Certification that the study is not duplicative and that there are no substitute methods									
To master / know the wide and complex legislation									
Evaluation of the protocols currently lost the ethical connotation, predominating technique and legality.									

15. Punctuate from 1 to 9 the items below to indicate how much your Ceua relates to Conceca, being 1 for an issue not yet resolved and 9 for a fully resolved question

	1	2	3	4	5	6	7	8	9
Communication with Conceca									
Training of coordinators and members to apply new regulations									
Online submission									
Pressure for inspection									
Organization of Ceua with representation									

16. Score from 1 to 9 the following items referring to the vision of your Ceua about practical class, being 1 for an issue not yet resolved and 9 for a fully resolved question.

	1	2	3	4	5	6	7	8	9
Approval of protocols involving the use of animals in CBT									
Pressure for approval of traditional classes as surgical technique									
Conflict of students who want or not lessons with animals									
How to certify the validity of alternative methods									
Pressure on denunciations of students opposing practical classes									
Communication regarding conscientious objection									

17. Score from 1 to 9 the following items about the relationship of your Ceua with the follow-up (inspection) of the researches, being 1 for an issue not yet resolved and 9 for a fully resolved question.

	1	2	3	4	5	6	7	8	9
Implementation of a monitoring project									
Lack of mechanism (software) to record and monitor project execution, reporting and publications									
Manage non-official reporting									
Manage formalized reporting									
Embargo on peer research oversight									

18. With regard to its participation in Ceua:

- Are you a current member? How many months? \_\_\_\_\_
- Have you been a member? For how many months? \_\_\_\_\_
- Are you current coordinator? How many months? \_\_\_\_\_
- Have you been a coordinator? For how many months? \_\_\_\_\_
- Are you an administrative member (secretary)? How many months? \_\_\_\_\_
- Are you an external member (NGO representative)? How many months? \_\_\_\_\_



19. If you are an external member, score from 1 to 9 the following items about how much your action relates to Ceua, being 1 for an issue not yet resolved and 9 for a fully resolved issue.

	1	2	3	4	5	6	7	8	9
Feeling dislocated from the group by not mastering technical content									
Difficulty in allocating time and resources to attend meetings									
Feeling embarrassed to be just one among so many other academics									
Feeling distraught for not agreeing with the activities carried out at the institution (goes against your convictions)									

20. For you, what is the role of bioethics in Ceua's performance?

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21. How do you perceive Ceua's performance before and after legal regulation?

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22. Do you identify any conflict between the interests and aspirations of the members and coordinators of a Ceua and the current management model? If your answer is positive, tell us what you believe it can be mitigated.

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