Marilia Sá Carvalho¹ Maurício Lima Barreto" Cláudia Medina Coeli™ Rafael Monteiro Raposo™ Eduardo Luiz Andrade Mota™ Bruce Bartholow Duncan™

Publications committee of a multicenter study and computerized support system – publiELSA

ABSTRACT

The publications committee of a multicenter study has the aim of organizing the proposals for articles, so as to ensure wide-ranging access to the data, quality and precedence. An online information and management system for study proposals (publiELSA) was developed, composed of three modules: (i) submission and approval of proposals; (ii) follow-up of approved proposals; and (iii) consolidated reports. The first module allows any interested party to search for and become acquainted with articles that have already been published or are in progress and submit new proposals. The approval process and data transfer to the researcher responsible is organized at this stage. In the second module, the aim is to monitor proposals approved until they are finally published. The third module enables searching for and viewing proposals and articles. The system has innovative characteristics, especially with regard to encouraging cooperation between different researchers, through circulation of information on each proposal submitted. In this manner, interaction between different viewpoints and experiences involved in the research is stimulated.

DESCRIPTORS: Publications, ethics. Scientific and Technical Publications. Authorship and Co-Authorship in Scientific Publications. Information Systems, organization & administration. Scientific Publication Ethics. Multicenter Studies as Topic. Cohort Studies.

- Fundação Oswaldo Cruz. Rio de Janeiro, RJ, Brasil
- Universidade Federal da Bahia. Salvador, BA, Brasil
- Universidade Federal do Rio de Janeiro. Rio de Janeiro, RJ, Brasil
- Universidade Federal do Rio Grande do Sul. Porto Alegre, RS, Brasil

Correspondence:

Marilia Sá Carvalho Fundação Oswaldo Cruz Antiga Residência Oficial Av. Brasil, 4365 Manguinhos 21045-900 Rio de Janeiro, RJ, Brasil E-mail: carvalho@fiocruz.br

Received: 6/10/2011 Approved: 7/2/2012

Article available from: www.scielo.br/rsp

INTRODUCTION

Any large-scale multicenter study with a perspective of long-term data-gathering in successive waves necessarily has to develop a mechanism that makes it possible to organize the proposals for articles. This mechanism must ensure that: the data and biological material of the participants are used exactly as foreseen in the free and informed consent statement;² the data access is sufficiently wide for the scientific community to benefit from it;¹ the same issue is not investigated by two groups of researchers independently and at the same time; a proposal not accomplished over a reasonable time frame does not prevent other researchers from investigating the same issue; and the studies published have a high academic standard.⁴

Based on the experience accumulated in several large cohort studies, a Publication Committee was created in the Brazilian Longitudinal Study for Adult Health (Estudo Longitudinal de Saúde do Adulto, ELSA-Brasil). A member of each Investigation Center participates in the Committee, which is coordinated by a senior researcher with great experience in similar sized projects. Development of an online information and management system to register and make it possible to follow up proposals for studies and publications was considered essential for the committee's tasks. This article presents the system called publiELSA, with emphasis on the characteristics of ELSA-Brasil that distinguish it, especially its setup as a consortium of six research centers.

DESCRIPTION OF THE SYSTEM: PUBLIELSA

The creation of publiELSA followed the modeling principles of the stages of the editorial process, with a standardized set of analysis tasks on proposals for publication, on communication between the committee and the researchers making the proposals and on deadlines and demands, thereby establishing specific routines and modes of validation that would be appropriate for the purposes of ELSA-Brasil. A collaborative and dynamic environment was created, with a computerized interface that made it easy to organize, publish and retrieve research papers, even by individuals who are unfamiliar with applications used for these purposes.

The system is composed by three modules: (i) submission and approval of the proposal; (ii) follow-up of the approved proposal; and (iii) reports. The guidance manual for using the system is available on the Internet^b and can be accessed directly through this address, or from the ELSA platform^c in the area devoted to researchers.

The first module has the objective of allowing any researcher interested in analyzing the data of the study to submit a proposal in a structured manner, with sufficient information to avoid overlapping with ongoing studies. In this module, researchers are registered, have access to a system for searching for ongoing proposals and can submit their own proposals.

In this regard, some innovative aspects of this instrument were implemented for the publication committee to function. The abstract of the proposed study with the respective list of authors is forwarded to all the members of the committee and to the entire research steering committee (CDir) through electronic mail. For 15 days, the study awaits evaluation and, during this period, other authors can be added to the proposal. This deadline has the objective of stimulating joint analyses and publications among investigators at the different study centers. The final decision on co-authorship is under the responsibility of the researcher who submitted the proposal.

Following this, the proposal is evaluated by the coordinator of the committee, who can request the opinion of *ad-hoc* consultants. The final decision is up to the members of the publication committee, who issue a conclusive opinion, consisting of definitive approval, rejection or recommendations for alterations (Figure). After the proposal has been approved, the researcher responsible for the proposal is authorized to request the database containing the variables needed for the study, from the Data Center. PubliELSA allows researchers, including those who are not registered in the system, to consult the approved proposals without restriction, with the aim of promoting wide dissemination of information on the study proposals that are under development within ELSA-Brasil.

The aim in the second module is to monitor the approved proposals. The researchers responsible for an approved proposal have a deadline of one year to conduct the study and finalize the proposed manuscript. Prorogations can be obtained on request, but if the researchers responsible for the original proposal are unable to implement it within the deadline offered, the publication committee will be prepared to consider similar proposals submitted by other groups of researchers.

The quality of the final manuscript is evaluated by the committee, which indicates a main reporter from among its members and, when necessary, requests the opinion of a specialist. The system provides differentiated treatment (fast-tracking) for congress abstracts or for

^a Atherosclerosis Risk In Communities. Procedure for submitting a manuscript proposal: updated 30 March, 2011. [cited 2011, Oct 1]. Available from: http://www.cscc.unc.edu/aric/policy/PUBLICATProcedureforSubmittingaManuscriptProposalandorAbstract03302011.pdf ^b PubliELSA. [cited 2013, Feb 27]. Available at: http://www6.ufrgs.br/publielsa/

^cELSA Brasil. [cited 2013, Feb 27]. Available at: http://www.elsa.org.br/

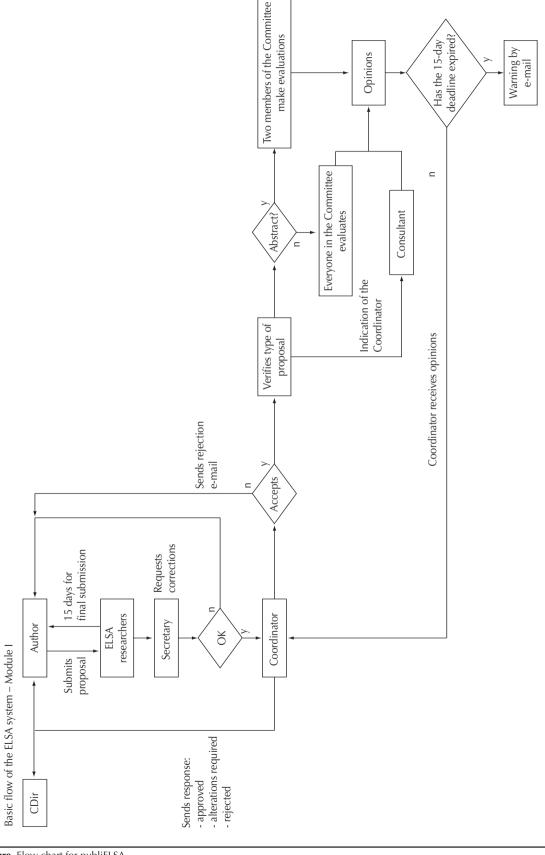


Figure. Flow chart for publiELSA.

findings that have clinical or epidemiological implications that demand rapid publication. The evaluation of the general quality of the product includes the matching between the proposed question and the analysis used, the writing and the language proposed for the paper. The manuscript can then receive the final decision from the committee in one of the following categories: approved, approved with comments (a situation in which the author is not obliged to accept the comments), approved conditionally or rejected.

Once approved, the authors are authorized to submit the study to any scientific journal that they choose. Every six months, publiELSA will demand information on the situation of the manuscript, and this requirement will only end when the manuscript has been accepted by a journal. The authors should inform the definitive and complete reference whenever there is one, as well as the Digital Object Identifier.³

Master's, doctoral or postdoctoral projects are treated in a differentiated manner. This is firstly because of the time needed to conclude the studies, which is a period during which the topic is reserved for the student. In this case, a balance is sought between the time that the student needs and the blocking of a topic that may be of interest to other researchers. Once the project has been submitted, CDir receives the abstract and has one month to evaluate the proposal. If the topic is of specific interest to researchers of the central nucleus of the project, this time is sufficient to resolve the issue between the interested parties.

Finally, the report module consists of search routines for proposals and published articles, with access to differentiated information according to the type of users (members of the publication committee/secretary and authors). The outputs available include: viewing of all the proposals submitted with information on deadlines, titles and types of study; viewing of proposals that are late and/or for which extensions of the deadline have been requested; viewing of the *ad hoc* consultants who have not responded to the requests; final opinions on the study; list of the articles submitted for publication, with the journal, title, author, abstract and deadline; list of the proposals approved; list of the finalized articles and the published articles, with the bibliographic details.

The system was developed using free languages and code programs. The language used was PHP with the MySQL database management system, hosted on a server using the GNU/Linux operating system.

POINTS FOR DEBATE

Some innovations in the processes of evaluation and management of proposals for studies and publications have clearly been introduced through publiELSA.

However, some issues form renovated challenges for the model adopted. For example, with regard to proposals for doctoral theses, because of their authorship nature, the exact form in which other researchers will be included still awaits definitions, also taking into consideration the different practices and regulations in different postgraduate courses. The priority is to encourage cooperation, but in some specific situations it may be necessary to seek alternative solutions for implementing this.

These issues also include the mechanisms and documentation needed for accessing the data, such as the commitment statement that is to be signed by the proposing researcher, which has to be coherent with the ethical requirements of ELSA-Brasil. The system site, links, viewing space for variables, published papers and manuals, among other issues, are currently under development. The relationship between the publication committee and the approval of supplementary studies is particularly relevant in this debate. These studies need to be approved by CDir, especially when they involve new samplings and examinations on participants. However, some studies mix data from different sources, partly from ELSA-Brasil and partly from contextual variables, such as those relating to the home or work environment, without new samplings. In these cases, the publications committee itself decides how to forward each proposal, requesting attention from CDir when necessary.

One important issue, common to all large multicenter studies like ELSA-Brasil, is the change in culture demanded by this evaluation model. The opportunity to take part in a study of this size, with the quality of the generated data, presents to researchers fulfillment of two additional stages in proposing a research project and preparing an article: evaluation of the proposal and evaluation of the finalized manuscript. On the one hand, this represents a potential problem when it increases the length of time between the idea and formulation of the problem by the researcher and the submission of the manuscript to a scientific journal. On the other hand, this process ensures quality of scientific production for ELSA-Brasil and adds value to the article through revisions prior to the formal submission to a scientific journal. This may reduce the evaluation time by the journal and may even increase the chance of acceptance. There is also the risk that the procedures of publiELSA represent bureaucratization of the evaluation process of scientific production in this context, especially because the quality control and verification of the proposal's primacy in relation to the objectives of ELSA-Brasil falls under the responsibility of the publication committee. However, the cultural changes caused by these matters are directed towards the quality of the products and, thus, their scientific impact. Every effort towards simplifying the administrative stages is made,

so that the committee can always concentrate on issues of merit and ethics in evaluating any proposal or article.

The most innovative aspect of the system is the stimulus towards wider cooperation among ELSA-Brasil researchers. This is coherent with the decentralized and cooperative nature of this study in which there is no principal investigator, but a network structure that has been continually improved throughout the development phases of the project. Even considering that the responsibility regarding co-authorship formally lies with the person who submitted the proposal, circulation of information among the individuals responsible for the study will contribute towards clear demarcation of the real co-authorship, in line with the recommendations of the International Committee of Medical Journal Editors.^d

Moreover, formulation and application of new information technology to the management of scientific knowledge production, which characterizes publiELSA, constitutes a legacy for institutions, other research projects and researcher communities, who have at their disposal an auxiliary instrument for evaluating and following up studies and publications. Two other Brazilian multicenter projects have recently asked to use the system.^e

Lastly, ELSA-Brasil is committed to stimulating partnerships not only among its researchers, but also with the national and international scientific community, and to supporting researcher training, especially in the neediest regions. Overall, the ELSA-Brasil network aims to ensure fulfillment of these objectives; the publication committee aims to make them easier to accomplish, and publiELSA is its main instrument. We invite interested researchers to visit the webpage or to contact publiELSA. The source code of the software is available on request.

d International Committee of Medical Journals Editors. Uniform requirements for manuscripts submitted to biomedical journals: ethical considerations in the conduct and reporting of research: authorship and contributorship. [cited 2012, Jun 1]. Available from: http://www.icmie.org/ethical_lauthor.html

e Nascer no Brasil: inquérito nacional sobre parto e nascimento. Rio de Janeiro; ENSP/Fiocruz; 2012 [cited 2012, Jun 1]. Available from: http://www.ensp.fiocruz.br/nascernobrasil/

^f Projeto ÉPIGEN-Brasil: epidemiologia genômica de doenças complexas em coortes brasileiras de base populacional. Salvador; Instituto de Saúde Coletiva/UFBA; 2013 [cited 2013, Mar 5]. Available from: http://www.inct-citecs.ufba.br/pesquisa_completa. php?cod=33&page=2&active=2

REFERENCES

- Carvalho ECA, Batilana AP, Simkins J, Martins H, Shah J, Rajgor D, et al. Application description and policy model in collaborative environment for sharing of information on epidemiological and clinical research data sets. *PLoS ONE*. 2010;5(2):e9314. DOI:10.1371/journal.pone.0009314
- 2. Council for International Organizations of Medical Sciences CIOMS. International ethical guidelines
- on epidemiological studies. Geneva: World Health Organization; 2009.
- Paskin N. The DOI handbook. ed. 4.4.1. Oxford: International DOI Foundation; 2006 [citado 2011 out 1]. Disponível em: http://www.doi.org/ handbook 2000/DOIHandbook-v4-4.pdf
- Szklo M. Quality of scientific articles. Rev Saude Publica. 2006;40(N. Espec):30-5. DOI:10.1590/S0034-89102006000400005

The system was financed by the Research Support Foundation of the State of Rio de Janeiro (Fundação de Amparo à Pesquisa do Estado do Rio de Janeiro, FAPERJ; procedural number E-26/102.877/2008).

The Brazilian Longitudinal Study for Adult Health (ELSA-Brasil) was funded by the Brazilian Ministry of Health (Division of Science and Technology [DECIT] of the Department of Science and Technology) and the Brazilian Ministry of Science and Technology (FINEP – Studies and Projects Finance Organization and CNPq – National Council for Scientific and Technology Development, protocol numbers 01 06 0010.00 RS, 01 06 0212.00 BA, 01 06 0300.00 ES, 01 06 0278.00 MG, 01 06 0115.00 SP, 01 06 0071.00 RJ).

The authors declare that there are no conflicts of interest.

This manuscript was submitted for publication and underwent a peer review process as any other manuscripts submitted to this publication, and anonymity was guaranteed for authors and reviewers. Editors and reviewers declare no conflicts of interest that may affect the peer-review process.