Title	Biomedical Research Regulation within a Social Security System: the case of Costa Rica
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Project Overview

Statement of the Problem: The Caja Costarricense de Seguro Social (CCSS) in Costa Rica is the major healthcare provider, with an actual coverage of approximately 87% of the country total population, including citizens and foreign. It has more than 40.000 employees working in 2695 healthcare centers distributed along the country. Over the past decade, the amount of clinical research in Costa Rica has been increasing dramatically, including those that were performed within the CCSS, due to three main reasons: 1) healthcare index comparable to those of the developed countries; 2) best healthcare system in Central America and 3) costs are cheaper for the industry. This increase generated the necessity of a normative based on the international regulation but also according to the national reality. However, once implemented the first regulation for clinical research within the CCSS, in 1998, associated to the constant changes on it and the lack of resources, the quantity of clinical research decreased in the CCSS (including the investigator-initiated proposals). This fact has produced a significant scientific regression for the CCSS. For the reasons mentioned above, the development of clinical research in the CCSS reached its lowest point between the period 2003 -2005, where the amount of investigations was 0.

Definition of the Intended Outcome: To implement a new standardized platform for biomedical research proposals, in order to improve the research capacity building within the CCSS, by the establishment of an adequate regulatory framework for the development of biomedical research.

Description of Program: A new regulatory structure was implemented in December 2005. First of all, the Division of Research Ethics (DRE) was created. Afterwards, the regulation was modified, with the aim to provide only one signification and, therefore, avoiding any wrong interpretation of its meaning. This regulation creates the Institutional Committee of Bioethics in Research (COIBI-CCSS) and the Local Committees of Bioethics in Research (CLOBI). At this time, there are 27 CLOBI distributed along the country. Also, the DRE focus its attention in several strategic actions: a) the establishment of well defined and standardized processes for the submission of biomedical research proposals, using formularies and guidelines for the investigators. b) A training program focused in the education of the members of these CLOBI, so they could understand better their functions. So far, 60% of the CLOBI members have received a formal training in research ethics and it is expected that 100% of these members will be trained by the end of this year. c) A net to coordinate the 27 CLOBI, by the creation of an Advisory Council of CLOBI, with the participation of each CLOBI coordinator plus the president of the COIBI-CCSS. d) Improvement of the website regarding the regulatory processes and bioethics in general. f) Implementation of a divulgation program directed to the staff and to the population in its total, oriented to inform the goals to participate in biomedical research and to teach about the ethic principles that must be followed, especially those aspects related to the informed consent.

Evaluation Method: Even thought it is not possible to evaluate the impact of these regulatory changes within the system so far, it needs to be mentioned that once implemented the new platform, we have seen a renascence of the interest of the CCSS staff to perform research and, therefore, an increase in the registration of biomedical research within the Institution.

Suggestions:

The regulation of biomedical research within the Costa Rican social security system works based in the patterns that have been standardized internationally and, at the same time, according to the CCSS reality, in such a manner that it warranties the protection of: a) the research subjects, b) the scientific interest of the investigators and c) the social interests of the CCSS. This fact makes possible the feedback of the system, proposing a few measures that constitutes aggregate values to the regulatory affairs: a) to promote, by the recognition of incentives focus on investigators and healthcare centers, the development of research projects, with the aim to solve local problems and b) to use the funds generated by the industry- sponsored clinical research for the improvement of the technologic structure of the CCSS healthcare centers, in the development of research within the system and the extension of the educative programs directed by the DRE.