

## **The Buenos Aires Declaration on Ethics and Clinical Trials**

"The Buenos Aires Declaration on Ethics and Clinical Trials" was unanimously approved at the First Latin American Workshop on Ethics and Clinical Trials and endorsed by the Latin American organizations that are listed at the end of the Declaration.

Both the Workshop and the Declaration were a response to the rapidly increasing number of clinical trials that are taking place in the region and to the questions being raised as a result of the many alleged violations of ethics during the approval and implementation of the trials.

The Workshop was organized by the non-profit organization Salud y Fármacos (<http://www.boletinfarmacos.org>), incorporated both in the USA and Argentina, which also publishes the free-access electronic bulletin Boletín Fármacos. The Dutch Foundation WEMOS, the Health Science Center of the University of Texas and the Pan American Health Organization-Argentina also provided financial assistance for the Workshop.

Salud y Fármacos and WEMOS perceive serious ethical flaws in the conditions surrounding clinical trials in Latin America and believe that the international health community should be aware of the situation.

### **The Declaration**

At the General Assembly of the First Latin-American Workshop on Ethics and Clinical Trials (Buenos Aires May 12 and 13, 2008) participants unanimously approved the following declaration:

1. Clinical trials can only be carried out if the population where the trials take place can benefit from their results.
2. Authorities of countries where clinical trials take place should require from researchers to strictly adhere to the "Universal Declaration of Bioethics and Human Rights" (UNESCO 2005).
3. All clinical trials that take place in Latin America must be registered with the national drug agency of the country where the trials take place or with the appropriate authority created for this purpose. The key information of the protocols should be made electronically available to the public.
4. In Latin America, protocols originating from outside the region must be translated by competent expert translators for presentation to local authorities (the regulatory agencies, ethics committees, etc.) into the language of the country where the clinical trial takes place (Spanish, Portuguese, or French).
5. The informed consent should fulfill the following requirements:
  - a) Informed consent forms originating from outside the region must be translated by competent expert translators.
  - b) Persons, totally independent from the clinical trial, must verify that all social and ethnic strata that participate in the trial understand clearly the content of the informed consent form.
  - c) When indigenous populations participate in the trial, the informed consent form should be presented to them in their native language.
6. The ethics committees that approve the implementation of a clinical trial must be active in the supervision and monitoring of all critical steps followed including recruiting of participants, data gathering and publication of results. The tasks should be specified in writing at the time the ethics committee approves the trial.
7. National health authorities should create a national registry of approved ethical committees, of research centers that have proven to have the technical competence to carry out clinical trials, and of researchers of known qualifications and honesty.

8. New drugs to be tested in clinical trials should be tested against the best available preventive, diagnostic and therapeutic methods. Placebos can be used only when no other therapeutic procedure exists, or under exceptional qualified circumstances, when this method is indispensable.

9. The results and findings of all the clinical trials should be communicated within a reasonable time to those who participated in the trials, and should be made available electronically to the public through the national drug agencies of the countries where the trials took place.

10. We condemn those clinical trials whose main objectives include the promotion of the commercialization of the tested drug.

11. In order to obtain authorization for a clinical trial, the pharmaceutical industry must commit itself to make, if the drug tested is useful for the treatment of a disease, economically accessible to those who need it in the country where the clinical trial took place.

12. It is necessary to initiate as soon as possible multicentric studies of Contract Research Organizations (CROs) that work in Latin America. The research should document the financial benefits, obtained from the trials, their business history, and any complaints raised against them. Regulatory agencies should publish electronically the results of these studies to allow other countries to know the qualifications of the firms.

13. Following the initiative of the United States and European Union leading professional health journals, Latin American medical journals should not publish any results of clinical trials unless their protocols have been electronically posted before the initiation of the trial. Similarly, articles should not be published unless the authors declare possible conflicts of interest.

14. All benefits that clinical trials researchers obtain from trials should be made public. The information must be specific regarding the amount that researchers receive by each participant they recruit, and by each participant that completes the trial. This information should be shared with trial participants as part of the informed consent. Other fringe benefits that the investigator receives from the industry should also be specified.

15. All persons who participate in clinical trials should be insured for potential risks they may suffer during the course of or as a result of the trial. The insurance policy should be paid by the pharmaceutical firm, CRO or organization that carries out the trial. The policies should be issued by reputable national or foreign insurance companies, and the damage payment should be equivalent to the amount that a person suffering a similar injury would receive in the country where the pharmaceutical firm responsible for the trial is headquartered.

16. As soon as it is discovered that a person appears as the author of an article on the results of a clinical trial that in fact was written by somebody else paid by a pharmaceutical industry or that his/her participation was minimal, the academic center to which the author is affiliated should start proceedings leading to an adequate sanction. If the author is a member of a CRO, the firm should be sanctioned and not be allowed to carry out new clinical trials in the country.

17. We believe that clinical trials should be carried out by nonprofit organizations such as universities on their own or in collaboration with the ministry of health. The participation of nonprofit organizations should be promoted.

18. Every effort should be made to insure that those in the lowest income group and other vulnerable groups do not participate in clinical trials, unless they directly benefit from their findings.

19. The end of a clinical trial is not to create wealth for an enterprise, organization or individual. Clinical trials can only take place to improve or augment the available therapeutic arsenal for the benefit of mankind.

20. There is a need to establish procedures to protect the blood and tissue samples obtained from clinical trial participants in order to preclude future abuses related to patent protection and the for-profit commercialization of derivatives of such samples.

Buenos Aires, May 13, 2008

The Declaration of Buenos Aires was written by the following: Dr. Jose Rubén Alcântara Bofim, Dr Patricia Andreotti, Dr. Corina Bontempo Duca de Freitas, Dr. Martín Cañas, Dr. Hernán Collado, Dr. Elisa Dibarbora, Ms. Susie Dutra, Dr. José Miguel Esquivel, Dr. Duilio Fuentes, Dr. Carmen Lidia Guerrero, Dr Núria Homedes, Dr. Gabriela Minaya, Ms. Susy Olave, Ms. Jimena Orchuela, Dr. Agustín Páez, Dr Analia Perez, Dr. Mario Salinas, Mr. Jacob Sijtsma, Dr. Juan Carlos Tealdi, Dr. Antonio Ugalde, Dra. Edith Valdez, Dra. Emma Verastegui, Dr. Susana Vidal

**The Declaration has been endorsed by the following organizations:**

Acción Internacional para la Salud-Coordination Center for Latin America (AIS-LAC)  
Roberto López Linares - Coordinator

Acción Internacional para la Salud-Bolivia (AIS-Bolivia)  
Óscar Lanza MD - Coordinator

Acción Internacional para la Salud-Nicaragua (AIS-Nicaragua)  
Leonel Arguello, MD -President

Asociacion Mexicana para el Uso Racional de los Medicamentos,  
A.C.  
Rogelio Fernández MD - President

Cátedra de Derechos Humanos de la Facultad de Medicina de la  
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Claudio Capuano MD - Director

Cátedra Unesco de Bioética de la Universidad Nacional de Brasilia  
Prof. Volnei Garrafa -Coordinator

Centro de Información de Medicamentos de la Universidad de  
Colombia (CIMUN)  
José, Julián López QF - Coordinator General

Centro Universitario de Farmacología, Facultad de Ciencias  
Médicas, Universidad Nacional de La  
Plata (CUFAR) (Argentina) - Centro Colaborador OPS/OMS  
Perla Mordujovich de Buschiazzi MD - Director

Comité de Defensa de los Derechos del Consumidor- Bolivia  
(CODECO)  
Rodrigo Urquieta Arias - Coordinador

Drug Utilization Research Group, Latinoamérica (DURG-LA)  
Claudia Vacca QF - President

Fundación Instituto para la Investigación del Medicamento en los  
Sistemas de Salud, Colombia (IFARMA)  
Francisco Rossi MD- Director

Grupo Argentino para el Uso Racional del Medicamento (GAPURMED)  
Luis Castiglioni MD - President

International Health Central American Institute Foundation (IHCAI FOUNDATION)  
Dr. Mario Tristan, Director-General

Red Latinoamericana de Ética y Medicamentos RELEM (The Latin American Network of Ethics and Medicines)  
Núria Homedes MD, DrPH - Coordinator

Red Latinoamericana y del Caribe de Bioética de UNESCO-Redbioética  
Volnei Garrafa, DDS, PHD - President of Council of Directors

Salud y Fármacos  
Antonio Ugalde, PhD - President, USA  
Martín Cañas MD - President, Argentina

Sociedade Brasileira de Vigilância de Medicamentos (Sobravime)  
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