Since its creation in 2002, the "Corporación Nuevos Rumbos" has developed research projects involving human beings, usually in low-risk environments, but in vulnerable communities. Nowadays, few institutions that conduct research with international entities may not have an ethics committee, and CNR has had it since 2015; however, until now the specific principles that serve as a guide to the members of the Corporation had not been formulated. The following document is based on the ethics regulation document produced by the Universidad de Los Andes, which also is the outcome of the fusion of many different proposals.

ARTICLE 1. Establishment of the Ethics Committee

a) Establishment of the Ethics Committee: the director of CNR will appoint for a renewable indefinitely three years period, three (3) external social sciences professionals of recognized prestige to form the Committee.

For the period 2021-2024 there are the doctors:

- Telmo Eduardo Peña

- Rebecca Puche

- María Fernanda Reyes

(b) The Committee shall meet in person or virtually every time it is called upon to evaluate a project.

c) Each Committee members shall exercise the presidency of the Committee on a rotating basis in each of their meetings.

(d) The Committee shall take its decisions by consensus.

(e) Each member of the Committee shall receive the symbolic amount of COL $300,000 per external project evaluation. In the case of projects financed with internal resources (usually small, low-budget, and low-budget projects extension), the remuneration shall be COL $100,000.

f) The director of CNR may request the participation of a special consultant in cases in which it is necessary.

g) The director of CNR will be responsible for sending the projects to the Committee of Ethics for review, accompanied by a brief explanatory letter.

h) All members of the Committee, including occasional consultants, shall sign at the beginning of their functions a confidentiality agreement on the projects and the information discussed in the Committee sessions.

i) The president of the Committee will send the CNR director the evaluation report signed by the three members in the format developed by CNR.

ARTICLE 2: Ethics Committee Functions

1. The main function of the CNR Ethics Committee is the following:

"Verify the rigor and quality of the project from an ethical point of view. The committee's function is to guarantee the institutional purposes and verify that planning and development of research projects with prevalence to respect, dignity, protection of rights and well-being of persons". To achieve this goal, the CNR Ethics Committee has the following functions:

a. Review, analyze and evaluate the ethical aspects of research projects in accordance with the provisions of Art. 3 of these regulations.

b. Make observations to researchers about the ethical aspects of their research.

c. Require modifications to the documentation presented.

d. Establish the project risk level in accordance with the provisions of Art. 4 of these regulations.

e. Decide on the request for endorsement of projects based on four response possibilities:

- Approved. The researcher receives a direct endorsement.

- Conditionally approved: The Committee makes observations on the presented documentation. Each one should be answered separately by writing.

- Pending - important adjustments: Each observation response is reviewed by the whole Ethics Committee, and may include an invitation to attend a Committee session to resolve concerns.

- Rejected: In this case, the Ethics Committee requires researchers to examine in-depth one or more key ethical aspects in their application. This option implies completely reformulating the project.

It is important to note that the Ethics Committee does not issue post factum guarantees, that is, when Projects are issued to the Committee after data collection has started and/or finished.

ARTICLE 3. Tasks of the Ethics Committee

In accordance with the WHO guidelines (2011) for Ethics Committees of Research, the main task is to evaluate the ethical aspects of a research proposal in accordance with the national and international standards and guidelines (see Annex one). These aspects include but are not limited to:

a. The scientific competence of the researcher to carry out all the activities of the proposed study.

b. The characteristics of the target population; size; criteria of inclusion and exclusion; sample rationale, especially when working with vulnerable populations or sensitive issues (see Annex 2).

c. The analysis of the physical, economic, social, psychological, or other risks to which study participants are exposed, especially when working with vulnerable populations or sensitive issues.

d. The measures are taken to reduce the risks for the participants.

e. The way to advertise the study and how the potential participants are summoned and contacted.

f. The way to guarantee the people autonomy in decision-making about participating or withdrawing from the study.

g. The way to protect the confidentiality of the information and the anonymity of the participants.

h. The means to communicate to participants the general information about the research and its findings and to answer their inquiries and complaints.

i. The risks to which the researcher could be exposed by carrying out this research.

J. Potential conflicts of interest.

k. Verify the changes and adjustments made to the project after the first revision.

ARTICLE 4. Definition of risk

In the present context, “risk” will be defined as the possibility of causing social, moral, physical, economic, or psychological harm to a person, and will classify the projects into levels of minimum, medium, and high risk, as follows:

a. Minimum risk project: one in which participation in the research does not have consequences or inconvenience greater than those encountered in everyday life.

b. Medium risk project: one in which is worked on or obtained personal information from people; interact with or gather private information from vulnerable groups; or worked or obtains sensitive information from people through direct questions in interview or observation.

c. High-risk project: one in which interventions or modifications are made

to biological, physiological, psychological, or social aspects of the participants, or where the probability of negatively affecting a participant is significant.

The possibility of establishing the risk of an investigation as a minimum requirement does not mean that researchers can omit in their application the ethical aspects assessment described in Article 3.

ARTICLE 5. Responsibilities

The CNR Ethics Committee will review the research projects in the areas of their competence: that is, those projects in which the information is obtained through the interaction with human beings (i.e., through participant observation, interviews, or focus groups), or in which private and identifiable information is gathered about them (for example, through clinical records).

ARTICLE 6. Exempted projects

Projects may be exempt from review by the Committee of Ethics, when:

- Obtain their data from deceased and unidentifiable persons, or

- Work exclusively with one or several types of public documents (for example, public policies, press, blogs, etc.), or

- Use non-participant observations (in which there is no verbal interaction between researchers and subjects) in educational institutions for the evaluation of learning processes, or

- Use secondary databases that have no restrictions to be used.

ARTICLE 7. On the duties of investigators

CNR investigators must:

a. Know and respect the institutional ethical framework, national laws, agreements, and current regulations that apply to the study, as well as the established procedures by the Ethics Committee and these regulations.

b. Include a reflection on the ethical aspects of their project in their study. The investigators must ensure that they bring to the Committee's attention all activities in which the participants will be involved.

c. Prepare and present all the information and complete documentation required by the Committee (see Annex 5-Guide for Submitting Projects to the Ethics Committee).

d. If summoned, attend the Committee session, and answer questions and comments made by its members.

e. Respond in writing, completely and separately, to each and every one of the observations generated by the Committee in its reviews.

F. Ensure that all persons working on the study under their supervision and responsibility know and work with the existing ethical rules and regulations.

g. Ensure that the Informed Consents, observation records, and responses of the participants to any instrument used in the research process are kept under lock and key or password for a period of three years, after the end of the draft.

h. Request by writing the review of any modification to the activities, instruments, or project procedures when such changes relate to ethical issues.

i. Communicate in writing to the Ethics Committee any unanticipated adverse event that has occurred as a result of the participation of one or more persons in the study, and that results in intense psychological discomfort, physical injury, or threat to the integrity, health, or safety of a participant. The communication to the Ethics Committee must occur within 48 hours of the adverse event.

J. Communicate respectfully and cordially with the Ethics Committee and its members.

k. Carry out the investigation in accordance with the procedures established in the application endorsed by the Ethics Committee.

Appendix 1

INTERNACIONAL

Nuremberg Code. Available in: https://history.nih.gov/research/downloads/nuremberg.pdf

CIOMS: International Ethical Guidelines for biomedical Research Involving Humans (2002). Available in: https://cioms.ch/wpcontent/uploads/2016/08/PAUTAS_ETICAS_INTERNACIONALES.pdf

CIOMS: International Ethical Guidelines on Epidemiological Studies (2009). Available in: https://cioms.ch/wp-content/uploads/2017/01/International_Ethical_Guidelines_LR.pdf

Declaration of Helsinki. Available in: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1995496/

Declaración Universal sobre Bioética y Derechos Humanos de la UNESCO (2005). Available in: http://portal.unesco.org/es/ev.phpURL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html}

Belmont Report (1979). Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Available in: http://www.bioeticayderecho.ub.edu/archivos/norm/InformeBelmont.pdf

Nuffield Council on Bioethics: The Ethics of Research related to Health- care in Developing Countries (2002). Disponible en http://nuffieldbioethics.org/wpcontent/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countriesI.pdf

UNAIDS/WHO: Ethical Considerations in Biomedical HIV Prevention Trials (2008). Available in: http://www.unaids.org/es/resources/documents/2012/20120701_jc1399_ethical_consideritions

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Resolution 008430 of Ministry of Health (1993). Available in: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLU

CIO
N-8430-DE-1993.PDF

Law 1090 of 2006. "By which the exercise of the profession of Psychology is

regulated, dictates the Deontological and Bioethical Code and other provisions".
Available in in
http://www.colpsic.org.co/quienes-somos/ley-1090-de-2006/182

Appendix 2

VULNERABLE POPULATIONS AND SENSITIVE RESEARCH ISSUES

In this appendix, you can find examples of populations or research topics that can cause vulnerability in a person or group. Note that this list is not exhaustive and that in all cases a specific analysis of the context, situation, and sample from your study is needed.

VULNERABLE POPULATIONS

Vulnerability type	Description	Examples
Cognitive Vulnerability	Related to the cognitive capacity of an individual, with the experience of high-stress situations (affecting the decision-making process) or with communication difficulties. These people are more vulnerable to control, manipulation, coercion, and inappropriate influence.	Boys and girls because of cognitive development, or maturity Disorder A person under the influence of Psychoactive substances Emergency situation A person has difficulties understanding the language or has difficulty reading
Institutional Vulnerability	Related to the limited autonomy, given to the subordination of potential participants.	Public Force members People deprived of their liberty hospitalized people Institutionalized people in psychiatric centers
power relationships Vulnerability	The person accepts to participate to avoid looking bad with who is supporting the research inside the institution	patients students Colleagues People with whom you have a previous relationship

Medical Vulnerability	People with serious or terminal illnesses may overestimate the potential or expected benefits. Other people can participate because they are desperate.	Terminal stage cancer individuals
Economic Vulnerability	When the research offers the distribution of unavailable goods for the population. The group perception can be less concerned about the risks and what they are asked to do. Also, they can have a higher expectation receive compensation.	Low income individuals
Social vulnerability	When the investigation seeks to work with over-intervened populations (of which many researchers seek to obtain information)	Sexual, ethnic minorities, or victims of certain types of violence
Populations that have experienced violence, or discrimination situations	The research is developed with people who have experienced threats or have been involved in situations that affects their physical integrity or psychological.	Armed Conflict Victims Crime victims LGBTI population
Population in need or in a subordination situation	The research is developed with people who are in necessity or subordination circumstances. These circumstances can make them think that they are obliged to participate, therefore, otherwise, they will not obtain services, or they will receive a punishment	Armed Conflict Victims Soldiers

SENSITIVE TOPICS

Description	Examples
The research that seeks information about painful experiences	Victimization Duel Illness Trauma
Research that seeks to obtain information on private or intimate matters	sexual intercourse Couple relationships Pregnancy relationships with children
Research that seeks to obtain behavioral or illegal activities information	Commission of crimes by participants

Obviously, this list includes practically everything that may be of interest; its mention only implies that researchers should take special precautions, wherein a concrete way all the measures to reduce the risks of doing harm are identified and enhance the possibilities of benefiting the target population.