Human Rights Guideline

Novartis Global Guideline

Approved: May 01, 2017

(Update of original Human Rights Guideline from 2003)
1 Background, Guiding Principles and References

**Background**
As a healthcare company, Novartis aims to provide solutions to existing and evolving health needs of patients worldwide. Our business can bring major benefits to individuals and societies: first and foremost through our healthcare products, but also in our role as an employer, a business partner – and as a member of international and local communities that cares about the impact of its decisions on people and society.

**Guiding Principle**
As a responsible company that strives to be a good corporate citizen, we are committed to conducting our business in a manner that respects the rights and dignity of all people. This means that the duty to "do no harm" is at the foundation of our corporate responsibilities. Therefore, within our sphere of control, we must avoid violating human rights and should address adverse human rights impacts. Likewise, we must use appropriate standards and processes to make sure that we are not complicit in human rights abuses within our sphere of influence. Additionally, we also strive to promote and positively support internationally proclaimed human rights.

**External References**
We respect and support the protection of human rights, as enshrined in the Universal Declaration of Human Rights (UDHR) issued by the General Assembly of the United Nations on December 10, 1948.
We are also committed to upholding the core labor standards set out by the International Labor Organization (ILO).
Since 2001 Novartis is a signatory of the UN Global Compact, endorsing the 10 universal principles covering human rights, labor, the environment and anti-corruption. This led to our first Human Rights Guideline, which was put in force in 2003. In the spirit and in continuity of our early Human Rights commitments, we also support the UN Guiding Principles on Business and Human Rights and take care of the appropriate implementation within Novartis.

**Internal References**
Corporate Responsibility (CR), including human rights, is endorsed and ingrained at the highest level in our company. The general obligation of each and every Novartis employee to respect human rights is defined in the Novartis Code of Conduct. Specific Human Rights topics are governed and managed by issue- and function-specific standards in Novartis (e.g. Novartis Supplier Code, Human Resources Guidelines etc.) that have a binding character in the respective function or area of responsibility. Our CR Guideline provides overall guidance on governance, roles and responsibilities, and management of corporate responsibility across Novartis.

**Responsibilities and Assessment of Impacts on Human Rights**
Employees must adhere to the binding obligations set out in this guideline. Management supervises the implementation of and adherence to this guideline within their areas of respective responsibility. The actual or potential human rights impact of Novartis activities is assessed through appropriate processes.
General Rights and Obligations

Non-discrimination

All Novartis policies, including but not limited to those relating to recruitment, hiring, discharge, promotion and training are non-discriminatory.

The diversity and individuality of our associates is valued as a key success factor for Novartis. Novartis is committed to treat all associates with fairness and respect. Any form of discrimination or harassment based on personal characteristics such as nationality, gender, age, ethnicity, religion, sexual orientation, disability, membership of an association or any other subject protected by law, will not be tolerated and must be addressed in an adequate manner.

In our capacity as an employer, we do not select or discriminate against our associates on the basis of their genetic profile. Novartis does not perform any genetic tests in any pre-placement or employment-related examinations.

Novartis maintains a strict zero-tolerance policy with respect to inappropriate treatment and any incidents should be addressed in an adequate manner.

Labor Conditions

Novartis does not engage in forced, compulsory, bonded or child labor.

Forced or compulsory labor means work or services extracted from persons under the threat of non-contractual penalty; and work or services which such persons have not voluntarily offered to perform.

Bonded labor means work or services extracted under economic conditions that leave employees without reasonable choice as to whether they want to continue to perform the work or service.

The absolute minimum age for employment is higher of 15 years of old age at which compulsory schooling is no longer required by law. Wherever feasible, employees below 18 years should be employed as trainees or apprentices whose work is part of a regulated training scheme.

Accumulation of overtime and holiday entitlements is handled consistently with local law and procedures.

Re-integration after leaves of absence, illness or disability is facilitated with care management concepts, adapted work places and working conditions in line with local laws and regulations.

All Novartis workers and employees have the option to leave employment within lawful contractual terms and the right to be provided with the proper documentation of their working relationship with Novartis.

Fair and Competitive Wages

Our compensation principles are structured to foster personal accountability and underline the importance of competence and integrity as drivers of sustainable business success. Novartis pays wages for its employees which exceed what is needed to cover basic living needs, and monitors these defined living wages on a regular basis. Wages below these standards are adjusted.

Freedom of Association, Ensuring Fairness and Respect

Novartis fully respects the right of associates to join a trade union or an employee association. We commit to constructive dialogue with workforce representatives, and to the involvement of work councils or trade unions according to local laws and regulations. Novartis acknowledges each associate’s entitlement to freedom of opinion, expression and speech, consistent with our policies and standards of respectful behavior.

We value an open and fair culture and are committed to cultivating an environment where everyone feels comfortable about expressing opinions and contributing ideas.

Protecting Health & Safety

Our company culture considers protecting the health and safety of associates, neighbors, and others affected by our business activities, and protecting the environment, to be core values that are treated with equal importance with our other key business objectives. While management is responsible for implementing and maintaining good health, safety and environmental (HSE) practices and leading by example, associates need to understand HSE matters, and respond equivalently to them as they would to other key business objectives.

Compromising patient benefit or safety is not an option. We discover, develop and manufacture high-quality products that meet all regulatory requirements, and pursue quality beyond
corporate responsibility, public compliance in both our products and processes. We protect patient safety by identifying, assessing, managing and reporting any product-related risks in a timely manner.

**Privacy**

We respect the privacy rights of our associates, patients, physicians and other stakeholders. We inform individuals of collection and processing of their personal data, allowing them to make informed decisions and exercise their rights. We collect and process personal data for specific and legitimate business purposes only, and secure such data against unauthorized access.

**Right to Security of Persons**

Novartis does not engage in or benefit from war crimes, crimes against humanity, genocide, torture, forced disappearance, forced or compulsory labor, hostage taking, other violations of humanitarian law or other international crimes against the human person as defined by international law. Our security arrangements observe international human rights norms as well as the laws and professional standards of the country or countries in which they operate, and are used only for preventive or defensive services. Security personnel are instructed to only use force when strictly necessary and only to an extent proportional to the threat.

**Respect of Local Communities and Indigenous People**

Novartis respects the rights of local communities affected by Novartis activities and the rights of indigenous peoples and communities consistent with international human rights standards.

**Supplier Management**

Novartis promotes the societal and environmental values of the United Nations Global Compact with its suppliers and third parties, and uses its influence where possible to encourage their adoption. Novartis requires its suppliers to aspire to the standards defined in our Supplier Code. Suppliers shall commit to uphold the human rights of workers and to treat them with dignity and respect.

### 3 Sector Specific Issues

**Intellectual Property Rights and Technology Transfer**

Novartis protects and enforces intellectual property rights in a manner that contributes to the promotion of scientific and technological innovation and the dissemination of science and technology to the mutual advantage of both producers and users of technological knowledge in a manner conducive to social and economic welfare.

Novartis respects the right to the highest attainable standard of physical and mental health. We believe that each sphere of society – from government and charitable organizations, to medical professionals and business – has a role to play in support of this right.

States have the primary responsibility for realising the right to the highest attainable standard of health and increasing access to medicines.

The obligation to fulfil the right to the highest attainable standard of health requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures to fully realize this right. In our view, this includes a commitment to make adequate investments in healthcare, and to create and support an environment that sustainably incentivizes and protects innovation, including a sound intellectual property system.

Our primary contribution derives from our normal business activities that are based on our mission to discover new ways to improve and extend people’s lives. For this we use science-based innovation to address some of society’s most challenging healthcare issues and we find new ways to deliver our treatments to as many people as possible.

Our commitment to research – targeting unmet medical needs – contributes to the advance of medicine, and thus social welfare and economic development. We recognize the important role of generic drugs in providing society with lower cost medicines once intellectual property rights have expired.
Clinical Trials

Novartis conducts high quality research and complies with international and national legal and regulatory requirements, including the ICH-Good Clinical Practice guidelines. Patient safety and data integrity are paramount. We strive for the highest possible protection of clinical study participants. Novartis subscribes to the ethical principles that protect the safety and wellbeing of the clinical study subjects as laid down in the Declaration of Helsinki, and we apply one set of standards worldwide. Clinical studies must also respect international quality standards, such as Good Laboratory Practice (GLP), Good Clinical Practice (GCP), as well as national regulatory and legal requirements. Novartis only conducts clinical trials in countries where there is reasonable expectation that the product will be submitted for marketing authorization and be made available to patients who participated in the trials, once approved.

Special care is taken when recruiting trial participants from vulnerable populations, such as children or the economically deprived. Globally valid principles of voluntary and informed consent must respect local specification and language. If literacy or comprehension are of concern, family, community representatives and/or independent witnesses should be involved.

The choice of a comparator, i.e. placebo and/or active treatment, must be justified on both scientific and ethical grounds. If, at the end of a Novartis clinical trial, a responding patient volunteer is still in need of an investigational therapy as determined by the treating physician, it may be provided, as permitted by local legislation, in cases where the overall benefit to the patient is anticipated to be greater than that of alternative approaches and where the risks are considered acceptable considering the seriousness of the condition.

Novartis makes every effort to comply with national and international standards for registration of clinical trials and disclosure of clinical trial information and is committed to the timely disclosure of the design and results of all interventional clinical studies for innovative treatments in patients. Results are made publicly available whatever their outcome.

Organ Donation

When conducting clinical trials in transplantation, Novartis upholds the principles outlined in a) The Declaration of Istanbul that is a Transplantation Society sponsored initiative prohibiting transplant commercialism, organ trafficking and transplant tourism, b) The World Health Organization statements on “Human Organ and Tissue Transplantation” which urge member states specifically to protect the poor and vulnerable from transplant tourism and sale of tissues and organs, and c) The Organ Procurement and Transplantation Network report on “Ethical Principles in the Allocation of Human Organs” which defines the foundational ethical principles that create a framework for the equitable allocation of organs for transplantation.

Novartis does not sponsor or otherwise support any clinical studies which do not follow the standards and principles outlined in the above documents and which may be linked to organ transplant commercialism, organ trafficking and/or transplant tourism.

In a broader context, Novartis supports a) ethical, legal and non-commercial efforts to promote organ donation and specifically condemns all practices for obtaining human organs that do not follow these principles and b) organ donation by living donors as an acceptable means to alleviate the shortage of cadaver organs available for transplantation, provided the highest standards of protection for the health and human rights of organ donors are preserved.

4 Reporting of Violations and Non-Retaliation

The Business Practices Office (BPO) offers both employees and people outside of Novartis a channel to report misconduct. The BPO manages investigations into all complaints, and escalates any substantiated cases of misconduct to management for appropriate action. All associates are required to bring potential misconduct to the attention of Novartis. Associates who report potential misconduct or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

Contact the BPO: business.practicesofficer@novartis.com