Ethics in Clinical Trials [1]

For every Novartis clinical trial our primary responsibility is to protect the safety, well-being and legal rights of all participants and ensure adherence to the highest ethical standards for clinical research. This responsibility to trial participants includes the Novartis commitment to patients and caregivers [2].

Novartis manages every clinical study globally in compliance with international guidelines designed to protect patient rights and safety, including the Declaration of Helsinki and the Belmont Report, the Council for International Organizations of Medical Sciences (CIOMS), and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines [3]. To ensure compliance with these standards, Novartis requires training in ICH GCP guidelines for all staff and investigators involved in clinical trials, including the process of informed consent [4]. Our company-wide compliance assurance process ensures compliance with these requirements in all countries.

Every clinical trial must be approved by national and/or regional regulatory authorities [5] as well as independent local ethics committees or institutional review boards [4] in the countries where the trial takes place. These ethics committees are comprised of physicians, scientists, advocates, researchers and members of the community formally designated to review and monitor all research involving humans. The purpose of the ethics committee is to ensure that risks for clinical trial participants are responsibly managed and the risk to benefit ratio is as favorable as possible. At the time of trial approval, the ethics committee review includes an assessment of whether the proposed trial is acceptable, whether participants are fully informed about the benefits and risks related to the trial, and whether the healthcare professionals running the trial are competent to protect participants from harm. Once a clinical trial has started, the ethics committee has the authority to modify or stop the trial at any time based on emerging data.

Based on these international standards and guidelines, Novartis has developed a comprehensive framework of strict policies and procedures to ensure adherence to the highest ethical standards for clinical research. Mandatory education programs are used to train all employees on these Novartis policies and procedures. Novartis monitors and audits clinical trials on an ongoing basis to ensure compliance with Novartis standards. This includes audits of contract research organizations (CROs) that conduct or manage trials on behalf of Novartis, as well as any external vendors or companies that are involved in the conduct of Novartis clinical trials.

In addition, since 2017 Novartis has collaborated with an external Independent Bioethics Advisory Committee (IBAC), which provides analysis and recommendations on Novartis guidelines and policies for the ethical conduct of clinical research, and on selected ethical challenges which may arise in clinical trials, development programs and managed access programs. The IBAC is comprised of bioethicists, clinicians, healthcare practitioners, patient

advocates and other domain knowledge experts appropriate to the problem at hand.

Links
[1] https://www.novartis.com/clinicaltrials/ethics-clinical-trials
[2] https://www.novartis.com/our-focus/patients-caregivers/novartis-commitment-patients-and-caregivers
[3] https://www.novartis.com/sites/www.novartis.com/files/novartis-position-on-responsible-clinical-trials.pdf
[4] https://www.novartis.com/clinicaltrials/glossary-clinical-trial-terms#i
[5] https://www.novartis.com/clinicaltrials/glossary-clinical-trial-terms#h