



Global Code Of Ethics For Clinical Trials

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Signature: _____

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Date: _____

July 19, 2006

Amgen's Global Code Of Ethics For Clinical Trials

1. PURPOSE

As part of Amgen's commitment to conducting research that meets only the highest ethical standards, Amgen has developed this Global Code of Ethics for Clinical Trials to guide its clinical research efforts with particular attention to protecting the rights of human subjects worldwide. This Code draws from well-accepted international standards for clinical research, including standards published under the International Conference on Harmonization (ICH) and other standards associated with Good Clinical Practice (GCP).

2. SCOPE

This Code applies globally to all prospective interventional clinical research conducted by or on behalf of Amgen, including single site studies, multi-site and multi-national studies, studies involving investigational medicines and uses, and post-marketing studies. Amgen also conducts non-interventional clinical research and applies the policies in this Code to that research where applicable.

3. STATEMENT OF POLICY

Amgen's commitment to protecting clinical research participants and to conducting only the highest quality research applies to all Amgen sponsored clinical research irrespective of the location of the study. Amgen believes that the rights, dignity, safety, and well being of research participants are paramount in all clinical trials. To that end, Amgen clinical research will conform to local laws and will be conducted in accordance with established and widely accepted international standards, including standards published under ICH and GCP.

Amgen will only conduct clinical studies in countries where there is the reasonable expectation that Amgen or an Amgen licensee will commercialize the drug. Additionally, Amgen will adhere to the following principles when conducting clinical research:

3.1 APPROPRIATENESS

All Amgen prospective interventional clinical research, as well as some types of non-interventional studies, undergoes an independent ethical evaluation before commencement. In all cases, the potential benefits to society derived by the research must outweigh the risks and burdens to the individual participants. Amgen will strive to ensure that its clinical research is responsive to the medical needs of a host country. All Amgen clinical research will be designed to answer clearly defined questions.

3.2 ETHICAL REVIEW

All interventional clinical studies must be reviewed by a qualified Institutional Review Board (IRB) or Independent Ethics Committee (IEC) in both the sponsor and host country. No research may commence until appropriate approval is given by the IRB or IEC in the sponsor and host countries.

The use of IRBs or IECs should comply with local rules governing the composition and function of these bodies, and should be guided by leading international ethical standards, including those published under ICH.

3.3 INFORMED CONSENT

Amgen prospective interventional clinical research should conform to ICH and GCP standards for informed consent. Amgen will also follow local laws and customs as appropriate. For example, Amgen recognizes that in some cultures, acceptance by community leaders or a senior member in the family is commonly required. While investigators may seek to accommodate these cultural practices, they must also receive consent from the individual participants. Amgen also recognizes that there may be situations in which obtaining written consent is not consistent with local custom or the research participant's ability to understand written language. In these cases, investigators should, at a minimum, document the elements of the informed consent discussion and agreement by research participants, in the presence of an impartial witness.

Participants must receive information in a language understandable to the participant, and translators should be used when necessary. Research participants should be informed that Amgen reserves the right to terminate or suspend clinical trials for any reason and is obligated universally to terminate studies when presented with evidence of an unacceptable benefit:risk profile.

Proxy consent for vulnerable research participants, including minors and adults lacking capacity, should comply with host country legal standards. Where possible, the individual subject should also give their assent to participation in the clinical trial.

3.4 STANDARD OF CARE FOR CONTROL GROUPS AND USE OF PLACEBOS

Amgen will work actively to ensure that research participants are receiving quality medical care. The standard of care provided to control groups should be, at a minimum, equivalent to well established and commonly employed local treatments. Placebo-controlled studies are permitted only where there is genuine uncertainty about the therapeutic merits of the proposed treatments under study (clinical equipoise). The appropriate medical management of research participants who demonstrate disease progression during the course of study should be carefully considered in the design of the clinical trial protocol.

3.5 SAFETY MONITORING

Amgen maintains a sophisticated network for collecting and interpreting adverse event data for all clinical studies. Investigators must be informed of their obligations to report such events. Amgen medical staff must regularly review safety data and are responsible for informing investigators, regulatory agencies and IRBs/IECs, when appropriate, of potential new risks associated with use of a therapeutic product. Investigators must inform research participants of potential new risks associated with use of a therapeutic product as well as any additional monitoring or follow up testing that will be conducted following completion of a trial.

3.6 PRIVACY

Amgen is committed to complying with applicable laws addressing the privacy of research participants and will require that its agents are contractually obligated to do the same. Reasonable steps should be taken to ensure that the personal information of a research participant is not disclosed to a third party unless appropriate consent is obtained, where there is a legal requirement to do so, or where it is otherwise permitted by applicable law. Clinical data is generally coded at clinical sites and submitted to Amgen with minimal essential personal identifiers. Where data containing personal identifiers is made available to the company (e.g., in connection with a safety issue or as part of the company's clinical trial monitoring activities), Amgen will handle the data in a secure manner.

3.7 TRAINING AND TECHNOLOGY SUPPORT

Amgen will endeavor to provide training and technology support where the host country does not have a well-developed clinical research infrastructure. This may include medical, scientific, ethical, regulatory, and/or technological training for clinical investigators, medical personnel, local health authorities, and others. For example, when appropriate and where doing so will not compromise the independence of a host country committee, Amgen may provide ethical training and financial support for ongoing ethical review by IRBs or IECs in host countries.

When appropriate, Amgen may also consider investments in local health care facilities and technology to ensure the integrity of the scientific data derived from a clinical trial. These benefits should be evaluated by IRBs and IECs to ensure that they do not unduly influence communities or participants. These investments help to ensure the highest quality research and also provide Amgen with an opportunity to contribute to the research capabilities of the host country.

3.8 COMPENSATION

Amgen recognizes that research participant compensation, including gifts, is a particularly sensitive issue because such payments or gifts may be perceived as a form of coercion. The type of reimbursement or other compensation offered

to participate in a trial should be appropriate to the local economy and evaluated as part of the ethical review.

Payments to clinical investigators should represent fair market value and otherwise be consistent with ICH standards.

Amgen's policy concerning compensation for injuries sustained during a clinical trial sponsored by Amgen should be discussed with participants as part of the informed consent process. Amgen will work as appropriate to comply with local laws concerning compensation for injuries.

3.9 RESPECT FOR LOCAL CUSTOMS AND HEALTHCARE PRIORITIES

As discussed above, Amgen clinical research will be conducted in accordance with local laws and established international standards, including those published under ICH GCP. Whenever possible, Amgen will also work with local investigators and medical personnel to accommodate local customs, beliefs, and sensitivities, provided that they do not interfere with the research participant's safety or human rights. Amgen strives to conduct research within existing health care systems in a manner that does not detract from local health priorities.

3.10 CONTINUED ACCESS TO INVESTIGATIONAL THERAPEUTICS

It is Amgen's intent to ensure that research participants continue to receive effective treatment at the end of the study. Amgen will consider several factors in determining whether it may provide continued access to investigational therapeutics once a study has concluded. These factors include the nature of the investigational product, the phase of development, Amgen's manufacturing capabilities, the host country infrastructure, the host country regulatory system, the nature of the disease, and relevant safety and efficacy data.

4. AVAILABILITY OF AMGEN'S CODE OF ETHICS

Amgen's Code of Ethics for Clinical Trials will be posted on Amgen's external website for potential clinical investigators and potential research participants to review prior to committing to participate in an Amgen study.